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Delegations will find attached document SWD(2023) 850 final.

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COMMISSION STAFF WORKING DOCUMENT

Accompanying the documents

Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals
and
Proposal for a Directive of the European Parliament and the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

{COM(2023) 783 final} - {COM(2023) 781 final}

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1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1 Political context

Chemicals are everywhere in our daily lives and play a fundamental role in most of our activities, as they form part of virtually every device we use to ensure our well-being (be it for food, electronics, toys, clothes or industrial machines), protect our health and security, and meet new challenges through innovation. The EU is the second largest producer of chemicals in the world with EUR 541 billion turnover in 2018 (7.0% of EU manufacturing by turnover) and 14.4% of global sales in 2020 (CEFIC, 2022)[1] and chemical manufacturing is the fourth largest industry in the EU comprising 30 000 companies, 95% of which are SMEs, directly employing approximately 1.2 million people and 3.6 million indirectly.

At the same time, chemicals can cause harm to human health and the environment. Certain chemicals cause cancers, affect the immune, respiratory, endocrine, reproductive and cardiovascular systems and increase vulnerability to diseases. Exposure to these harmful chemicals is therefore a threat to human health. In addition, the pollution of environment with chemicals is one of the key drivers putting the Earth at risk[2], impacting and amplifying planetary crises such as climate change, degradation of ecosystems and loss of biodiversity, examples being negative effects on pollinators, insects, aquatic ecosystems and bird population.

In order to ensure a high level of protection of human health and the environment from the adverse effects of chemicals and to support the efficient functioning of the internal market for chemicals while promoting the competitiveness and innovation of EU industry, the European Union has developed a comprehensive regulatory framework for chemicals.

The framework has been developed progressively, with the first legislation coming in place as early as in 1967. The framework consists currently of over 40 pieces of legislation, addressing: the **production and placing on the market of chemicals and chemical products, such as** (e.g. industrial chemicals, biocidal products, plant protection products, human and veterinary pharmaceuticals, cosmetic products, detergents), **emissions of chemicals** (e.g. from industrial installations, waste water treatment plants or use of fertilisers), p**rotection of workers' health** (e.g. from carcinogens, mutagens and reprotoxic substances, from asbestos, or from chemical agents in general), **chemicals in waste** (e.g. in general, in packaging and packaging waste or in end-of-life vehicles), **safety of consumer products** (e.g. toys, food contact materials, batteries), **safety of foodstuff and feedstuff** (e.g. food improvements agents or maximum residue levels of food contaminants) and **protection of the environmental compartments (**e.g. surface waters, ground waters, marine waters, drinking water, air and soil).

The fitness check of the most relevant chemicals legislation assessing over 40 pieces of legislation concluded that overall the EU chemicals legislation delivers results as intended and is fit-for-purpose, but a number of significant weaknesses prevent the EU chemicals legislation from living up to its full potential. There were identified shortcomings across legislative pieces as regards the coherence of safety assessments, efficiency of the underlying technical and scientific work and the coherence of transparency rules. These shortcomings can lead to inconsistency and incoherence in safety assessments, slow procedures, inefficient use of resources, unnecessary burden, (perceived) lack of transparency and sometimes low quality of scientific advice (see section 2).

Building on the findings of the fitness check, the European Green Deal announced the commitment '*to review how to use better the EU's agencies and scientific bodies to move towards a process of 'one substance, one assessment' and to provide greater transparency when prioritising action to deal with chemicals*'. The Chemicals Strategy for Sustainability elaborated further on the concept of 'one substance, one assessment' and defined it as an approach to improve the overall efficiency, coherence and transparency of the delivery of safety assessments of chemicals across legislation. The strategy identified five key areas affecting the coherence and efficiency of delivery of safety assessments and for each of them defined number of specific

[1] Within the EU, two thirds of these sales are generated in four Member States: Germany (32.1%), France (13.5%), Italy (10.7%) and the Netherlands (8.9%) (CEFIC, 2022). See Annex 18 for more information on the chemical sector in the EU.

[2] Rockström, J. et al., Planetary Boundaries: Exploring the Safe Operating Space for Humanity. Ecology and Society, 2009

objectives and actions (see sections 2 and 3). Two key actions identified are to 'rationalise the use of expertise and resources by **proposing the reattribution of technical and scientific work on chemicals performed under the relevant pieces of legislation to European agencies**, including work of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and Scientific Committee on Consumer Safety (SCCS)' and to ensure 'a clear allocation of responsibilities and **good cooperation among the European Agencies**'.

The EU Action Plan 'Towards Zero Pollution for Air, Water and Soil' further contributed to the one substance, one assessment objectives through commitments to consolidate the roles of the European Environment Agency and the Commission's Joint Research Centre in close collaboration with the European Chemicals Agency, the European Food Safety Agency, the European Maritime Safety Agency and other relevant agencies as the EU's Knowledge Centres of Excellence for Zero Pollution Monitoring and Outlook Framework.

The European Parliament resolution of 10 July 2020 welcomed the Strategy and the 'one substance – one hazard assessment' principle in order to better use the resources of the Union's agencies and scientific bodies, avoid duplication of efforts, reduce the risk of diverging outcomes of assessments, speed up and bring consistency and transparency to chemicals regulation, and ensure enhanced health and environmental protection and a level playing field for industry. The resolution called to achieve coherence and synergies between legislation dealing with chemicals and chemical products, specific products regulation, general product legislation, legislation on environmental compartments, legislation on sources of pollution and legislation on waste. The resolution further called to pay special attention to reducing overlaps between legal frameworks, and between tasks allocated to the European Chemicals Agency, the European Food Safety Agency and the European Medicines Agency. The resolution also underlined the need to reinforce cooperation and coordination between the European evaluation agencies EFSA and ECHA together with national agencies, by developing common guidelines for risk assessment, namely for biocidal and phytopharmaceutical products, which take into account the most recent scientific results, so as to avoid inconsistencies. Finally, the European Parliament called on the Commission and Council to refrain from cutting ECHA's resources in annual budget procedures and to provide ECHA with additional resources for any other tasks that may be required, such as conducting evaluations of substances.

The Council conclusions of 15 March 2021 also welcomed the Strategy and the 'one substance, one assessment' approach intending to simplify and improve the transparency of the regulatory framework for hazard and risk assessment of chemicals, to enhance coherence, to better coordinate the EU rules on chemicals, and to make decision-making faster. The conclusions called to continue ensuring policy coherence and exploit synergies among the chemicals and other policies. The conclusion further emphasised that the one substance, one assessment approach should not create delays in regulatory actions nor increase administrative burden, that the Member States are closely involved in the development of the approach and that the right of initiative of the Member States to initiate regulatory action is maintained. The conclusions also underlined the importance of allocating the necessary resources for the European agencies in the light of the envisaged re-attribution of technical and scientific work on chemicals, including an appropriate and long-term budgetary framework, and, in particular, for ECHA, taking into consideration their central role in the implementation of some key objectives of the Chemicals Strategy.

1.2 Legal context

The reattribution of existing tasks or attribution of new tasks to EU Agencies requires targeted amendments of the existing pieces of legislation on chemicals. The preferred way of doing it is by introducing changes in allocation of tasks when the individual pieces of legislation are being revised. Therefore, the relevant changes have been already proposed as part of the proposals for the regulation on serious cross-border threats to health[3]

[3] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314 6.12.2022, p. 26).

and for revisions of drinking water directive[4], SEVESO III directive[5], batteries regulation[6], EPRTR regulation[7], industrial emissions directive[8], water framework directive, ground water directive, environmental quality standard directive[9], CLP regulation[10], packaging and packaging waste directive[11], legislation on medicinal products for human use[12,13], end-of-life vehicles directive[14] and directive on the safety of toys[15]. The relevant changes, including new or additional tasks, are also planned to be introduced in the upcoming proposals for a regulation on ECHA[16] and for the revisions of REACH[17] and cosmetics regulation[18].

Where the chemical legislation is not to be opened within this mandate of the Commission, the necessary changes in allocation of tasks is introduced through the horizontal proposals on reattribution of tasks to the EU Agencies consisting of a regulation and a directive, for reasons of legal consistency. The proposal for the regulation proposes targeted amendments to allocations of tasks in the POPs regulation[19], medical devices

[4] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435 23.12.2020, p. 1).
[5] Commission Implementing Decision (EU) 2022/1979 of 31 August 2022 on establishing the form and databases for communicating the information referred to in Articles 18(1) and 21(3) of Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances and repealing Commission Implementing Decision 2014/895/EU (OJ L 272 20.10.2022, p. 14).
[6] Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p.1).
[7] Proposal for a Regulation of the European Parliament and of the Council on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal (COM/2022/157 final).
[8] Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (COM (2022) 156 final).
[9] Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy (COM(2022) 540 final).
[10] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (COM (2022) 748 final).
[11] Proposal for a regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (COM(2022) 677 final).
[12] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM (2023) 192 final).
[13] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM (2023) 193 final).
[14] Proposal for a Regulation of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulation (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC (COM (2023) 451 final).
[15] Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC (COM(2023) 462 final).
[16] European Chemicals Agency – proposal for a basic regulation (europa.eu)
[17] Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment (europa.eu)
[18] EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision) (europa.eu)
[19] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169 25.6.2019, p. 45)

regulation[20], EEA founding regulation[21] and the general food law[22], while the proposal for a directive proposes targeted amendments to allocations of tasks in the RoHS directive[23].

The Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals is a standalone regulation aiming to implement one substance, one assessment actions related to data, information and transparency, namely:

- use a single 'Public activities coordination tool' to provide an up-to-date overview of all planned and ongoing initiatives on chemicals by authorities across legislation;
- develop a common open data platform on chemicals to facilitate the sharing, access and re-use of information on chemicals coming from all sources;
- promote reuse and harmonisation of human and environmental health-based limit values among EU risk assessors and managers through a centralised and curated EU repository;
- remove legislative obstacles for the re-use of data and better streamline the flow of chemical data between EU and national authorities;
- establish tools and practices to ensure that relevant academic data is easily and readily accessible for safety assessments and is suitable for regulatory purposes;
- enable EU authorities to commission testing and monitoring of substances as part of the regulatory framework when further information is considered necessary;
- extend the principle of open data and the relevant transparency principles from the EU food safety sector to other pieces of chemical legislation;
- develop an EU early warning and action system for chemicals to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research.

In order to implement these actions, the proposal also allocates some new tasks to EU agencies as regards the management, sharing and generation of data and information, operation of a monitoring and outlook framework for chemicals and formalises some existing tasks.

1.3 Scope of the document

This document summarises all actions taken as of 2020 to (re-)attribute scientific and technical work on chemicals to EU agencies and to ensure good cooperation among the EU agencies in the area of chemicals. The document accompanies the horizontal legislative proposals on reattribution of tasks to EU agencies, and explains changes in (re-)attributions proposed in those proposals. It also explains, for the purpose of completeness of information changes which will be made to allocation of tasks via revisions of individual pieces of legislation or via a new legislation, including via the proposal for a Regulation on establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals ('proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals'). The document explains how the changes in allocation of tasks to EU agencies contribute to achieving the one substance, one assessment objectives and provides an assessment of cumulative impacts of the changes in allocations of tasks on the functioning of the EU Agencies.

[20] Regulation (EU) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 5.5.2017, p.1)

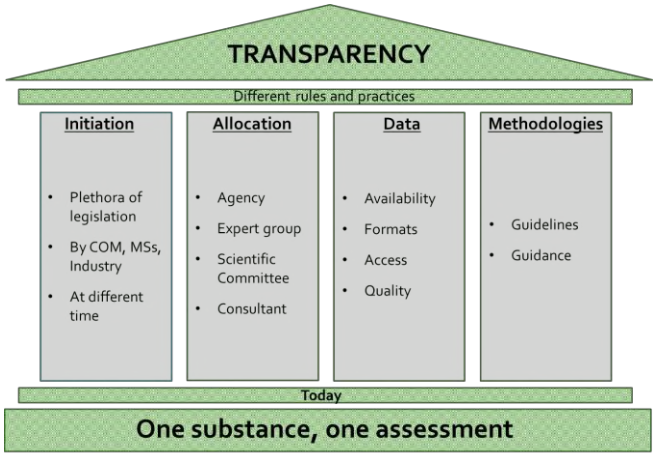
[21] Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Information and Observation Network (OJ L 126 21.5.2009, p.13)

[22] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p.1)

[23] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174 1.7.2011, p.88)

2. PROBLEM DEFINITION

The EU regulatory framework for hazard and risk assessment and management of chemicals is comprehensive. It consists of many pieces of legislation, addressing production and placing on the market of chemicals and chemical products, emissions of chemicals, chemicals in waste, protection of workers' health and safety of consumer products, foodstuff and feedstuff, and the environment. A high volume of technical and scientific work supports the implementation of the individual legislative acts. Depending on the legislation, the work is performed using different data and methodologies and involving various EU Agencies (the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), the European Environment Agency (EEA), the European Medicine Agency (EMA) and the European Agency for Safety and Health at Work (EU-OSHA)), scientific committees, (ad hoc) expert groups, Commission services or external contractors. This situation may lead to inconsistent and incoherent outcomes of assessments across legislation (in respect of the same chemicals), inefficient use of resources and unnecessary costs (from operating several committees performing similar assessments, from assessing the same chemical by several committees/bodies or from duplicating supporting technical and scientific work). In addition, the assessments that are not performed by the EU Agencies are often being criticised by the stakeholders as not sufficiently transparent and inclusive, having insufficient scientific quality and robustness or having insufficient separation between risk assessment and risk management.



The key drivers that one substance, one assessment approach intends to address are:

- Assessments are initiated under various pieces of legislation, by various actors and at different points in time;
- Assessments are performed by various agencies, scientific committees, expert groups or external consultants;
- Assessments are using various data and they varies in their availability, accessibility, quality and are stored in different formats;
- Assessments are using various methodologies and guidance documents;
- Various transparency rules and practices are applied.

The key problems arising from these drivers that the legislative proposals on (re-)attribution of tasks to EU Agencies aim to address are:

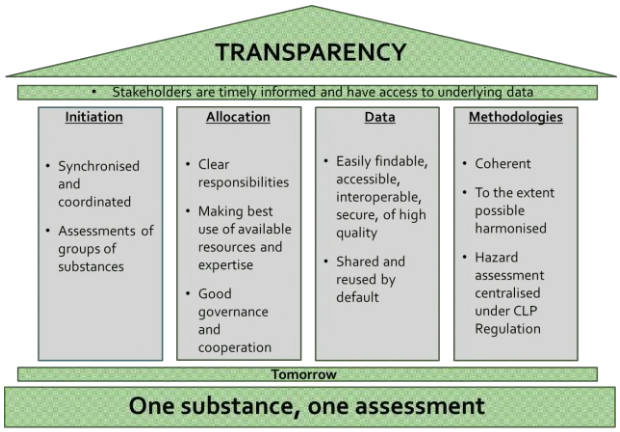
- multiple actors performing scientific and technical work;
- varying degree of scientific robustness and procedural rigour of the actors performing scientific and technical work;
- incoherent methodologies and guidance documents;
- insufficient cooperation and coordination among the actors performing scientific and technical work on chemicals.

The other problems arising from these drivers are being addressed as part of other 'one substance, one assessment' legislative as well as non-legislative actions. For example, the problems related to complicated accessibility and availability of data underlying the assessments are being addressed by the proposal for a Regulation on establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

The problems have evolved as a consequence of the progressive development of the EU legislative framework for chemicals over the last 55 years and without this intervention, it will continue to persist.

3. OBJECTIVES: WHAT IS TO BE ACHIEVED?

The general objective of one substance, one assessment approach and of this initiative is to ensure coherent, efficient and transparent delivery of safety assessments of chemicals across EU chemical legislation and thus contribute to a well-functioning single market for chemicals and a high level of protection of human health and the environment from chemicals.



The specific objectives of the one substance, one assessment approach are:

- Initiation or triggering of the assessments is to the extent possible synchronised and coordinated and substances are assessed in groups rather than substance-by-substance
- Responsibilities for performing the assessment are clear and allocated to make the best use of available expertise and resources and there is a good cooperation among all players
- Assessments have access to all available data without technical and administrative burden
- Methodologies used are coherent and to the extent possible harmonised
- There is a high level of transparency in performing assessments as well as in the underlying scientific data and information

The specific objectives of the legislative proposals on (re-)attribution of tasks to EU Agencies are one step to achieve the one substance, one assessment approach. They are to ensure that:

- allocation of responsibilities for performing the assessments and the underlying technical and scientific work on chemicals is clear, exploits and maximises synergies and makes the best use of available expertise and resources;
- there is a good cooperation among all players on all aspects underling the assessment of chemicals (such as methodology development and exchange of data);
- the deliverables are of high scientific quality and the procedures are transparent and inclusive.

4. AVAILABLE OPTIONS

Considering the problem drivers and the specific objectives to be achieved, there is very little discretion on the main policy choices. The **preferred option** is clearly to **consolidate the technical and scientific work on chemicals performed under the relevant pieces of EU legislation in the EU Agencies** and to **strengthen the cooperation among the EU Agencies** as regards technical and scientific work on chemicals. The EU agencies have been founded as independent bodies with adequate funding, they maintain the necessary expertise, provide robust and high quality scientific work and follow transparent and inclusive procedures. Any other possible option (*e.g.* consolidation of work at other actors than EU Agencies or bringing all the existing actors at the same level of scientific robustness and procedural transparency and ensuring cooperation among them) would be less efficient, more expensive and provide less benefits.

While the main policy option is clear and straightforward, there are sub-options as regards which tasks are suitable and useful to be reattributed to EU Agencies, which EU agency the (re-)attributed tasks should be assigned to and how and in which areas to strengthen the cooperation among the EU Agencies.

Guiding principles for (re-)attribution of scientific and technical work to EU Agencies

The following guiding principles were developed and followed to identify tasks for (re-)attribution to EU Agencies and to decide as to which EU Agency the task should be assigned:

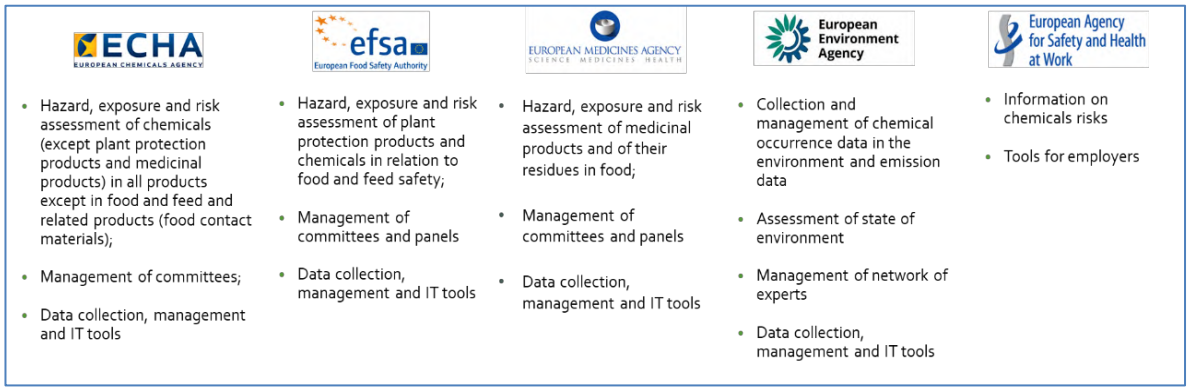
1. The '**technical and scientific work on chemicals**' **is considered in a broad sense** and includes:

- assessments of risk from, hazard of and exposure to chemicals;
- monitoring of occurrence and emissions of chemicals;
- determination of safe levels of chemicals for ecosystems and for humans;
- development of guidance documents;
- managing scientific committees, expert groups and network of experts;
- collecting, analysing and hosting data and information on chemicals and associated processes;
- hosting and operating (public) information platforms on chemicals;
- managing the data flows on chemicals and defining data formats; and
- assessments of socio-economic consequences/impacts of risk management measures on chemicals.

2. The existing technical and scientific work on chemicals performed at EU level under, or in support of, **all relevant EU legislation is considered**. No legislation is a priory excluded.

3. **Consider** attributing the scientific and technical work related to safety assessment of chemicals to one of the EU Agencies with a mandate related to chemicals, *i.e.* the European Chemicals Agency (**ECHA**), the European Food Safety Authority (**EFSA**), the European Medicine Agency (**EMA**), the European Environment Agency (**EEA**) or the European Agency for Safety and Health at Work (EU-**OSHA**);

4. **Ensure fit with the core focus** of the EU Agencies' work on chemicals, in terms of use of substance in specific products, the route of exposure assessed, the type of sectors covered and mission of the agency.



5. **Maximize synergies and coherence** with ongoing activities, by attributing new activities on the basis of similarity with:
   - Substances, data and data flows currently managed by the Agency;
   - Existing expertise and competence;
   - Output being provided by the Agency;
   - Existing processes and procedures implemented by the Agency;
   - Methodologies developed and applied by the Agency;
   - Existing IT tools and planned developments;
   - Networks of experts or committees governed or managed by the Agency.

6. Strive that the (re-)attribution of tasks brings synergies and benefits to the Union beyond a mere shift of responsibilities.

Solutions to strengthen the cooperation among the EU Agencies

The following solutions were identified for strengthening the cooperation among the EU Agencies:

1. All agencies have equal legal obligations to cooperate with other agencies. The areas to be covered are those identified under the one substance, one assessment as affecting the coherence and efficiency of the assessments of chemicals, such as
   - development of methodologies,
   - development of formats and controlled vocabularies,
   - exchange of data and information related to chemicals and their assessment.

2. All agencies have a clear and equal mandate to develop methodologies for assessments related to chemicals in the fields falling within their mandate and to set formats and controlled vocabularies for data and information they hold.
3. All agencies performing the assessment of chemicals should have an obligation to cooperate to prevent the divergent opinions and if divergent opinions appear, they should cooperate to solve it. A procedure for solving the divergent opinions should be specified.

The best results in terms of strengthening the cooperation among the EU Agencies and enabling coherence of scientific and technical work provided by the EU Agencies is achieved by implementing all three solutions. Requiring cooperation among the agencies on certain areas without providing a clear mandate for those areas would not achieve the desired objective. Providing a mandate to an agency for certain areas and not obliging the cooperation among agencies might lead to even more divergence.

5. STAKEHOLDER VIEWS

A call for evidence for the initiative on making best use of EU agencies to streamline scientific assessments was published on the Commission website 'Have your say' on 15 March 2022. The public and stakeholders were invited to provide feedback on this initiative until 12 April 2022. In total, 65 submissions were received. Most were from business associations and companies (in total around 70% of submissions), followed by submissions from EU citizens (11%), non-governmental organisations (6%), public authorities (6%), others (5 %) and academic/research institutions (1.5%). Generally, there was a large support of the initiative among the respondents, whether of the 'one substance, one assessment' approach as a whole or of the specific initiative on the reattribution of tasks. 67% of respondents expressed their explicit support, 23% did not expressed explicitly their opinion but provided relevant advices on how to develop the one substance, one assessment approach. About 10% expressed doubts about usefulness of the initiative or opposition to the initiative.

As the call for evidence was the first public consultation on an initiative under the one substance, one assessment, a lot of feedback received was not specific about the consulted initiative on the (re-)attribution of task to the EU Agencies but about the general scope of the one substance, one assessment approach as well as other initiatives announced under the one substance, one assessment. **Annex II** provides a summary of all the feedback received.

Stakeholders were also informed and consulted on the reattribution of tasks to EU agencies during the Information Session on One Substance, One Assessment with Stakeholders held on 1 June 2022. Some 800 participants followed this on-line event.

An extensive discussion on re-attribution of tasks to EU agencies was held with representatives of Member States and EU agencies at the meetings of the Expert Group on One Substance, One Assessment[7] held on 2-3 June 2022 and on 30 March 2023.

Representatives of Member States and EU agencies participating in the expert group meetings were supportive to the initiative as well, providing concrete suggestions on the reattributions.

The feedback regarding the (re-)attribution of tasks to the EU agencies received from the call for evidence and from Member States and EU agencies during meetings of the Expert Group on One Substance, One Assessment can be grouped in 6 areas and summarised as follows:

- *Level of centralisation:* Stakeholders and Member States suggested that re-attribution of work should not result in a single agency being responsible for the risk evaluations of all chemicals. The regulations must clearly set out the responsibilities of each agency.
- *Expertise:* Stakeholders suggested that reattributing tasks should be done based on the existing expertise available in the agencies to ensure that the agency receiving the task benefits from the necessary expertise. It should be ensured that valuable expertise acquired by existing bodies is preserved. Expertise in risk assessment under the different regulations should stay with those agencies currently responsible for them. Each Agency is best positioned to lead and carry out specific assessments because of their extensive experience in product-specific matters, e.g., EFSA for food use and EMA for medicines use.
- *Resources:* Member States insisted that the new tasks for the agencies must be accompanied by the required resources. Re-attributing work should not lead to an agency or a committee being unable to manage the workload and jeopardise the quality of the work.

- *Organisation of scientific committees:* Member State indicated that the agencies' committees, especially of ECHA, might need to be reorganised to deal with increased workload, as the committee for risk assessment of ECHA has already now a high workload. Instead of creating new scientific panels or committees, the agencies should preferably reinforce and reuse the existing panels, committees and expert/working groups. In any event, safety assessments should be performed by an independent panel, independent committee or expert group that is independent.
- *Tasks to re-attribute:* Some stakeholders and Member States suggested that the ECHA should be involved in hazard assessment as part of the assessment of food contact materials, and EFSA should be involved in risk assessments. The agencies should be involved in evaluating cosmetic ingredients, deriving environmental quality standards under the Water Framework Directive, and in opinions on chemical substances in products (for example in toys).
- *Impact assessment:* A few respondents from stakeholders suggested to carry out an impact assessment on the one substance, one assessment initiative to ensure that possible impacts on businesses are considered sufficiently and that businesses are involved in developing the initiative.

6. SCIENTIFIC AND TECHNICAL WORK ON CHEMICALS FOR (RE-)ATTRIBUTION TO THE EU AGENCIES AND STRENGTHENING THE COOPERATION AMONG THE AGENCIES

Scientific and technical work on chemicals for (re-)attribution to the EU Agencies have been identified under 36 pieces of legislation or work packages (see Table 1 below). The tasks for (re-)attribution have been identified through the targeted inter-service consultation including the EU Agencies, targeted consultation with Member States and targeted consultation with stakeholders and by applying the guiding principles for the (re-)attribution of scientific and technical work on chemicals to the EU Agencies (see section 4). The way how the tasks are (re-)attributed to the EU Agencies was discussed at length between the concerned Commission Service and the receiving Agency, taking into account the policy objectives, desired scientific rigour, scrutiny and technical and organisational feasibility. A particular attention was paid to the assessment of the proximity of a task for (re-)attribution with the Agency's mandate and to the identification of potential synergies and added value of the (re-)attribution.

There are various types of task (re-)attributions that have been proposed or are being considered (see 'task type' in Table 1). Reattribution of existing tasks from a non-agency body to the EU Agencies have been proposed or are being considered to be proposed under 12 pieces of legislation or work packages. Out of these 12 pieces of legislation or work packages, 3 contains reattributions that are accompanied with improvement or expansion of the reattributed tasks while 9 contains reattributions of tasks without their expansion. Attributions under 8 pieces of legislation or work packages are formalisation of the existing attributions of a task to an agency without a legal basis or are improvements of the specification of existing tasks. Attributions under 17 pieces of legislation or work packages contain tasks that are new. Either they are extension of the tasks that already exists at the agencies or they are completely new tasks.

The changes in the founding provisions of ECHA, EEA, EFSA and EMA to strengthen the cooperation among the agencies are listed here as a (re-)attribution, or improvement of the specification of existing tasks, under the respective founding regulations.

The (re-)attribution of tasks have been already adopted for 5 pieces of legislation / work packages, and it was proposed for another 8 pieces of legislation. The (re-)attributions are still to be proposed for 20 pieces of legislation/work packages and for 3 pieces of legislation the tasks are being defined and some of them might be suitable for attribution to the EU Agencies, but it is premature to conclude on this.

Following the guiding principles, the highest number of tasks is to be (re-)attributed to ECHA, followed by EEA, EFSA, EMA and EU-OSHA.

Table 1. **Overview of legislation and work packages with tasks for (re-)attribution to the EU agencies**			
Legislation/work packages with tasks for (re-)attribution		Receiving body	Task type
Already adopted by the co-legislators			
1	Drinking water directive	ECHA	N
2	Regulation on serious cross-border threats to health	ECHA, EEA, EFSA, EMA	RE
3	European Partnership for the Assessment of Risks from Chemicals	ECHA, EEA, EFSA	N
4	Commission implementing decision 2022/1979 under SEVESO directive	EEA	RE
5	Batteries regulation	ECHA	N
Already proposed by the Commission			
6	E-PRTR regulation	EEA	REwE
7	Industrial emissions directive	ECHA	FE, EwE
8	Water legislation (surface and ground water)	ECHA, EEA	RE,N,EwE
9	CLP regulation	ECHA, EFSA	N, EwE
10	Packaging and packaging waste directive	ECHA	EwE
11	Legislation on medicinal products for human use	EMA	FE
12	Directive on end-of-life vehicles	ECHA	RE
13	Toys safety directive	ECHA	RE
Proposed by the Commission as part of the package on one substance, one assessment			
	Proposal for a directive for reattribution of tasks		
14	RoHS directive	ECHA	REwE
	Proposal for a regulation for reattribution of tasks		
15	POPs regulation	ECHA, EEA	REwE
16	Medical devices regulation	ECHA	RE
17	EEA founding regulation	EEA	FE
18	General Food Law	EFSA	FE
	Proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals		
19	Common Data Platform on Chemicals	ECHA, EEA, EFSA, EMA, OSHA	N
20	Information Platform for Chemical Monitoring	ECHA, EEA, EFSA, EMA, OSHA	RE, FE
21	Information on regulatory processes on chemicals	ECHA, EEA, EFSA, OSHA	EwE
22	Repository of reference values	ECHA, EEA, EFSA, EMA, OSHA	N
23	Information on the obligations under Union acts on chemicals	ECHA	EwE
24	Environmental sustainability related data on chemicals	ECHA, EEA, EFSA, EMA, OSHA	N
25	Data generation mechanism	ECHA, EFSA	N
26	Mechanism for notification of studies & database for study notifications	ECHA, EFSA	N
27	Early warning and action system for emerging chemical risks and framework of indicators	ECHA, EEA, EFSA, EMA, OSHA	N, EwE
28	Observatory for specific chemicals with potential contribution to emerging chemical risks	ECHA	FE, EwE
Planned to be proposed by the Commission			
	Legislative proposal for a regulation on ECHA		
29	Cooperation of ECHA with other EU agencies	ECHA	FE
30	Scientific opinions on occupational exposure limits	ECHA	FE
31	REACH regulation	ECHA	EwE
32	Cosmetic products regulation	ECHA	RE
33	Scientific advice of SCHEER on non-chemical topics	SAM	RE
Tasks attribution considered			
34	Sustainable product regulation	-	N
35	Tobacco products directive	-	N
36	Regulation on fluorinated greenhouse gases and Regulation on ozone depleting substances	-	N

Legend: Colours are used to distinguish the legislative initiatives; N – attribution of a new task, EwE – existing task expanded; FE – formalisation of attribution of an existing task or better specification of an existing task, RE – reattribution of an existing task, REwE – reattribution of existing task and its expansion or improvement;

A brief description of the tasks and work for (re-)attribution per legislation or work package, including the strengthening the provisions for cooperation among the EU Agencies, is provided below (for detailed description see Annex III):

1. *Drinking water directive*[24]

Revision of the drinking water directive in 2020 attributed **new tasks** to **ECHA**. ECHA is responsible for establishing and maintaining four EU positive lists for substances and compositions authorized to be used for the manufacturing of organic, cementitious, metallic and inorganic materials in contact with water intended for human consumption. ECHA first supports the Commission in compiling the first EU positive lists based on the national lists. Once established, ECHA will maintain the lists through the review of all the entries in the lists and then through the addition, removal and updating of the entries.

2. *Regulation on serious cross-border threats to health*[25]

The new regulation on serious cross-border threats to health **reattributed an existing task** performed by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to **ECHA, EEA, EFSA, EMA** and also to the European Centre for Disease Prevention and Control and the European Monitoring Centre for Drugs and Drug Addiction. The regulation requires the agencies, on the request of the Commission, to carry out a risk assessment of the potential severity of the threat to public health, including possible public health measures when there is an alert of a cross-border threat of chemical origin. The responsibility for rapid risk assessment for risks of a cross-border threat that is linked to medicinal products and medical devices is assigned to the EMA, for risks of a cross-border threat of chemical origin is shared between the ECHA and the EFSA based on their mandate and for risk of a cross border threat of threats of environmental origin, including those due to the climate, are shared among the ECHA, the EFSA and the EEA based on their mandate. The agencies will have to set up and maintain a continuous readiness to provide rapid risk assessments and on the request provide the requested risk assessment.

3. *European Partnership for the Assessment of Risks from Chemicals (PARC)*[26]

PARC is a 7-year partnership funded by Horizon Europe that started in May 2022 and aims to advance research, share knowledge and improve skills in chemical risk assessment. **ECHA, EEA** and **EFSA** took a **new task** to provide input and support to the project in order to ensure maximum links with and benefits for the regulatory risk assessments of chemicals.

4. *Commission implementing decision (EU) 2022/1979 under the SEVESO Directive*[27]

The commission implementing decision **reattributed an existing task** performed by the Commission (DG JRC) to **EEA**. EEA is tasked to redevelop and maintain the databases and associated procedures for the reporting of information on industrial major accidents (eMARS) and for reporting of the location of Seveso establishments (eSPIRS) under the SEVESO III directive.

5. *Batteries regulation*[28]

The new regulation on batteries revising an old battery directive attributed a **new task** to **ECHA**. ECHA is tasked to prepare, on the request of the Commission, restriction dossiers for substances in batteries, to get opinions on them from the Committee for Risk Assessment and from the Committee on Socio-Economic Analysis and to submit the opinions to the Commission for potential restrictions via a delegated act.

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[24] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435 23.12.2020, p. 1).

[25] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314 6.12.2022, p. 26).

[26] https://www.eu-parc.eu

[27] Commission Implementing Decision (EU) 2022/1979 of 31 August 2022 on establishing the form and databases for communicating the information referred to in Articles 18(1) and 21(3) of Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances and repealing Commission Implementing Decision 2014/895/EU (OJ L 272 20.10.2022, p. 14).

[28] Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p.1).

6. E-PRTR regulation[29]

The proposal for revision of the E-PRTR regulation proposes to **expand the existing task** of **EEA** to operate the European Pollutant Release and Transfer Register. EEA is tasked to operate an Industrial Emission Portal, which should replace the E-PRTR register and as compared to the E-PRTR should contain information on emissions for more substances and for more industrial activities and should contain also information on the use of water, energy and raw materials.

7. Industrial emissions directive[30]

The proposal for the revision of the Industrial Emissions Directive proposes to **formalise existing task** of **ECHA** performed at ad-hoc basis and **extend it** to cover holistic consideration of chemicals in the permits of the industrial emissions directive installations, from their presence in the (primary or secondary) raw materials to their presence in the emissions from the installations, as well as in the waste and by-products generated. ECHA is requested to support the Commission in the review of the Best Available Techniques Reference (BREF) documents as regards the chemicals and industrial chemicals processes.

8. Water framework directive, Environmental Quality Standard Directive and Ground Water Directive[31]

The proposal for the revision of the water framework directive, the environmental quality standard directive and the ground water directive proposes to **reattribute existing tasks** performed by the Commission and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to **ECHA, attribute a new task** to **ECHA** and **expand the existing tasks** performed by **EEA**. ECHA and its Committee for Risk Assessment are requested under the Environmental Quality Standard directive to take over performing assessments underpinning the amendment of priority list of substances, derivation of Environmental Quality Standards, amendment of the 'watch list' and coordination of the 'watch list' activities. ECHA and its Committee for Risk Assessment are requested under the Ground Water Directive to perform new assessments underpinning the review of Annexes I and II with limit values for chemicals in ground water, the amendment of 'watch list' and coordination of the 'watch list' activities. EEA is requested to expand its task on collection of monitoring data in surface waters and to harvest all chemical monitoring data in waters generated by Member States.

9. CLP Regulation[32]

The proposal for revision of the CLP regulation proposes to attribute a **new task** to **ECHA** and **EFSA** and **expand the existing tasks** of **ECHA**. ECHA and EFSA are required to prepare, on the request of the Commission, dossiers for harmonised classification of substances. ECHA's Committee for Risk Assessment is then expected to prepare opinions on the dossiers prepared by ECHA or EFSA, which will be submitted to the Commission for potential amendment of Annex VI of CLP.

10. Packaging and packaging waste directive[33]

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[29] Proposal for a Regulation of the European Parliament and of the Council on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal (COM/2022/157 final).

[30] Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (COM (2022) 156 final).

[31] Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy (COM(2022) 540 final)

[32] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (COM (2022) 748 final).

[33] Proposal for a regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (COM(2022) 677 final).

The proposal for revision of the packaging and packaging waste proposes to **extend the scope of task** of **ECHA** to process or eventually also to prepare a proposal for restriction under REACH that covers or is focused on a presence of a substance in packaging. Such restriction will be under the scope of REACH, so this relies on the existing REACH task.

11. Legislation on medicinal products for human use[34,35]

The proposal for revision of the regulation and directive on medicinal products for human use proposes to introduce a **new task** and **better specify existing tasks** of **EMA**. EMA is required to actively cooperate with other EU Agencies as regards exchange of data, methodologies and scientific assessments. EMA is further required to engage more in preventing or solving a divergent opinion with other EU Agencies. The goal is to ensure coherence, consistency and interoperability in the specified areas. EMA is also expected to receive marketing authorisation applications, like any other applications submitted to EMA, in electronic form and follow the digital by default principle. In addition, EMA is requested to set up an active substance based monograph system from environmental risk assessments.

12. Directive on end-of-life vehicles[36]

The proposal for the revision of the directive on end-of-life vehicles proposes **reattribution of an existing task** to **ECHA**. ECHA's Committee for Socio-Economic Assessment will be required to provide assessments underpinning review of exemption from existing restriction on lead, mercury, cadmium or hexavalent chromium. ECHA is also required as part of REACH process to provide assessments underpinning restriction of hazardous substances in end-of-life vehicles. Such restriction will be under the scope of REACH, so this relies on the existing REACH task.

13. Toy safety directive[37]

The proposal for the revision of the toy safety directive proposes **reattribution of existing tasks** to **ECHA** and **extending** some of them. ECHA's committees for risk assessment and socio-economic analysis is required to provide assessments underpinning the establishment or strengthening of chemical limit values in toys, the amendment of the limit values for heavy metals in toys, the amendments to the lists of allergenic fragrances that are prohibited in toys or that have to be labelled if present in toys and the granting of derogations for the use of carcinogenic, mutagenic and reprotoxic substances in toys.

14. Directive on restriction of hazardous substances (RoHS) in electrical and electronic equipment

The proposal for amendment of the RoHS directive adopted as part the one substance, one assessment package proposes to **reattribute the existing tasks** performed by the Commission to **ECHA** and **improve how those tasks are executed**. ECHA is required to prepare, on the request of the Commission, a restriction dossier for substances in electrical and electronic equipment. Such dossier can be also prepared by a Member State. ECHA's Committees for Risk Assessment and for Socio-Economic Analysis are then requested to prepare an opinion on the restriction dossier (prepared by itself or by a Member State) and submit such opinions to the Commission. ECHA is also requested to receive applications for granting, renewing or revoking an exemption

[34] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM (2023) 192 final).
[35] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM (2023) 193 final).
[36] Proposal for a Regulation of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulation (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC (COM (2023) 451 final).
[37] Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC (COM(2023) 462 final).

from the substance restrictions, verify its completeness, get an opinion of its Committee for Socio-Economic Analysis and if necessary from its Committee for Risk Assessment and submit the opinions to the Commission.

15. POPs regulation

The proposal for amendment of the POPs regulation via the omnibus regulation on (re-)attribution of tasks adopted as part of the one substance, one assessment package proposes to **reattribute the existing tasks** performed by the Commission to **ECHA** and **EEA** and **improve how those tasks are executed**. On the request of the Commission, ECHA is expected to provide assessments underpinning setting concentration limit values for substances subject to waste management provisions as part of the review of Annexes IV and V of the POPs regulation. As part of that assessment, ECHA is required to prepare a report on the assessment with the proposal for concentration limit values, get opinion of its Committee for Socio-Economic Assessment on the report and submit the opinion to the Commission as an input for amendment of Annexes IV and V via the delegated act. EEA is expected to host the chemical monitoring data in the environment of the POPs listed in Annex III, Part I.

16. Medical devices regulation

The proposal for amendment of the medical product regulation via the omnibus regulation on (re-)attribution of tasks adopted as part of the one substance, one assessment package proposes to **reattribute the existing tasks** performed by the Commission and its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to **ECHA**. ECHA is required every 5 years to review the guidelines on how to perform the benefit-risk assessment of the presence of phthalates in medical devices. In addition, on the request of the Commission, ECHA is required to prepare and review the guidelines on how to perform the benefit-risk assessment of the presence of carcinogenic, mutagenic, reprotoxic or endocrine-disrupting substances in medical devices.

17. EEA founding regulation

The proposal for amendment of the EEA founding regulation via the omnibus regulation on (re-)attribution of tasks adopted as part of the one substance, one assessment package proposes to **better specify existing tasks** of **EEA**. EEA is given a mandate to develop assessment methodologies related to chemicals within the mission of the agency and EEA is required to actively cooperate with other EU Agencies as regards exchange of data and development of methodologies. The goal is to ensure coherence, consistency and interoperability in the specified areas.

18. General Food Law

The proposal for amendment of the General Food Law establishing EFSA via the omnibus regulation on (re-)attribution of tasks adopted as part of the one substance, one assessment package proposes to **better specify existing tasks** of **EFSA**. EFSA is required to actively cooperate with other EU Agencies as regards exchange of data and development of methodologies. EFSA is further required to engage more in preventing or solving a divergent opinion with other EU Agencies. The goal is to ensure coherence, consistency and interoperability in the specified areas.

19. Common Data Platform on Chemicals

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package assigns **new tasks** to **ECHA, EEA, EFSA, EMA and EU-OSHA**. ECHA is requested to set up and operate the common data platform on chemicals, including the database of standard formats and controlled vocabularies. All agencies are requested to make the data on chemicals they hold available to the platform in appropriate formats for sharing among the authorities, to set formats and controlled vocabularies in their area of competence so data can be easily shared and to cooperate with ECHA and among each other in developing and operating the common data platform.

20. Information platform for chemical monitoring (IPCHEM)

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes to **reattribute the existing task** performed by the Commission to **ECHA** and **EEA**. ECHA is required to operate the IPCHEM as part of the common data platform on chemicals and host occupational monitoring data. EEA is requested to collect and host the human biomonitoring data and host environmental occurrence data and indoor air quality data. The proposal will also **formalise the tasks** of ECHA, EFSA, EEA, EMA and EU-OSHA to provide available chemical monitoring data to ECHA for integration into IPCHEM.

21. Information on regulatory processes on chemicals

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes to **extend the existing task** currently managed by **ECHA**. ECHA is requested to continue operating the (public) activities coordination tool ((P)ACT) system and extend it to other pieces of legislation. **EFSA**, **EEA and EU-OSHA** are required to provide the relevant information to ECHA.

22. Repository of reference values

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes a **new task** to **ECHA**, **EFSA, EEA, EMA and EU-OSHA**. ECHA is requested to set up, operate and populate with scientific and regulatory reference values a repository of reference values and to collate in it the regulatory reference values. **EFSA, EEA, EMA and EU-OSHA** are required to cooperate with ECHA in the operation of the repository and provide to ECHA the scientific reference values they derive.

23. Information on regulatory processes on chemicals

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes to formalise and **expand the existing task** ECHA is already carrying out with the EU chemicals legislation finder (EUCLEF). **ECHA** is required to continue the operation of EUCLEF and extend it to cover all relevant legislative pieces on chemicals.

24. *Database on environmental sustainability related data*

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes a **new task to ECHA**. ECHA is requested to set up and operate a database with environmental sustainability data on chemicals. ECHA, EEA, EFSA, EMA and EU-OSHA are required to make available to the ECHA any environmental sustainability related data they host or hold. The agencies also need to provide the necessary technical cooperation to ECHA to enable the integration of the data in the common data platform on chemicals.

25. *Data generation mechanism*

The proposal a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes a **new task** to **ECHA** and **EFSA**. ECHA is required to commission studies in support of the implementation of chemicals legislation and to contribute to the support, evaluation or development of EU chemicals policy. ECHA is required to do it on its own initiative or on the request of the Commission. The procedure is complementary to the existing procedure operated by EFSA under Article 32 of the General Food Law and ECHA and EFSA should cooperate in designing and commissioning the studies under both procedures.

26. Mechanism for notification of studies and database for study notifications

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes a **new task** to **ECHA**. ECHA is required to set up a database of study notifications for studies beyond the food sector (*i.e.* for studies

not already subject to the notification obligation of Article 32b of the General Food Law and notified to EFSA). ECHA and EFSA are required to cooperate to ensure compatibility of the respective systems. ECHA is expected to control fulfilment of the obligations to notify the studies as part of the compliance check under REACH and as part of approval of biocidal active substances and products.

27. Early warning and action system for emerging chemical risks and framework of indicators

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes a **new task** on an early warning and action system to **EEA, ECHA, EFSA, EMA and EU-OSHA. It also proposes to formalise the existing task** on an indicator framework performed by **EEA and ECHA.** For the early warning system, EEA is required to compile and collect annually the early warning signals into a report to be presented to the Member State authorities, relevant EU agencies and the Commission to consider whether any regulatory action is needed. ECHA, EFSA, EMA and EU-OSHA are required to cooperate with EEA and provide early warning signals from their areas of responsibility. For the framework of indicators, EEA and ECHA are required to operate and populate the indicator framework for chemicals policy.

28. Observatory for specific chemicals with potential contribution to emerging chemical risks

The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals adopted as part of the one substance, one assessment package proposes to **formalise the existing task** performed by **ECHA** and **expand** its scope. ECHA is required to continue operating the existing observatory for nanomaterials and extend its scope to chemicals and materials of potential emerging risk.

29. Cooperation of ECHA with other EU agencies

The proposal for the regulation on ECHA will consider proposing **a new task to ECHA** and **better specify the existing tasks**. ECHA should be given a formal mandate to develop methodologies for assessment of chemicals in the areas falling within its mission. ECHA should be required to actively cooperate with other EU Agencies as regards exchange of data and development of methodologies. Finally, ECHA should be further required to engage more in preventing or solving a divergent opinion with other EU Agencies. The goal is to ensure coherence, consistency and interoperability in the specified areas.

30. Scientific opinions on occupational exposure limits

The proposal for the regulation on ECHA will consider to **formalise the existing task** of **ECHA**. ECHA and its Committee for Risk Assessment should be given a legal mandate to provide opinions on occupational exposure limits in support of the Directive on carcinogens, mutagen or reprotoxic substances at work, Chemical Agent Directive and Asbestos Directive. ECHA already does so, but without a formal mandate and via a service level agreement with the Commission.

31. REACH regulation[38]

The proposal for a REACH revision will consider proposing **changes in the existing** tasks of **ECHA**. ECHA should be required to implement the changed tasks. This should include expanded registration obligations (to polymers), changes in the restriction (expansion of the generic approach to risk management) and authorisation procedures and changes in enforcement provisions.

32. Cosmetic products regulation[39]

The proposal for the targeted revision of the Cosmetic Products Regulation will consider proposing **reattribution of existing tasks** to **ECHA**. ECHA should be required to take over hosting of the Scientific Committee on Consumer Safety (SCCS) which assesses the safety of chemicals underpinning the process for the authorisation of colorants, preservatives and UV-filters, the process for prohibition or restriction of ingredients used in cosmetic products where concerns are raised due to potential risks to human health, the

[38] Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment (europa.eu)
[39] EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision) (europa.eu)

process for granting an exemption from the prohibition of chemicals that cause cancers, gene mutations, affect the reproductive or endocrine system and the process for examining the safety of substances used in cosmetic products that could affect the respiratory system and chemicals toxic to a specific organ. ECHA and its committee should be also required to produce a technical guidance document concerning different aspects of testing and safety evaluation of cosmetic substances including for nanomaterials used is cosmetics.

33. Non-chemical assessments performed by SCHEER

The Commission Decision on discontinuing the operation of scientific committees SCHEER and SCCS will result in **reattribution of existing tasks** to **the Commission Scientific Advisory Mechanism (SAM).** SAM will be required on the ad hoc basis to provide a scientific advice on non-chemical topics currently provided by SCHEER.

34. Ecodesign for sustainable products regulation[40]

The proposal for regulation on eco-design for sustainable products envisages some new tasks that could be potentially attributed to EU Agencies. These tasks are not defined in the proposal but rather to be specified in the envisaged implementing acts. Such envisaged tasks include involvement of ECHA in the development of a product passport that should hold also information on substances of concern.

35. Tobacco products directive[41]

The tobacco directive is undergoing an evaluation and a revision of the directive is being envisaged. As part of the revision, a new scientific and technical work is being envisaged that could be potentially attributed to EU Agencies. This includes managing the laboratory network on tobacco control, checking compliance with product presentation provisions, running the procedure determining characterizing flavour, updating negative/positive lists of additives, hosting product database and making publicly available the product information, monitoring of data in product notifications and assessing information on leaflets. The tasks are not yet clear but those that are being considered do not naturally fit to the agencies considered in this initiative.

36. Regulation on fluorinated greenhouse gases[42] *and the Regulation on ozone depleting substances*[43]

The proposal for a regulation on fluorinated greenhouse gases establishes an obligation on the Commission to operate an electronic system for the management of the quota system, licensing of imports and exports and reporting and introduces invoicing fees for the quotas. Similarly for the Regulation on ozone depleting substance, the Commission has the obligation to operate a licencing and reporting system. It is not yet clear how the tasks can be implemented most effectively, but it is envisaged that an agency could take some of the tasks in case that would be deemed to be the best option at a later stage.

7. ASSESSMENT OF IMPACTS

The fitness check of all chemical legislation (excluding REACH) assessed most of the challenges and risks addressed through this initiative and concluded that there are significant opportunities for streamlining the technical and scientific work through EU agencies. Moreover, there is little discretion of the policy choice as to achieve objectives of the initiative. The consolidation of the technical and scientific work on chemicals at the EU level is possible only in the EU Agencies. Therefore, no formal impact assessment was carried out.

Overall impact

Although no formal assessment of social, economic and environmental impacts was carried out, such impacts were qualitatively assessed by the Commission with the help of external consultants. The outcomes of the

[40] Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting eco-design requirements for sustainable products and repealing Directive 2009/125EC (COM (2022) 142 final).
[41] Evaluation of the legislative framework for tobacco control (europa.eu)
[42] Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (COM (2022) 150 final).
[43] Proposal for a Regulation of the European Parliament and of the Council on substances that deplete the ozone layer and repealing Regulation (EC) No 1005/2009 (COM (2022) 151 final).

assessment is provided in the sub section 'overall impact' of the section 8 for the legislative proposals on reattribution of tasks and of the section 9 for the legislative proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals. The overall impacts from all reattributions are summarised in the section 10.1. 'added value and synergies of the (re-)attributions'.

Assessment of impacts on resources and committees of EU agencies

As the (re-)attribution of tasks to EU agencies will have a major impacts on their resource and capacity needs, these impacts were assessed in great detail. Assessment of impacts of the (re-)attribution of each task to the EU Agencies included assessment of synergies and added value of the (re-)attribution, estimation of the impacts on Agencies' committees, data model and IT infrastructure and key experts and estimation of the workload and associated resource needs for the Agencies. For the existing tasks to be reattributed, the assessment also included description of the current workload and estimation of the current use of resources. The detailed assessment of impacts for each task per legislation or work package is provided in **Annex III**.

The estimation of the current resource use included an estimation of the full time equivalents dedicated to the tasks. This consisted of the estimation of the full time equivalent of the Commission staff as well as estimation of the full-time equivalents of the contracted staff (external and intramurous consultant, interim staff). To convert the cost of consultants into full time equivalents, the cost of 1 full time equivalent of a consultant was estimated based on the contracts and average Belgium salary at ca. EUR 66 000 annually[44]. It should be noted that the estimation of full-time equivalents for the Commission staff does not include administrative or IT overhead of the Commission.

The estimation of the resource needs for the Agencies was done in close and frequent consultation with the Agencies concerned. The operation of each (re-)attributed task to Agencies has been assumed to be done through implementing similar processes and similar level of scientific scrutiny and digitalisation to what is already in place for Agencies' current tasks. The benefit of this approach is to ensure a consistent standard of scientific quality, transparency and data interoperability as well as to maximise the reuse of existing processes and tools. In general, internal experts were assumed to be used for scientific and technical work underpinning assessments related to chemicals and the agencies' committees to be used to validate the work through provisions of opinions. External contracting was envisaged for the IT development as well as for the collection of data or information.

ECHA is the agency to receive most of the assessment work on chemicals. The estimation of the resource needs for the new assessment task to be allocated to ECHA was built on the ECHA's experience of the resource needs for their existing processes. The experience shows that resource requirement for the development of an opinion on harmonised classification varies between 0.35 – 0.65 FTEs per dossier (0.35 for low complexity dossier, 0.5 for average complexity and 0.65 FTE for complex dossier), for scientific opinion on the occupational exposure limit values is average of 0.7 FTE per dossier, for opinion on REACH authorisation is 0.15 FTE pre dossier of low complexity up to 0.35 FTE per dossier of high complexity, for opinion on REACH restriction is 1 FTE per dossier of low complexity up to 1.5 FTE per dossier of high complexity. An overhead of 15% was added to the resource estimate for the development and maintenance of common IT components and additional 15% for the contribution to the horizontal support (governance & enablers / administrative overhead).

8. IMPACTS OF THE LEGISLATIVE PROPOSALS ON REATTRIBUTION OF TASKS

Overall impact

Overall, this proposal is expected to improve the efficiency, effectiveness, coherence and transparency of EU processes for chemical assessments for the benefit of all stakeholders. Citizens and the environment will benefit from better protection from dangerous chemicals as a result of more efficient and effective assessment processes. Companies will benefit from more harmonised and transparent processes across legislation, from a

[44] This number corresponds to a medium to high BE annual salary cost (see e.g. An overview of Belgian wages and salaries | Statbel (fgov.be)); Belgian average salaries were used because many companies contracted by the Commission are based on Belgium.

reduced number of bodies involved in safety and risk assessments, as well as from strengthened certainty regarding the validity of assessments. Finally, the national and EU authorities will benefit from improved efficiency of delivery of assessments and improved public trust and acceptance of regulatory decisions.

- **Improved scientific consistency and coherence of assessments** – The reduced number of actors involved in the scientific and technical work, as well as an increased cooperation and obligation to solve divergent opinions among agencies leads to improved coherence and scientific consistency - both across the various Union acts, and across the assessment processes laid out therein. The consolidation of work allows to better align priority setting, timelines, processes, and methodologies used for the assessments. It facilitates re-use of assessment insights developed under one Union act on chemicals in the assessment process of another.
- **Improved robustness of assessment, trust and acceptance of regulatory decisions** – The involvement of the EU agencies and their committees in the scientific and technical work on chemicals adds more scientific expertise, ensures high quality of scientific advice and leads to improved robustness of assessments and thus their acceptance.
- **Strengthen independence of the scientific advice** – Moving scientific and technical work on chemicals from the Commission, ad hoc committees or consultants to EU agencies and their committees reinforces the independence of the scientific advice and the separation between science and policy or between risk assessment and management. Agencies are independent and their committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
- **Improved transparency** – The involvement of the EU agencies in scientific and technical work will ensure transparency to the process in terms of overall process transparency.
- **Improved efficiency of delivery of assessments** – Centralising assessment work in the EU agencies will allow the re-use of capabilities, the re-use of knowledge and experience, and the re-use of IT tools and support services.

Impact on resources of Agencies and the Commission

The proposal for a directive on reattribution of tasks will amend RoHS directive to reattribute the assessment work under this directive to ECHA. The proposal for a regulation on reattribution of tasks will amend 2 legislative pieces (POPs Regulation and Medical devices regulation) to reattribute the assessment work under these pieces of legislation to ECHA and it will amend the EEA founding regulation and the general food law (EFSA founding regulation) to ensure better cooperation among agencies on methodology development and on exchange of data. In summary for these two proposals on reattribution, in the first year, there will be a need of **4 FTEs (4 TAs)** and operational costs of **EUR 101 000** per year and as of the second year, there will be a need of **9 FTEs (6 TA + 3 CA)** per year and operational budget of **EUR 83 000 per year**. All new resources are needed for ECHA, no additional resources are needed for EEA and EFSA. Considering the resources currently used for the tasks to be reattributed, there will be a total **net increase** in the resources from 2026 and beyond as compared to today of **4.5 FTEs** per year and **EUR 59 000 per year**.

Table 2. Resource needs per legislation amended via the directive and regulation on reattribution of tasks (operational costs in EUR 1 000)

	FTEs								Operational costs			
Legislation	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Proposal for a directive on reattribution of scientific and technical work												
RoHS directive	3	0	4	3	4	3	4	3	66	33	33	33
Proposal for a regulation on reattribution of scientific and technical work												
POPs regulation	1	0	2	0	2	0	2	0	35	50	50	50
Medical devices regulation	0	0	0	0	0	0	0	0	0	0	0	0
EEA founding regulation	0	0	0	0	0	0	0	0	0	0	0	0

General food law (EFSA founding regulation)	0	0	0	0	0	0	0	0	0	0	0	0
SUM	**4**	**0**	**6**	**3**	**6**	**3**	**6**	**3**	**101**	**83**	**83**	**83**

Table 3. Current resource use for technical and scientific work to be reattributed to ECHA	
RoHS directive • Assessments underpinning restrictions of hazardous substances in electrical and electronic equipment • Review of applications for exemptions from the restrictions	Total ca. 2.74 FTEs/year: EUR 145 000 annually (on average) for outsourcing the review of exemptions (= ca. 2.2 FTEs/year) + a contract of EUR 180 000 on average each 5 years for reviewing restrictions (= 0.54 FTE/year). (In addition, DG ENV ca. 1.5 FTE/year (for overall RoHS implementation) whose work will remain).
POPs regulation • Technical assistance in reviewing Annexes IV and V • Hosting POPs monitoring data	Total ca. 1.5 FTEs/year: EUR 300 000 for consultants every 3 years (=1.5 FTE/year). (In addition, DG ENV ca. 0.5 FTE/year (implementing the review of Annexes IV and V) whose work will remain).
Medical devices regulation • Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of phthalates in medical devices • Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of CMR and endocrine-disrupting substances in medical devices	Total ca. 0.3 FTE/year + EUR 24 000/year: DG SANTE SCHEER secretariat 0.3 FTE (ca. 10% of SCHEER secretariat work), EUR 24 000/year for indemnities, travel, *e.g.* costs for members of the committee. (In addition, DG SANTE (policy unit) 0.1 FTE/year whose work will remain).
SUM	**0.3 FTEs/year of regular staff; 4.2 FTEs/year of intramurous contractors or interim staff (ca. EUR 281 000/year); Operational costs of ca. EUR 24 000/year**

Changes to RoHS directive will reattribute the assessments underpinning restrictions of hazardous substances in electrical and electronic equipment and review of applications for exemptions from the restrictions to ECHA. For this work, ECHA will require in the first year 3 FTEs (3 TAs) and operational budget of EUR 66 000 and as of the second year 7 FTEs (4 TAs + 3 CAs) per year and operational budget of EUR 33 000 per year. The work is currently performed with the help of consultants and amounts to approximately 2.74 FTE per year (ca. EUR 145 000 annually for outsourcing the review of exemptions (ca. 2.2 FTEs/years) + ca. EUR 180 000 every 5 years for contracts to review restrictions (ca. 0.54 FTE/year)). DG ENV uses ca. 1.5 FTE of core staff for overall RoHS implementation, which will need to continue. The resources currently spent are however insufficient leading to the accumulation of requests for exemptions without processing them to the legal drafting (by December 2022, over 60 exemption requests were pending) and the revision of the restriction was delayed (the review not finalised although it has started in 2018). There are also complaints about the quality and robustness of the assessments, the transparency of the process and involvement of stakeholders. The reattribution to ECHA and using its processes will address these shortcomings and will ensure alignment with other chemicals legislation.

Changes to POPs regulation will reattribute the technical assistance in reviewing Annexes IV and V to ECHA and hosting the POPs monitoring data to EEA. For this work, ECHA will require in the first year 1 FTE (1 TA) and operational budget of EUR 35 000 and as of the second year 2 FTEs (2 TAs) per year and operational budget of EUR 50 000 per year. No resources are needed for EEA. The work on reviewing the Annexes IV and V is currently performed by the Commission with the help of consultants and amounts to approximately 1.5 FTEs per year (EUR 300 000 for consultants every 3 years (=1.5 FTE/year)). DG ENV uses ca. 0.5 FTE/year of core staff for implementing the review of Annexes IV and V, which will however need to continue. The involvement of ECHA and its Committee for Socio-Economic Analysis is envisaged to provide a significant increase in the scientific quality, the consistency, the robustness and the level of independence of the assessments upon which the Commission develops its proposals on this matter. The hosting of chemicals monitoring data under the POPs regulation is currently done by the Commission. Transfer of this work to EEA will require no additional resources, as POPs monitoring data in waters are to be reported to EEA under the water legislation and resources for that were proposed in the recent proposal, the POPs monitoring data in air are already being reported to EEA as part of the air quality legislation and covered by resources for that activity.

In addition, hosting of any additional data sets in the environment is also covered in the resource for common data platform.

Changes to medical devices regulation will not require any additional resources for ECHA. The work is currently performed by the Commission supported by the SCHEER committee. The current resource use is estimated to be 0.3 FTE per year and EUR 24 000 per year (DG SANTE SCHEER secretariat 0.3 FTE (ca. 10% of SCHEER secretariat work), EUR 24 000 per year for indemnities, travel, e.g. costs for members of the committee). DG SANTE uses (policy unit) uses ca. 0.1 FTE of core staff per year for implementation of the related provisions, which will however need to continue. Considering that the envisaged frequency of the work is very low, the involvement of the Committees is only where necessary and the first work will likely materialise only in 2029, the work can be absorbed by ECHA without any additional resources.

Changes to the regulation on the European Environment Agency and to the regulation on the general principles and requirements of food law and establishing the European Food Safety Authority will have no resource implications. The provisions formalise the activities already performed, they prescribe the procedural steps to follow and they enable the implementation of the proposal for a regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals. Any possible resource needs stemming from these provisions can be absorbed by the existing resources of the agencies.

Impact on committees of Agencies

There will be an impact on ECHA's committees for risk assessment and for socio-economic analysis. It is estimated that the **committee for risk assessment** will have to process *ca.* **4 opinions per year**: one opinion on new restriction of a substance (which is of equivalent of low complexity restriction under REACH) and 3 opinions per year on requests for new exemptions (which is expected to be lighter dossier than the low complexity restriction dossier under REACH) under RoHS. The **committee for socio-economic analysis** is expected to process *ca.* **33 opinions per year**: 1 opinion on restriction of a substance and 30 opinions on the requests for exemption under RoHS, and 2 opinions on the revision of Annex IV and V and the proposed limit value under the POPs regulation.

Table 4. Expected number of opinions from ECHA's committees per year and per legislation

	RAC	SEAC
RoHS directive		
- Restriction	1	1
- Request for exemption	3	30
POPs regulation		
- Review of Annexes IV and V	-	2
SUM	**4**	**33**

9. IMPACT OF THE LEGISLATIVE PROPOSAL FOR A REGULATION ESTABLISHING A COMMON DATA PLATFORM AND A MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS

Overall impact

Overall, this proposal is expected to contribute to an improvement of the efficiency, coherence, quality and transparency of chemicals assessments under EU legislation as well as to the early identification of emerging chemicals risks. It will therefore improve the protection of human health and the environment from chemicals, for the benefit of Member State authorities, stakeholders and citizens. In addition, the initiative simplifies access to chemicals information for everyone (citizens, industry, national authorities, EU agencies, the Commission) thus increasing transparency. Moreover, it will improve predictability and thus the possibility for the industry, national authorities and EU agencies to plan – and where relevant coordinate – their activities:

- Bringing together chemicals data in one common data platform will increase findability and simplify access, which is beneficial for all users. The platform will operationalise the ambition of the one-substance one-assessment approach, supporting quality and mutual coherence of chemicals

assessments. The use of standard formats and controlled vocabularies will enhance interoperability of information, thus increasing its findability. In addition, information across regulatory dossiers will be easier to compare. An increased findability and comparability will in turn reduce administrative burden for risk assessors, which include national administrations, and have a positive impact on the effectiveness, efficiency and coherence of chemical safety assessments.

- Through the extended utility of shared information in the common data platform, this proposal will help minimise potential duplication of efforts and optimise data generation strategies. With an increased volume and transparency of data on chemical properties and supported by adequate context data that enables the responsible use of that chemicals data, compliance with and enforcement of existing obligations should be facilitated.
- Building on integrated access and services the common data platform is expected to provide additional insight into effective risk management measures and to facilitate the search for safe and sustainable alternatives, leading to improvements in the protection of human health and the environment.
- Bringing together chemicals data and being allowed to use it will increase the knowledge base for scientific assessments and opinions, thus improving their robustness. This will in turn increase the acceptance by society of conclusions and regulatory decisions. Knowing through the notification of studies that all studies have been considered in an assessment further strengthens the trust of citizens in regulatory decisions.
- A dedicated service in the common data platform related to information on regulatory processes planned or ongoing by the Commission, EU agencies and Member States will improve the coordination of activities, which in turn will allow better planning for the authorities and agencies involved, thus increasing efficiency. That information will also allow better predictability and planning for industry, facilitating receipt of comprehensive but also consistent input to the activities, where required. It will be easier for industry but also other stakeholders to know when and how to contribute to regulatory processes.
- A dedicated service in the common data platform related to obligations under EU legal acts on chemicals will be very valuable for industry, and in particular for SMEs and microenterprises, to easily get an overview of their legal obligations, which will give them certainty on what exactly their duties are. Acting with such full knowledge in turn supports compliance and correspondingly reduces burden on national authorities.
- The establishment of a monitoring and outlook framework including an early warning and action system for emerging chemical risks will allow to shorten the reaction time between early signals of risks and regulatory measures to reduce those rusks, and as such will lead to an improved protection of human health and the environment.
- The establishment of a data generation mechanism allows the commissioning of studies when there are no legal provisions to obtain them. This will contribute to the creation of a complete knowledge base.

The establishment and operation of the platform will not impose any costs on industry. Economic operators will continue to have to fulfil their legal obligations as they are doing today under the relevant specific pieces of legislation. Economic operators and laboratories will experience some administrative burden linked to the requirement to submit a notification when a study is intended to be commissioned or carried out. Quantified costs associated with the notification obligation are set out in the staff working document accompanying this proposal[45].

The establishment of the platform will be associated with significant costs for the EU agencies, but they should principally be seen as investment in technical progress within the data economy, enhancing the value of existing and future data. The task requires investment in entirely new data structures and IT

[45] Commission staff working document accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

systems/capabilities, principally on the ECHA's side, but also on the side of other EU agencies as data source owners who are to prepare datasets for integration in the platform.

Impact on resources of Agencies and the Commission

The legislative proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals consists of 10 distinct activities that will have an impact on the resource needs of ECHA, EEA, EFSA, EMA and the Commission. The first three years there will be a need for up to **32 FTEs (12 TA + 20 CA) per year** and an operational budget of up to **EUR 8 657 000 per year**. In the fourth year and beyond, there will be a need of **20 FTEs (12 TAs and 8 CA)** per year and **EUR 7 080 000** per year. Considering the resources currently used for the existing tasks to be reattributed (i.e. resources for IPCHEM), there will be a total **net increase** in the resources in the fourth year and beyond as compared to today of **15.5 FTEs** per year and operational budget of **EUR 7 080 000 per year**.

Table 5. Resource needs per activity of the legislative proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Common data platform	5	16	5	16	5	16	5	4	950	3 442	4 077	1 300
Information Platform for Chemical Monitoring (IPCHEM)	1	0	2	1	2	1	2	1	0	200	380	230
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	1	0	1	0	1	0	1	0	0	650	650	200
Information on the obligations under Union acts on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	1	0	1	0	1	0	0	0	0	0
Data generation mechanism	1	0	1	1	1	1	1	1	0	1 000	3 000	5 000
Mechanism for notification of studies and database for study notifications	1	2	1	2	1	2	1	2	0	1 200	400	200
Early warning and action system for emerging chemical risks and framework of indicators	1	0	1	0	1	0	1	0	0	300	150	150
Observatory for specific chemicals with potential contribution to emerging chemical risks	0	0	0	0	0	0	0	0	0	0	0	0
SUM	**10**	**18**	**12**	**20**	**12**	**20**	**12**	**8**	**950**	**6 792**	**8 657**	**7 080**

Table 6. Current resource use for existing activities that are (re-)attributed

IPCHEM	Total 4.5 FTEs/year: DG JRC staff 2.5 FTEs/year + IT experts intramurous 2 FTEs/year (EUR 130 000 per year).
Information on regulatory processes on chemicals	ECHA already operates (P)ACT for REACH, CLP and POPs processes. EFSA already operates OpenEFSA which has a similar level of information as PACT. Resources for the operation and continuous provision of information are to be absorbed by the Agencies.
Information on the obligations under Union acts on chemicals	ECHA already operates EUCLEF and this is financed through the contribution agreement between DG GROW and ECHA: Total ca. EUR 1.0 - 1.4 million annually, with no posts. ECHA runs the service through the employment of 4 interim staff members (*ca.* EUR 270 000/year) and via contractors: communication activities and external helpdesk *ca.* EUR 60 000/year, IT costs EUR 200 000/year, data costs EUR 430 000/year. No additional resources needed but the formalisation of the resource allocation should be done via the proposal for a regulation on ECHA.
Observatory for specific chemicals with potential contribution to emerging chemical risks	ECHA already operates the EU Observatory on Nanomaterials and this is financed via a contribution agreement between DG GROW and ECHA: Total of EUR 700 000 annually including 3 CAs/year. No additional resources needed but the formalisation of the resource allocation should be done via the proposal for a regulation on ECHA.
SUM	**2.5 FTEs/year of regular staff; 2 FTEs/year of intramurous contractors or interim staff (*ca.* EUR 130 000 per year)**

The highest attribution of resources is necessary for ECHA, both in terms of FTEs and operational budget, followed by EEA, EFSA and EMA. After initial higher numbers for the first three years (2025-2027), as of the fourth year **ECHA** will need **13 FTEs (9 TA + 4 CA)** and an operational budget of **EUR 6 180 000** per year, **EEA** will need **3 FTEs (3 TAs)** and **EUR 400 000** per year, **EFSA** will need **2 FTEs (2 CA)** and **EUR 500 000** per year, **EMA** will need **2 FTEs (2 CAs) and EUR 0** per year and JRC **0 FTEs** and EUR **0** per year. No additional resources are required for **EU-OSHA**.

Table 7. Resource needs per agency (operational costs in EUR 1 000)

	FTEs								Operational costs			
Agency / Service	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
ECHA	7	8	9	10	9	10	9	4	0	5 076	7 023	6 180
EEA	3	2	3	2	3	2	3	0	0	766	684	400
EFSA	0	5	0	5	0	5	0	2	670	670	670	500
EMA	0	3	0	3	0	3	0	2	100	100	100	0
EU OSHA	0	0	0	0	0	0	0	0	0	0	0	0
JRC	0	0	0	0	0	0	0	0	180	180	180	0
SUM	**10**	**18**	**12**	**20**	**12**	**20**	**12**	**8**	**950**	**6 792**	**8 657**	**7 080**

Common Data Platform will be established and operated by ECHA with close involvement and contribution from EEA, EFSA, EMA, EU-OSHA and the Commission. The work will include development and operation of the infrastructure and the governance and provision of data into the platform. The principal aim of new IT infrastructure operating as part of the Green Deal Data Space is to support effective and coherent chemical safety assessments. It shall provide integrated, user-differentiated and highly functional access to chemicals-related datasets owned or managed by EU agencies and provide space for the dedicated services supporting EU chemicals policy and legislative implementation. The work will require resources for 4 agencies involved and the Commission (JRC). The resource requirement is higher for the first 3 years to set up the infrastructure and all the underlying processes to share the data and make them interoperable and in adequate formats. This will require for the first 3 years:

- for ECHA, 10 FTEs (4 TAs + 6 CAs) per year and operational budget of EUR 0 for the first year, EUR 2 226 000 for the second year and EUR 2 793 000 for the third year;
- for EEA, 3 FTEs (1 TA + 2 CAs) per year and operational budget of EUR 0 for the first year, EUR 266 000 for the second year and EUR 334 000 for the third year;
- for EFSA, 5 FTEs (5 CAs) per year and an operational budget of EUR 670 000 per year;
- for EMA, 3 FTEs (3 CAs) per year and an operational budget of EUR 100 000 per year;
- for EU-OSHA, 0 FTEs per year and operational budget of EUR 0 per year;
- for JRC, an operational budget of EUR 180 000 per year to cover integration of IPCHEM in the common data platform and handing over of IPCHEM operation to ECHA.

After the initial phase of 3 years, the resource requirement is reduced to maintain the infrastructure and the underlying processes. This phase will require

- for ECHA, 4 FTEs (4 TAs) per year and operational budget of EUR 600 000 per year;
- for EEA, 1 FTE (1 TA) per year and operational budget of EUR 200 000 per year;
- for EFSA, 2 FTEs (2 CAs) per year and operational budget of EUR 500 000 per year;
- for EU-OSHA, 0 FTEs per year and operational budget of EUR 0 per year;
- for EMA, 2 FTEs (2 CAs) per year and operational budget of EUR 0.

Information Platform for Chemical Monitoring (IPCHEM) will be formally established and its operation will be reattributed to the Agencies. For this work,

- ECHA will need as of the second year 2 FTEs (1 TA + 1 CA) per year and as of the third year operational budget of EUR 180 000 per year;

- EEA will need as of the first year 1 FTE (1 TA) per year and the operational budget in the first year EUR 0, in the second year EUR 200 000, in the third year EUR 200 000 and as of the fourth year EUR 50 000 per year.

The operation of IPCHEM is currently done by the Commission and the resource use accounts for total of 4.5 FTEs/year (DG JRC staff 2.5 FTEs/year + IT experts intramurous 2 FTEs/year (EUR 130 000/year)). The operation of IPCHEM will be entrusted to ECHA which will also integrate it into the Common Data Platform. As this work will be reattributed to ECHA, the resources at the Commission's side will be saved. Hosting of data will be entrusted to the Agencies based on their mandates (ECHA will host occupational data) and EEA will host indoor air data and collect and host human biomonitoring data. EFSA already provides data to IPCHEM and contributes to its operation and will not require any additional resources to continue in this activity. EMA and EU-OSHA currently do not systematically collect or receive data relevant for IPCHEM and therefore will not require any additional resources.

Database containing information on regulatory processes on chemicals will be established on the basis of existing (public) activities coordination tool ((P)ACT) and enlarging its scope to cover all relevant legislation with safety assessment processes and initiatives to promote coordination of safety assessment activities across EU legislation and provide transparency on the ongoing assessments. This work will impact ECHA, EEA, EFSA and EU-OSHA but will not require additional resources for the agencies. ECHA already operates (P)ACT for REACH, CLP and POPs processes. EFSA already operates OpenEFSA which has similar level of information as PACT for food and feed legislation. Resources for the operation and continuous provision of information are to be absorbed by the Agencies as part of the existing processes. EEA and EU-OSHA are currently not involved in any processes relevant for the database, therefore no resources are required for them. The development and coordination of the system is covered by the resources provided for the common data platform.

Repository of reference values will be established to promote the reuse of existing reference values and thus improve coherence of assessments and reduce repetition of deriving reference values. The proposal will impact ECHA, EEA, EFSA, EMA, EU-OSHA and the Commission. To perform the required work, ECHA will need as of the first year 1 FTE (1 TA) per year and operational budget of EUR 0 in the first year, EUR 650 000 in the second year, EUR 650 000 in the third year and as of the fourth year EUR 200 000 per year. No additional resources will be needed for EEA, EFSA, EMA, EU-OSHA or the Commission. ECHA has developed and operates the EU Chemicals Legislation Finder (EUCLEF). EUCLEF lists some regulatory reference values derived and applicable under these legislative pieces. ECHA will have to collate the 'old scientific reference values' which can be done via contracting. The new scientific reference values will be provided to the repository progressively as part of ECHA's assessment processes. ECHA will require additional resources for developing, operating and maintain the repository, being in contact with data providers. EFSA has developed and is maintaining the OpenFoodTox database that summarises the scientific reference values derived by EFSA as part of its assessment activities. EFSA will continue its activity and will provide the information to the new repository as part of its existing resources. Therefore, no additional resources are required. EMA will need to provide to the new repository on continuous basis all new predicted no effect concentrations (PNECs) derived for human and veterinary medicinal products after entry into force of this legislation. This can be done efficiently as part of EMA's future assessment activities. In addition, this can be automatized for human medicines as digitalisation of environmental risk assessment is foreseen as part of the revision of human medicinal product legislation. Therefore, no additional resources are required. EEA and EU-OSHA currently do not hold any relevant data for the repository. Therefore, no additional resources are required.

The establishment and operation of a **database with information on applicable laws and legal obligations** applicable to chemicals under Union legislation to promote compliance will be formalised. This work will impact ECHA but will not require additional resources under this proposal. ECHA already operates EU chemical legislative finder (EUCLEF) as part of the contribution agreement with DG GROW. The contribution agreement amounts to ca. EUR 1.0 – 1.4 million annually. ECHA runs the service through the employment of 4 interim staff members (ca. EUR 270 000/year) and via contractors: communication activities and external helpdesk ca. EUR 60 000/year, IT costs EUR 200 000/year, data costs EUR 430 000/year. These existing resources will be used to continue operating, further developing and slightly expanding the system. The

resources for major extension of the system, such as the repository of reference values, are provided under the work on repository of reference values. Although no resources are required under this proposal, the legislative proposal for a regulation on ECHA should address the fact that the operation of the EUCLEF became a structural task for ECHA and that the financing should become part of the annual contribution to ECHA.

Database on **environmental sustainability related data on chemicals** will be established. The work will impact ECHA. ECHA will be required to set up the database, operate it, establish and maintain the flows of adequate data into the database and provide interpretation of data. Other agencies (EEA, EFSA, EMA and EU-OSHA), if they host environmental sustainable data on chemicals, will provide that data to ECHA. To perform the work, ECHA will need as of the second year 1 FTE (1 TA) per year and operational budget of EUR 0 per year. Other agencies will not need additional resources as their task is small, currently do not hold any relevant data and the potential work can be absorbed by the agencies' current resources.

Data generation mechanism will be established to allow ECHA and the Commission to commission studies supporting the implementation of Union chemicals legislation within ECHA's mandate or contributing to the development of Union chemicals policy. The studies can be commissioned only when results cannot be obtained through existing legal provisions and they shall not have predominant research and development objective. The mechanism will allow ECHA and the Commission to generate data where needed and cannot be obtained otherwise. ECHA's involvement is necessary as commissioning of such studies requires technical expertise. To perform the work, ECHA will require in the first year 1 FTE (1 TA) and operational budget of EUR 0, in the second year 2 FTEs (1 TA and 1 CA) and operational budget of EUR 1 000 000, in the third year 2 FTEs (1 TA and 1 CA) and operational budget of EUR 3 000 000 and as of the fourth year 2 FTEs (1 TA and 1 CA) per year and operational budget of EUR 5 000 000 per year. No current process exists, but there is a complementary process operated by EFSA for the food sector (4 FTEs/year, EUR 15 000 000/year). This will continue to be operated next to the new one and the two Agencies (ECHA and EFSA) are required to cooperate when commissioning such studies and develop a joint plan.

The **obligation to notify studies** before they start will be expanded from food sector to all chemical sector. The work will require additional resource for ECHA. ECHA will need as of the first year 3 FTEs (1 TA and 2 CAs) per year and operational budget in the first year of EUR 0, in the second year EUR 1 200 000, in the third year EUR 400 000 and as of the fourth year EUR 200 000 per year. ECHA will be required to develop the database, operate it, facilitate and check compliance with the provisions and provide feedback to the duty holders. EFSA already operates a database of notification of studies to serve the obligation under the food sector legislation. The resource use amounts to 2 FTEs/year and EUR 400 000/year. EFSA and ECHA will be required to ensure compatibility of the systems. No additional resources are needed for this for EFSA.

The operation of the **indicators framework for chemicals** will be formalised and an **early warning and action system for chemicals** will be established**.** The work will require additional resources for EEA. EEA will need as of the first year 1 FTE (1 TA) per year and operational budget for the first year of EUR 0, for the second year EUR 300 000 and as of the third year EUR 150 000 per year. EEA and ECHA already jointly develop the indicators framework for chemicals as part of the commitment under the 8th Environment Action Programme. As the resources for indicator framework (2 FTEs per year for ECHA, 1 FTE per year for EEA) were already attribution as part of the 8th EAP, no additional resources are needed for this work. The establishment of the early warning and action system is a new, non-existing task that aims to significantly shorten the regulatory response to identified risks. The EEA will be tasked to collect early warning signals from other agencies, Member State and by its own activity and compile annually a report for discussion and decision on the follow up with Member States authorities. Other contributing agencies (ECHA, EFSA, EMA and EU-OSHA) will absorb the costs as part of exiting activities. In case of ECHA, the resources attributed for the indicator framework will be partly used to support the EEA by generating relevant early warning signals.

Observatory for specific chemicals with potential contribution to emerging chemical risks will be established**.** This will de facto formalise the operation of existing EU Observatory for nanomaterials and extend its scope to specific chemicals considered to benefit from additional scrutiny and reliable information on their properties, safety aspects, uses and market presence. This work will impact ECHA but will not require

additional resources under this proposal. ECHA operates the EU Observatory for nanomaterials as part of a contribution agreement with DG GROW. The resource use amounts to approximately EUR 700 000 per year including the 3 FTEs (3 CA). These existing resources will be used to continue operating, further developing and slightly expanding the system. The legislative proposal in preparation for a regulation on ECHA should address the fact that the operation of the EUCLEF became a structural task for ECHA and that the financing should become part of the annual contribution to ECHA.

Impact on committees of Agencies

There is no or a low impact of this proposal on committees of ECHA, EFSA and EMA and on the network of EEA. The rapporteurs of ECHA, EFSA and EMA committees that derive reference values will have to record the reference values and associated metadata into the repository of reference values or structure this information in the opinion to enable automatic extraction of that information to the repository. In addition, ECHA committees might be required to provide their suggestions for testing and monitoring of substances. The network of EEA will be required to assist in the collection of human biomonitoring data and early warning signals from member countries activities. There is no impact of this proposal on advisory groups of EU-OSHA.

10. OVERALL IMPACTS FROM ALL (RE-)ATTRIBUTIONS

10.1 Added value and synergies of the (re-)attributions

Added value

The consolidation of scientific and technical work in the EU agencies provides for several benefits:

1. Scientific consistency and coherence - Less actors involved in the scientific and technical work, centralising the work in the Agencies and requiring the Agencies to cooperate and solve possible divergent opinions leads to improved coherence and scientific consistency among the legislative pieces and among the assessments. The consolidation of work allows to better align priority setting, timelines, processes and methodologies used for the assessments. It facilitates reuse of assessment insights developed under one piece of chemical legislation in the assessment under another piece of legislation. It also facilitates the reuse of data collected under one piece of chemical legislation in the assessment under another piece of legislation. It contributes to alignment of data formats, IT solutions, data storing practices and thus contribute to improved interoperability of data.
2. Robustness of assessment and acceptance - Involvement of the EU agencies and their committees in the scientific and technical work on chemicals adds more scientific expertise, ensures high quality of scientific advice and leads to improved robustness of assessments and thus their acceptance. Centralising data on chemicals in the EU Agencies will increase the knowledgebase and improve the robustness of the scientific advice provided. Re-use of (same) data will further facilitate acceptance of conclusions.
3. Independence - Moving scientific and technical work on chemicals from Commission services, ad hoc committees or consultants to EU agencies and their committees reinforces the separation between science and policy or between risk assessment and management. Agencies and their committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
4. Transparency - Involvement of the EU agencies in scientific and technical work will ensure transparency to the process in terms of
   - overall process transparency;
   - publication of regulatory intentions of EU authorities and application submission intentions improves predictability for all stakeholders;
   - public consultation/call for evidence;
   - stakeholder involvement/observer status;
   - dissemination of scientific data and outcomes.

   The increased transparency will further increase the acceptance of the outcomes and trust in the regulatory system.

Synergies

The EU agencies already perform similar work to the work that is to be (re-)attributed to them. The consolidation of scientific and technical work in the EU agencies therefore provides for number of synergies:

1. Reuse of capabilities - The existing agencies' capabilities, such as hazard, risk and exposure assessment, development of committee opinions, development of methodologies, IT capabilities for submission of information by industry and Member States, collection and processing of data, stakeholder consultations, dissemination, can be reused in performing the (re-)attributed tasks.
2. Reuse of data, information and knowledge - The information collected by the agencies on substances under one piece of legislation can be reused under other pieces of legislation. The knowledge on a substance developed under one piece of legislation can be reused under other legislation.
3. Workload balancing - More similar work consolidated at one place allows for better balancing the workload across the year and thus better using existing capacities at the Agencies.
4. IT tools: automation and economies of scale - Existing IT tools of the Agencies after some adaptation of the tools or the processes can be reused to support the tasks to be reattributed to the Agencies. This includes data submission and reporting tools, tools for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination
5. Support services: economies of scale - Existing scientific support services (such as committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination) and administrative services of the agencies can be reused to support the tasks to be (re-)attributed to the agencies.

10.2 Overall impact on resources

Overall impact on resources per legislation and per agency

The (re-)attribution of scientific and technical work on chemicals to the EU Agencies with accompanying resources has been already proposed under 8 legislative proposals and one research cooperation action. The accompanying resources already attributed to the EU agencies following legislative initiatives already proposed by the Commission and some of which are already adopted by the co-legislator vary per year (see Table 8), with **54 FTEs (42 TA + 12 CA)** and **EUR 2 260 000** in **2024**, **76 FTEs (63 TA + 13 CA)** and **EUR 1 873 000** in **2025**, **92 FTEs (79 TA + 13 CA)** and **EUR 1 726 000** in **2026** and **98 FTEs (88 TA + 10 CA)** and EUR **1 463 000** in **2027**. The majority of resources were allocated to EMA (42 – 60 FTEs per year), followed by ECHA (24 – 29 FTEs and EUR 1 257 000 – EUR 1 364 000 per year) and EEA (9 – 11 FTEs and EUR 180 000 – EUR 919 000 per year). The majority of resources proposed for EMA are not related to the scope of the one substance, one assessment, but to improvement of processes for authorisation of medicinal products for human use.

Table 8. Resource already allocated or proposed (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2024**		**2025**		**2026**		**2027**		**2024**	**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Already adopted by the co-legislators												
Drinking water directive	3	2	6	3	7	3	8	3	510	520	530	540
Regulation on serious cross-border threats to health	0	0	0	0	0	0	0		0	0	0	0
European Partnership for the Assessment of Risks from Chemicals	0	4	0	4	0	4	0	2	289	289	289	0
Commission implementing decision 2022/1979 under SEVESO directive	3	1	3	1	3	1	3	1	330	70	70	70
Batteries regulation	2	1	2	1	2	1	2	0	158	158	25	25
Already proposed by the Commission (with resources)												
E-PRTR regulation	2	0	2	0	2	0	2	0	170	70	30	30

Industrial emissions directive	3	0	3	0	3	0	3	0	0	0	0	0
Water legislation	10	4	10	4	10	4	10	4	803	766	782	798
Legislation on medicinal products for human use	19	0	37	0	52	0	60	0	0	0	0	0
SUM	**42**	**12**	**63**	**13**	**79**	**13**	**88**	**10**	**2 260**	**1 873**	**1 726**	**1 463**

Table 9. Resources already allocated or proposed (operational costs in EUR 1 000)												
	FTEs								**Operational costs**			
Agency	**2024**		**2025**		**2026**		**2027**		**2024**	**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
ECHA	15	9	18	10	19	10	20	9	1 341	1 364	1 257	1 283
EEA	8	3	8	3	8	3	8	1	919	509	469	180
EMA	19	0	37	0	52	0	60	0	0	0	0	0
SUM	**42**	**12**	**63**	**13**	**79**	**13**	**88**	**10**	**2 260**	**1 873**	**1 726**	**1 463**

The (re-)attribution of scientific and technical work has been already proposed by the Commission also under the revision of CLP regulation, packaging and packaging waste directive, end-of-life vehicle directive and toys safety directive but without the allocation of resources. As the resource allocation is still pending, these initiatives are mentioned in the table with pending resource needs below.

The re-attribution of tasks to the EU agencies is still to be proposed under 5 upcoming legislative proposals and under the reattribution of non-chemical assessment work from SCHEER to SAM within the Commission. After considering all possible synergies from the reattributions, the pending resource needs for the work attributed to the EU Agencies without the resources and for the work to be attributed varies between **56 – 69 FTEs (34-38 TA + 19-31 CAs)** per year and operational budget of **EUR 1 051 000 – EUR 10 300 000** per year. The details are provided in Table 10. The majority of the resources is to be allocated to ECHA (46 – 55 FTEs and EUR 101 000 – EUR 8 666 000 per year), followed by EEA (3 – 5 FTEs and EUR 400 000 – EUR 766 000 per year), EFSA (2 – 5 FTEs and EUR 500 000 – EUR 670 000 per year), EMA (2 – 3 FTEs and EUR 0 – EUR 100 000 per year) and SAM (1 FTE per year). The details of allocations per agency are provided in Table 11.

Table 10. Pending resource needs per legislative proposal (operational costs in EUR 1 000)												
	FTEs								**Operational costs**			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Already proposed by the Commission (but without resources)												
CLP regulation	3	2	3	2	3	2	3	2	0	0	0	0
Directive on packaging and packaging waste	1	0	1	0	1	0	0	0	0	0	0	0
Directive on end-of life-vehicles	1	0	1	0	1	0	1	0	0	0	0	0
Toy safety directive	2	0	2	0	2	0	2	0	0	0	0	0
Proposed by the Commission as part of the package on one substance, one assessment												
Directive on reattribution	**3**	**0**	**4**	**3**	**4**	**3**	**4**	**3**	**66**	**33**	**33**	**33**
RoHS directive	3	0	4	3	4	3	4	3	66	33	33	33
Regulation on reattribution	**1**	**0**	**2**	**0**	**2**	**0**	**2**	**0**	**35**	**50**	**50**	**50**
POPs regulation	1	0	2	0	2	0	2	0	35	50	50	50
Medical devices regulation	0	0	0	0	0	0	0	0	0	0	0	0
EEA founding regulation	0	0	0	0	0	0	0	0	0	0	0	0
General Food Law	0	0	0	0	0	0	0	0	0	0	0	0
Regulation on chemicals data	**10**	**18**	**12**	**20**	**12**	**20**	**12**	**8**	**950**	**6 792**	**8 657**	**7 080**
Common data platform	5	16	5	16	5	16	5	4	950	3 442	4 077	1 300

Information Platform for Chemical Monitoring	1	0	2	1	2	1	2	1	0	200	380	230
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	1	0	1	0	1	0	1	0	0	650	650	200
Information on the obligations under Union acts on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	1	0	1	0	1	0	0	0	0	0
Data generation mechanism	1	0	1	1	1	1	1	1	0	1 000	3 000	5 000
Mechanism for notification of studies & database for study notifications	1	2	1	2	1	2	1	2	0	1200	400	200
Early warning and action system for emerging chemical risks and framework of indicators	1	0	1	0	1	0	1	0	0	300	150	150
Observatory for specific chemicals with potential contribution to emerging chemical risks	0	0	0	0	0	0	0	0	0	0	0	0
Planned to be proposed by the Commission												
Proposal for regulation on ECHA	**5**	**6**	**5**	**6**	**5**	**6**	**5**	**6**	**0**	**1 260**	**1 260**	**1 260**
Cooperation of ECHA with other agencies	0	0	0	0	0	0	0	0	0	0	0	0
Scientific opinions on OELs	3	2	3	2	3	2	3	2	0	200	200	200
Information on the obligations under Union acts on chemicals	2	1	2	1	2	1	2	1	0	630	630	630
Observatory for specific chemicals with potential contribution to emerging chemical risks	0	3	0	3	0	3	0	3	0	430	430	430
REACH regulation	0	0	0	0	0	0	0	0	0	0	0	0
Cosmetic products regulation	7	0	7	0	7	0	7	0	0	300	300	300
Scientific advice of SCHEER on non-chemical topics	1	0	1	0	1	0	1	0	0	0	0	0
SUM	**34**	**26**	**38**	**31**	**38**	**31**	**37**	**19**	**1 051**	**8 435**	**10 300**	**8 723**

Table 11. Pending resource needs per agency (operational costs in EUR 1 000)

	FTEs								Operational costs			
Agency / Service	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
ECHA	30	16	34	21	34	21	33	15	101	6 719	8 666	7 823
EEA	3	2	3	2	3	2	3	0	0	766	684	400
EFSA	0	5	0	5	0	5	0	2	670	670	670	500
EMA	0	3	0	3	0	3	0	2	100	100	100	0
EU-OSHA	0	0	0	0	0	0	0	0	0	0	0	0
JRC	0	0	0	0	0	0	0	0	180	180	180	0
SAM	1	0	1	0	1	0	1	0	0	0	0	0
SUM	**34**	**26**	**38**	**31**	**38**	**31**	**37**	**19**	**1 051**	**8 435**	**10 300**	**8 723**

Overall resources saved

It must be noted that some activities that have been reattributed were performed also before the reattribution and resources were used for those activities (see Table 12 below). The resources used for rapid risk assessment for serious cross-border threats, the operation of databases under the SEVESO directive and implementation work on chemicals under surface and ground water legislation consisted of **3.6 FTEs/year of regular staff, 7 FTEs per year of intramurous contractors or interim staff (ca. EUR 460 000 per year) and operational budget of EUR 127 000 per year.** These resources will be saved at the institution that has performed the tasks so far.

Table 12. Resource use for technical and scientific work before it was (re-)attributed to EU Agencies	
Regulation on serious cross-border threats to health	Total ca. 0.6 FTE/year + EUR 48 000/year: DG SANTE SCHEER secretariat 0.6 FTE (ca. 20% of SCHEER secretariat work), EUR 48 000 /year for indemnities, travel, *e.g.* costs for members of the committee

Commission implementing decision (EU) 2022/1979 under the SEVESO Directive (2012/18/EU)	Total 4 FTEs: DG JRC 1 FTE (core staff) + 3 FTEs external contractors
Water legislation (surface and ground)	Total: ca. 6.0 FTEs and EUR 79 200/year: EQSD: DG JRC 1 FTE /year (core staff) + contracting out for EUR 232 030 per year (= 3.5 FTEs), DG ENV contracting out for EUR 100 000 every 6 years for impact assessment (= ca. 0.25 FTEs/year). In addition, 1/3rd of the SCHEER Committee capacity is dedicated to water legislation (17 committee members + external experts); DG SANTE = 1 FTE (core staff) and EUR 79 200 EUR per year (30% of 3 FTEs - the secretariat to SCHEER. GWD: DG ENV contracting out EUR 10 560/year to get support to voluntary watchlist (=0.16 FTEs)
SUM	**3.6 FTEs / year of regular staff; 7 FTEs / year of intramurous contractors or interim staff (ca. EUR 460 000/ year); Operational costs of ca. EUR 127 000 per year**

Some tasks that are still to be (re-)attributed via the upcoming proposals are being currently performed and the resources are allocated to them (see Table 13 below). The resources currently used for the RoHS directive, POPs regulation, medical devices regulation, operation of IPCHEM, EUCLEF and observatory for nanomaterials, for scientific opinions on OELs, end-of-life vehicle directive, cosmetics regulation and toy safety directive amount to 12.8 FTEs per year of regular staff, 10.9 FTEs of intramurous contractors or interim staff (705 K€ per year) and an operational budget of EUR 2 023 000 – EUR 2 423 000 /year. As these tasks will be reattributed or formalised, the current resources used for these tasks will not be needed and will be saved at the institution that performs or finances the tasks today. Therefore, the **total net increase in the resources is lower than indicated in the Table 10, and for the tasks to be still reattributed accounts for 32 – 45 FTEs per year** and an operational budget of up to EUR 8 277 000 per year.

Table 13. Current resource use for technical and scientific work that is to be (re-)attributed to EU Agencies	
RoHS directive	Total ca. 2.74 FTEs/year: EUR 145 000 annually (on average) for outsourcing the review of exemptions (= ca. 2.2 FTEs/year) + a contract of EUR 180 000 on average each 5 years for reviewing restrictions (= 0.54 FTE/year). (In addition, DG ENV ca. 1.5 FTE/year (for overall RoHS implementation) whose work will remain)
POPs regulation	Total ca. 1.5 FTEs/year: EUR 300 000 for consultants every 3 years (=1.5 FTE/year). (In addition, DG ENV ca. 0.5 FTE/year (implementing the review of Annexes IV and V) whose work will remain)
Medical devices regulation	Total ca. 0.3 FTE/year + EUR 24 000/year: DG SANTE SCHEER secretariat 0.3 FTE (ca. 10% of SCHEER secretariat work), EUR 24 000/year for indemnities, travel, *e.g.* costs for members of the committee. (In addition, DG SANTE (policy unit) 0.1 FTE/year whose work will remain).
IPCHEM	Total 4.5 FTEs/year: DG JRC staff 2.5 FTEs/year + IT experts intramurous 2 FTEs/year (EUR 130 000 per year)
Information on regulatory processes on chemicals	ECHA already operates (P)ACT for REACH, CLP and POPs processes. EFSA already operates OpenEFSA which has similar level of information as PACT. Resources for the operation and continuous provision of information are to be absorbed by the Agencies.
Information on the obligations under Union acts on chemicals	ECHA already operates EUCLEF and this is financed through the contribution agreement between DG GROW and ECHA: Total ca. EUR 1.0 – 1.4 million annually, with no posts. ECHA runs the service through the employment of 4 interim staff members (ca. EUR 270 000/year) and via contractors: communication activities and external helpdesk ca. EUR 60 000/year, IT costs EUR 200 000/year, data costs EUR 430 000/year.
Observatory for specific chemicals with potential contribution to emerging chemical risks	ECHA already operates the EU Observatory on Nanomaterials and this is financed via a contribution agreement between DG GROW and ECHA: Total of ca. EUR 700 000 per year including the 3 posts per year: 3 CAs/year (ca. EUR 270 000/year) and operational costs of ca. EUR 430 000/year.
Scientific opinions on OELs	Total 4 FTEs/year and operational budget of ca. EUR 575 000/year: DG EMPL Service Level Agreement with ECHA for assessment of 5 substances annually – in total EUR 975 000 that includes 4 CA posts.
End-of-life vehicle directive	Total ca. 0.36 FTE/year for assessment of exemptions: a contract of EUR 60 000 every 2.5 years for reviewing exemptions (= ca. 0.36 FTE annually). (In addition, DGENV ca. 0.1 FTE dedicated to the work on hazardous substances whose work will remain).
Cosmetic products regulation	Total ca. 3 FTEs/year + full SCCS membership + EUR 240 000/year: DG SANTE 3 FTEs for the secretariat of SCCS + 14 members of SCCS and 4 external experts + ca. EUR 240 000 /year for reimbursement of members (at peak up to EUR 340 000/year). (In addition, DG GROW ca. 1 FTE for overall implementation of the related provisions whose work will remain)
Toy safety directive	Total ca. 0.3 FTEs/year + EUR 24 000/year: DG SANTE for SCHEER secretariat ca. 0.3 FTE (ca. 10% of SCHEER secretariat work) + EUR 24 000/year for reimbursements of SCHEER

	members (10% of SCHEER work). (In addition, DG GROW ca. 1 FTE/year for overall implementation of the related provisions) whose work will remain).
SUM	**12.8 FTEs/year regular staff; 10.9 FTEs/year interim staff + contracted staff; Operational budget: EUR 2 023 000 – 2 423 000 per year**

10.3 Overall impacts on ECHA

Impact on ECHA's resources

The proposals made by the Commission so far have already proposed to strengthen ECHA in the long term by 29 FTEs (see Table 14). An additional 48 FTEs are necessary in the long term to deal with the envisaged tasks that were already proposed by the Commission but without allocation of resources or are still to be proposed (see Table 15). Although the required reinforcement of ECHA seems significant, the allocation of 11 FTEs out of 48 will be de facto a regularisation of resources that already exist in ECHA via administrative agreements (4 FTEs for worker protection legislation and 3 FTEs for operation of EUON) or via a service level agreement (4 interim employees for operation of EUCLEF). In addition, the allocation of some additional 11 FTEs is a reattribution from other sources, mainly from contracting out the support (2.7 FTEs for RoHS directive, 1.5 FTEs for POPs regulation, 0.3 FTEs for medical devices, 3.5 FTEs for IPCHEM, 3 FTEs for cosmetics regulation, 0.3 FTEs for toy safety directive and 0.36 FTEs for end-of-life vehicle directive).

Table 14. Resource already allocated to or proposed to be allocated to ECHA (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2024**		**2025**		**2026**		**2027**		**2024**	**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Drinking water directive	3	2	6	3	7	3	8	3	510	520	530	540
Regulation on serious cross-border threats to health	0	0	0	0	0	0	0	0	0	0	0	0
European Partnership for the Assessment of Risks from Chemicals	0	2	0	2	0	2	0	2	0	0	0	0
Batteries regulation	2	1	2	1	2	1	2	0	158	158	25	25
Industrial emissions directive	3	0	3	0	3	0	3	0	0	0	0	0
Water legislation	7	4	7	4	7	4	7	4	673	686	702	718
SUM	**15**	**9**	**18**	**10**	**19**	**10**	**20**	**9**	**1 341**	**1 364**	**1 257**	**1 283**

Table 15. ECHA pending resource needs per legislative proposal (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Already proposed by the Commission (but without resources)												
CLP Regulation	3	2	3	2	3	2	3	2	0	0	0	0
Directive on packaging and packaging waste	1	0	1	0	1	0	0	0	0	0	0	0
Directive on end-of life-vehicles	1	0	1	0	1	0	1	0	0	0	0	0
Toys safety directive	2	0	2	0	2	0	2	0	0	0	0	0
Proposed by the Commission as part of the package on one substance, one assessment												
Directive on reattribution of tasks	**3**	**0**	**4**	**3**	**4**	**3**	**4**	**3**	**66**	**33**	**33**	**33**
RoHS Directive	3	0	4	3	4	3	4	3	66	33	33	33
Regulation on reattribution of tasks	**1**	**0**	**2**	**0**	**2**	**0**	**2**	**0**	**35**	**50**	**50**	**50**
POPs regulation	1	0	2	0	2	0	2	0	35	50	50	50
Medical devices regulation	0	0	0	0	0	0	0	0	0	0	0	0
Regulation on chemicals data	**7**	**8**	**9**	**10**	**9**	**10**	**9**	**4**	**0**	**5 076**	**7 023**	**6 180**
Common data platform	4	6	4	6	4	6	4	0	0	2 226	2 793	600
Information Platform for Chemical Monitoring	0	0	1	1	1	1	1	1	0	0	180	180
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	1	0	1	0	1	0	1	0	0	650	650	200
Information on the obligations under Union acts on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	1	0	1	0	1	0	0	0	0	0
Data generation mechanism	1	0	1	1	1	1	1	1	0	1 000	3 000	5 000
Mechanism for notification of studies & database for study notifications	1	2	1	2	1	2	1	2	0	1 200	400	200

Early warning and action system for emerging chemical risks and framework of indicators	0	0	0	0	0	0	0	0	0	0	0	0
Observatory for specific chemicals with potential contribution to emerging chemical risks	0	0	0	0	0	0	0	0	0	0	0	0
Planned to be proposed by the Commission												
Proposal for regulation on ECHA	**5**	**6**	**5**	**6**	**5**	**6**	**5**	**6**	**0**	**1 260**	**1 260**	**1 260**
ECHA's cooperation with other agencies	0	0	0	0	0	0	0	0	0	0	0	0
Scientific opinions on OELs	3	2	3	2	3	2	3	2	0	200	200	200
EUCLEF	2	1	2	1	2	1	2	1	0	630	630	630
EU Observatory for Nanomaterials	0	3	0	3	0	3	0	3	0	430	430	430
REACH regulation	0	0	0	0	0	0	0	0	0	0	0	0
Cosmetic products regulation	7	0	7	0	7	0	7	0	0	300	300	300
SUM	**30**	**16**	**34**	**21**	**34**	**21**	**33**	**15**	**101**	**6 719**	**8 666**	**7 823**

Impact on ECHA's expertise

As regards the expertise, ECHA has adequate expertise to address the majority of the new tasks. One exception is the extension of the scope of assessments for waste stage under the batteries regulation, RoHS directive, directive on end-of-life vehicles, packaging and packaging waste directive and POPs regulation, for which ECHA will need to build or recruit additional expertise. ECHA will also need to acquire a new expertise as regards water monitoring and derivation of water quality standards. ECHA will further need to build expertise on the assessment of chemicals in materials coming in contract with drinking water, where assessment is similar to food contact materials managed by EFSA.

Impact on ECHA's committees

The estimated number of opinions per year from (re-)attribution of tasks is provided in the table below. It is expected that **RAC** will have to deliver additional **80 opinions** per year as compared to today, while **SEAC** additional **50 opinions** per year. The increase in number of RAC opinions represents 72% increases as compared today. It should be noted that the biggest increase comes from drinking water directive (50 opinions) and from CLP regulation (13.5 opinions). The rest of legislations accounts for just 16.5 opinions. In order to cope with increased workload, the RAC will require some adaptation aiming on increasing the number of committee members (currently RAC membership is at 50% capacity), attractiveness of rapporteurship and flexibility in structuring the work of the committee. This is envisaged to be tackled under the legislative proposal for regulation on ECHA that is in preparation. The increase in number of SEAC opinion is moderate. The SEAC in its current set up should be able to absorb the additional tasks, after some adaptations in similar direction as for the RAC.

As regards the expertise, RAC has adequate expertise to address the majority of new tasks. The only exception is the extension of scope of assessments for waste stage under the batteries regulation, RoHS directive, directive on end-of-life vehicles and packaging and packaging waste directive, for which RAC will need to build or recruit additional expertise. The SEAC expertise might need to be extended to cover the waste stage of products and chemicals as well.

Table 16. Expected number of opinions from ECHA's committees per year

Legislation / process	RAC	SEAC	SCCS
Drinking water directive			
- Positive lists of substances	50	-	-
Batteries regulation			
- Restriction	1	1	-
Water legislation			
- Annex I Ground Water Directive	1	1	-
- Annex II Ground Water Directive	1	1	-
- Annex I EQS Directive	4	4	-
- Annex II EQS Directive	1	1	-
CLP Regulation			
- COM request for new hazard classes	13.5	-	-
RoHS directive			
- Restriction	1	1	-
- Request for exemption	3	30	-

POPs regulation			
- Review of Annexes IV and V	-	2	-
Directive on end-of-life vehicle			
- Review of existing exemptions	-	5	-
Cosmetic products regulation			
- Opinions on substances	-	-	11
- Notes of guidance	-	-	1
Toy safety directive			
- Assessments	4.2	4.2	-
SUM	**79.7**	**50.2**	**12**

10.4 Overall impacts on EEA

Impact on EEA's resources

The proposals made by the Commission so far have already proposed to reinforce EEA in the long term by 11 FTEs (see Table 17). An additional 3 FTEs are necessary in the long term, topped up with 2 FTEs for short term, to deal with the new envisaged tasks under the Regulation on chemicals data (see Table 18). The first three years there will be a need of **5 FTEs (3 TA + 2 CA)** and operational budget of up to **EUR 766 000**. In the fourth year and beyond, there will be a need of **3 FTEs (3 TA)** per year and an operational budget of **EUR 400 000** per year. It should be noted that the allocation of 1 FTE out of those required by EEA is a reattribution of the existing resources used for operation of IPCHEM.

Table 17. Resource already allocated or proposed to EEA per legislative proposal (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2024**		**2025**		**2026**		**2027**		**2024**	**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Regulation on serious cross-border threat to health	0	0	0	0	0	0	0	0	0	0	0	0
European Partnership for the Assessment of Risks from Chemicals	0	2	0	2	0	2	0	0	289	289	289	0
Commission implementing decision 2022/1979 under SEVESO directive	3	1	3	1	3	1	3	1	330	70	70	70
E-PRTR regulation	2	0	2	0	2	0	2	0	170	70	30	30
Water legislation (chemicals related tasks)	3	0	3	0	3	0	3	0	130	80	80	80
SUM	**8**	**3**	**8**	**3**	**8**	**3**	**8**	**1**	**919**	**509**	**469**	**180**

Table 18. EEA pending resource needs per legislative proposal (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Regulation on reattribution of tasks	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
POPs regulation	0	0	0	0	0	0	0	0	0	0	0	0
EEA founding regulation	0	0	0	0	0	0	0	0	0	0	0	0
Regulation on chemicals data	**3**	**2**	**3**	**2**	**3**	**2**	**3**	**0**	**0**	**766**	**684**	**400**
Common data platform	1	2	1	2	1	2	1	0	0	266	334	200
Information Platform for Chemical Monitoring	1	0	1	0	1	0	1	0	0	200	200	50
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Early warning and action system for emerging chemical risks and framework of indicators	1	0	1	0	1	0	1	0	0	300	150	150
SUM	**3**	**2**	**3**	**2**	**3**	**2**	**3**	**0**	**0**	**766**	**684**	**400**

The proposal for amendment of the POPs regulation via the regulation on (re-)attribution of tasks proposes to reattribute the existing task performed by the Commission to EEA. EEA is expected to host the chemical monitoring data in the environment of the POPs listed in Annex III, Part I and reported to ECHA under the POPs regulation. It is expected that this data stream will be very small or even zero. Member States are required to report those monitoring data only if they did not provide it to EEA under other reporting obligation. However, such data in air are already reported to EEA and the proposal for revision of water legislation

proposed that such data in water will be reported to EEA as well. As the potential hosting of data will be close to zero, this work, if any, can be absorbed by EEA's existing resources.

The proposal for amendment of the EEA founding regulation via the regulation on (re-)attribution of tasks proposes to better specify existing tasks of EEA. EEA is given a mandate to develop assessment methodologies related to chemicals within the mission of the agency and EEA is required to actively cooperate with other EU Agencies as regards exchange of data and development of methodologies. There are no resource implications as part of this work as the provisions formalise the activities performed, they prescribe the procedural steps to follow and they enable the implementation of the legislative proposal on exchange of data. Any possible resource needs stemming from these provisions can be absorbed by the existing resources of EEA or the resources allocated for the common data platform.

The proposal for a regulation on chemicals data proposes to reattribute some of the existing tasks related to IPCHEM from the Commission to EEA and to expand it. Under this task, the EEA will be requested to collect and host human biomonitoring data and host all environmental occurrence data and indoor air quality data currently held in IPCHEM. Additional resources are needed for these tasks.

The proposal for the regulation on chemicals data will further attribute a new task to EEA related to the common data platform. EEA will be required to make the data it holds on chemicals available on a continuous basis to the common data platform in appropriate formats. Moreover, it will be required to set formats and controlled vocabularies in its area of competence so data can be easily shared, and it will be required to cooperate with ECHA and other agencies in developing and operating the common data platform. Additional resources are needed for these tasks.

The proposal will also attribute to EEA a new task on the early warning and action system and formalise the existing task on the indicator framework which is already carried out by EEA. EEA will be required to compile and collect annually the early warning signals into a report to be presented to the Commission, relevant agencies and Member State authorities to consider whether any regulatory action is needed. EEA together with ECHA will be required to continue operating and populating the indicator framework for chemicals policy. Additional resources are needed for these tasks.

Finally, the proposal will require EEA to provide available data into the database on information on regulatory processes on chemicals, the repository of reference values and the database on environmental sustainability related data on chemicals and to cooperate with ECHA on the development of the databases and the repository. No additional resources are needed for these tasks. EEA currently does not hold any relevant data for those databases and the repository and the small contribution to the development of the tools is covered by the resources for the common data platform.

Impact on EEA's expertise

As regards expertise, EEA has the necessary expertise, experience and the network to perform the allocated tasks.

Impact on EEA's network

No significant impact on EEA's network. The network might however be required to assist in the collection of human biomonitoring data and early warning signals from activities of EEA member countries.

10.5 Overall impacts on EFSA

Impact on EFSA's resources

The proposals made by the Commission so far have not proposed additional resources for EFSA (see Table 19). EFSA was significantly reinforced in 2019 (by some 106 FTEs per year and operational budget of EUR 17 800 000 per year) as part of the Regulation (EU) 2019/1381 on the transparency and sustainability of the

EU risk assessment in the food chain[46] and the tasks attributed were small, thus could be covered by the existing EFSA's resources. Additional **2 FTEs** are necessary in the long term, topped up with **3 FTEs** for short term, to deal with the envisaged tasks for EFSA under the proposal for regulation on chemicals data (see Table 20). In total, the first three years there will be a need of **5 FTEs (5 CA)** per year and operational budget of up to **EUR 670 000** per year. In the fourth year and beyond, there will be a need of **2 FTE (1 CA)** per year and operational budget of **EUR 500 000** per year.

Table 19. Resource already allocated or proposed to EFSA per legislative proposal (operational costs in EUR 1 000)												
	201FTEs								**Operational costs**			
Activity	**2024**		**2025**		**2026**		**2027**		**2024**	**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Regulation on serious cross-border threat to health	0	0	0	0	0	0	0	0	0	0	0	0
European Partnership for the Assessment of Risks from Chemicals	0	0	0	0	0	0	0	0	0	0	0	0
SUM	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Table 20. EFSA pending resource needs per legislative proposal (operational costs in EUR 1 000)												
	FTEs								**Operational costs**			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
CLP Regulation	0	0	0	0	0	0	0	0	0	0	0	0
Regulation on reattribution of tasks	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
General Food Law	0	0	0	0	0	0	0	0	0	0	0	0
Regulation on chemicals data	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**2**	**670**	**670**	**670**	**500**
Common data platform	0	5	0	5	0	5	0	2	670	670	670	500
Information Platform for Chemical Monitoring	0	0	0	0	0	0	0	0	0	0	0	0
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Data generation mechanism	0	0	0	0	0	0	0	0	0	0	0	0
Mechanism for notification of studies	0	0	0	0	0	0	0	0	0	0	0	0
Early warning and action system and framework of indicators for chemicals	0	0	0	0	0	0	0	0	0	0	0	0
SUM	**0**	**5**	**0**	**5**	**0**	**5**	**0**	**2**	**670**	**670**	**670**	**500**

The proposal for revision of the CLP regulation proposes to attribute a new task to EFSA. EFSA on the request of the Commission is required to prepare a dossiers for harmonised classification of a substance. As hazard assessment is the core task of the Authority and the requests are unlikely to be too numerous, this work can be absorbed within the existing resources of the Authority.

The proposal for amendment of the general food law via the regulation on (re-)attribution of tasks proposes to better specify the existing tasks of EFSA. EFSA will be required to actively cooperate with other EU Agencies as regards exchange of data and development of methodologies. EFSA will be further required to engage more in preventing or solving a divergent opinion with other EU Agencies. There are no resource implications of these amendments. The provisions formalise the activities performed, they prescribe the procedural steps to follow and they enable the implementation of the legislative proposal on exchange of data. Any possible resource needs stemming from these provisions can be absorbed by the existing resources of EFSA.

The proposal for a regulation on chemicals data proposes to formalise existing tasks and to attribute new tasks to EFSA.

- EFSA will be required to make data on chemicals it holds available on a continuous basis to the common data platform in appropriate formats. In addition, it will be required to set formats and controlled vocabularies in its area of competence so data can be easily shared, and it will be required

[46] Regulation (EU) of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283) and Directive 2001/18/EC (OJ L 231 6.9.2019, p.1)

to cooperate with ECHA and other agencies in developing and operating the common data platform. For this, EFSA will need 5 FTEs during 3 years to launch the common data platform with all its functionalities and data and then 2 FTEs from the 4th year and onwards to ensure adequate input, operation and the further development of the common data platform and its underlying services.

- EFSA will also be required to contribute to the operation of and provide data to IPCHEM. This is an existing task of EFSA, so no additional resources are needed.
- EFSA will furthermore be required to provide on a continuous basis information on the status of regulatory processes into the database with information on regulatory processes on chemicals.. EFSA already compiles such inform in the OpenEFSA database, which will be fed into the new database. There is no need for additional resources for this work as the compilation of information is ongoing and streamlining the information into the common data platform will be covered by the resources for the common data platform.
- EFSA will further be required to provide relevant information to the repository of reference values and contribute to its development. EFSA already compiles reference values in its OpenFoodTox database, which will be fed into the repository of reference values. There is no need for additional resources for this activity as it already exists and streamlining it to the repository of reference values will be covered by the resources for the common data platform.
- EFSA will be also required to provide available data into the database on environmental sustainability related data on chemicals. No additional resources are needed for this tasks, as EFSA currently does not hold any relevant data for this database and the potential small contribution to the development of the tools is covered by the resources for the common data platform.
- EFSA will be required to cooperate with ECHA on the commissioning of scientific studies. EFSA already commissions such studies under General Food Law and the additional resource needs for the cooperation with ECHA in doing so should be absorbed by EFSA within the existing allocation of resources.
- EFSA will be required to provide input to the indicators framework and early warning and action system. There is no need for additional resources for this activity, because EFSA already operates the emerging risk exchange network (EREN) for the food sector and the output of that work will be fed into the early warning and action system on chemicals.
- Finally, EFSA will be required to ensure the compatibility of its system of study notifications established under Article 32b of the General Food Law with the database of study notifications to be set up by ECHA for remaining chemical legislation. The resources for this should be absorbed by the resources available in EFSA for the operation of its system of notification of studies.

Impact on EFSA's expertise

As regard expertise, EFSA has the necessary expertise and experience to perform the allocated tasks.

Impact on EFSA's committees

No significant impact on EFSA committees. The rapporteurs of EFSA committees that derive reference values might need to record the derived reference values and associated metadata into the repository of reference values or structure this information in the related opinion for automatic processing.

10.6 Overall impacts on EMA

Impact on EMA's resources

The proposals for legislation on medicinal products for human use proposed a significant strengthening of EMA to deal with the new tasks proposed to be entrusted to EMA (see Table 21), with some of the tasks being relevant for the proposals on reattribution of tasks and on chemicals data. However, additional **2 FTEs** are necessary in the long term, topped up with **1 FTE** for short term, to deal with the envisaged tasks for EMA under the proposal for regulation on chemicals data (see Table 22). In total, the first three year there will be a need of **3 FTEs (3 CA)** per year and an operational budget of **EUR 100 000.** In the fourth year and beyond, there will be a need of **2 FTEs (2 CA)** per year and **EUR 0** per year.

Table 21. Resources already allocated or proposed to EMA per legislative proposal (operational costs in EUR 1 000)												
	FTEs								Operational costs			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Serious cross-border threat regulation	0	0	0	0	0	0	0	0	0	0	0	0
Legislation on medicinal products for human use	37	0	52	0	60	0	60	0	0	0	0	0
SUM	**37**	**0**	**52**	**0**	**60**	**0**	**60**	**0**	**0**	**0**	**0**	**0**

Table 22. EMA pending resource needs per legislative proposal (operational costs in EUR 1 000)												
	FTEs								Operational costs			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Regulation on chemicals data	**0**	**3**	**0**	**3**	**0**	**3**	**0**	**2**	**100**	**100**	**100**	**0**
Common data platform	0	3	0	3	0	3	0	2	100	100	100	0
Information Platform for Chemical Monitoring	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Early warning and action system and framework of indicators	0	0	0	0	0	0	0	0	0	0	0	0
SUM	**0**	**3**	**0**	**3**	**0**	**3**	**0**	**2**	**100**	**100**	**100**	**0**

The proposal for a regulation on chemicals data proposes new tasks for EMA.

- EMA will be required to make some of the data it receives after entry into force of this regulation available on a continuous basis to ECHA for integration into the common data platform, it will be required to set formats and controlled vocabularies in its area of competence so data can be easily shared and it will be required to cooperate with ECHA and other agencies in developing and operating the common data platform. EMA will need additional resources for these tasks.
- EMA will be also required to provide occurrence data it holds to IPCHEM and provide cooperation to ECHA in integration of such data in IPCHEM. However, EMA currently does not hold any data relevant to IPCHEM, therefore, no resources are required for this activity. Any cooperation required is covered by the resources for the common data platform.
- EMA will be required to cooperate with ECHA on the operation of the repository of reference values and provide on a continuous basis specific reference value it derives (i.e. predicted no effect concentration derived as part of the environmental risk assessment) to the repository. The cooperation with ECHA and provision of data is covered by the resources provided for the common data platform.
- EMA will be required to provide environmental sustainability related data on chemicals to ECHA and cooperate with ECHA to enable integration of the data into a database. EMA however does not currently host any such data, therefore, no additional resources are required for this for EMA. Any cooperation with ECHA on setting up the database is covered by the resources for the common data platform.
- EMA will be required to provide available early warning signals from their areas of responsibility to EEA. EMA will require no additional resources for this task, as the cooperation is covered by the resources for the common data platform and potential provision of data is a small task that can be absorbed by EMA's existing resources.
- Finally, EMA will be required to cooperate with EEA and other agencies on the establishment, operation and maintenance of the framework of indicators. EMA will require no additional resources for this task, as the cooperation is covered by the resources for the common data platform and potential provision of data is a small task that can be absorbed by EMA's existing resources.

Impact on EMA's expertise

As regards expertise, EMA has the necessary expertise and experience to perform the allocated tasks.

Impact on EMA's committees

No significant impact on EMA committees. The rapporteurs of EMA committees that derive reference values might need to record the derived reference values and associated metadata into the repository of reference values or structure this information in the relevant opinion for automatic processing.

10.7 Overall impacts on EU-OSHA

Impact on EU-OSHA's resources

No additional resources are necessary for EU-OSHA to deal with the envisaged tasks under the proposal for regulation on chemicals data (see Table 23).

Table 23. EU-OSHA pending resource needs per legislative proposal (operational costs in EUR 1 000)

	FTEs								Operational costs			
Activity	**2025**		**2026**		**2027**		**2028**		**2025**	**2026**	**2027**	**2028**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**				
Regulation on chemicals data	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Common data platform	0	0	0	0	0	0	0	0	0	0	0	0
Information Platform for Chemical Monitoring	0	0	0	0	0	0	0	0	0	0	0	0
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Repository of reference values	0	0	0	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	0	0	0	0	0	0	0	0	0	0
Early warning and action system and framework of indicators	0	0	0	0	0	0	0	0	0	0	0	0
SUM	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

The proposal for a regulation on chemicals data requires EU-OSHA to provide data to ECHA for the integration into the common data platform and to cooperate with ECHA in developing and operating the common data platform. It also requires EU-OSHA to provide relevant data to the information platform for chemical monitoring, database on regulatory processes on chemicals, repository of reference values, database of environmental sustainability related data on chemicals and to early warning and action system and framework of indicators. EU-OSHA, however, does not currently systematically collect or host any data relevant for the common data platform and its building blocks. EU-OSHA's role is therefore mainly to contribute with their inputs and suggestions to the development of the common data platform and its building blocks. EU-OSHA can be seen as a 'privileged' user of the system who can provide input to the development and operation to ensure that the systems are developed in such way that they suit also the needs of EU-OSHA. No additional resources are needed for these tasks, as they can be covered by the existing resources.

Impact on EU-OSHA's expertise

As regards expertise, EU-OSHA has the necessary expertise and experience to perform the allocated tasks.

Impact on EU-OSHA's committees

There is no impact on EU-OSHA's advisory groups or the management board.

ANNEX I: MISSION, CORE ACTIVITIES, COMPETENCES AND SCIENTIFIC BODIES OF THE AGENCIES

1. EUROPEAN FOOD SAFETY AUTHORITY

The European Food Safety Authority (EFSA) is an integral part of the EU's food safety system. As outlined in its Founding Regulation (Regulation (EC) No 178/2002), the Authority's mission is to contribute to the safety of the EU food and feed chain, mainly by:

- Providing EU risk managers with independent, up-to-date and fit-for-purpose scientific advice on questions related to food and feed safety, animal health and welfare, plant health, nutrition and environmental issues specific to the above[47] within the two main streams as described below:
    - *Generic risk assessments* in the following areas of work: Plant health, Animal health, Animal welfare, Chemicals Hazards, Biological hazards, Zoonoses-TSE-Antimicrobial resistance monitoring and Nutrition
    - *Regulated products* in the following areas of work: Novel foods, Feed additives, Food ingredients, Food contact materials, Genetically modified food/feed and Pesticides;
- Providing EU risk managers with scientific and technical support in areas falling under EFSA's competence
- Communicating to the public on matters falling under EFSA's competence and in particular on EFSA's outputs and the information on which they are based;
- Developing and applying uniform methodologies for fit-for-purpose scientific advice on questions related to food safety;
- Collecting and analysing data to allow the identification, characterisation and monitoring of current risks that have a direct or indirect impact on food safety;
- Cooperating with Member States, institutional partners and other interested parties/stakeholders[48] in the EU to promote coherent advice and increase trust in the EU food safety system;
- Identifying emerging risks to food safety and contributing to a high level of protection of human life and health.

EFSA's specific competences include:

- Risk Assessment in the areas within the EFSA's remit: Chemicals, micro-organisms, environment, plant health and plant protection, animal health and animal welfare, occupational;
- Efficacy Assessment, particularly in the area of feed additives;
- Chemistry, including chemical characterisation, and molecular characterisation;
- Animal sciences: Animal nutrition, Animal production, Animal pathology, Animal welfare;
- Environmental sciences;
- Food Sciences;
- Human sciences: Human medicine, nutrition;
- Plant sciences: plant pests, plant health, plant products, biodiversity, food security;
- Hazard Assessment: Human and veterinary toxicology, ecotoxicology and environmental fate;

[47] The phrase 'food safety' is used throughout the document as shorthand for 'food and feed safety, animal health and welfare, plant health, nutrition and environmental issues specific to the above'

[48] As defined in EFSA's founding regulation (Regulation (EC) No 178/2002), Article 3(13)

- Human exposure assessment, including dietary, non-dietary and cumulative;
- Data collection, data and information management: Zoonoses, Foodborne diseases, Food/Feed Contaminants, Pesticides and Veterinary medicine residues, Systematic literature reviews;
- Risk assessment methodological development;
- Identification of emerging risks, Foresight and Horizon scanning, Early Warning systems.

The scientific work related to risk assessment is entrusted to ten EFSA Scientific Panels and the Scientific Committee:

- Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Provides scientific advice on the safety and/or efficacy of additives and products or substances used in animal feed. The Panel evaluates their safety and/or efficacy for the target species, the user, the consumer of products of animal origin and the environment. It also looks at the efficacy of biological and chemical products/substances intended for deliberate use in animal feed.

- Panel on Animal Health and Welfare (AHAW). Provides scientific advice on all aspects of animal diseases and animal welfare. Its work chiefly concerns food producing animals, including fish.

- Panel on Biological Hazards (BIOHAZ). Provides scientific advice on biological hazards in relation to food safety and food-borne diseases. This covers animal diseases transmissible to humans; transmissible spongiform encephalopathies; food microbiology; food hygiene and associated waste management issues.

- Panel on Food Contact Materials, Enzymes and Processing Aids (CEP). Evaluates the safety of chemical substances added to food or used in food packaging, and related processes.

- Panel on Contaminants in the Food Chain (CONTAM). Provides scientific advice on contaminants in the food chain and undesirable substances such as natural toxicants, mycotoxins and residues of unauthorised substances.

- Panel on Food Additives and Flavourings (FAF). Evaluates the safety of chemical substances added to food and consumer exposure to them. The Panel's work mainly concerns substances evaluated by EFSA before their use can be authorised in the EU.

- Panel on Genetically Modified Organisms (GMO). Provides independent scientific advice on food and feed safety, environmental risk assessment and molecular characterisation/plant science. Its work chiefly concerns genetically-modified plants, micro-organisms and animals.

- Panel on Nutrition, Novel Foods and Food Allergens (NDA). Deals with questions related to human nutrition, novel foods, nutrient sources, foods for special groups such as infant formulae, health claims on food products, dietary reference values, and food allergies.

- Panel on Plant Health (PLH). Provides independent scientific advice on the risk posed by plant pests which can cause harm to plants, plant products or biodiversity in the EU. The Panel reviews and assesses those risks with regard to the safety and security of the food chain.

- Panel on Plant Protection Products and their Residues (PPR). Provides scientific advice on the risk assessment of pesticides for operators, workers, consumers and the environment. The Panel develops and reviews guidance documents on the risk assessment of pesticides. This work supports the evaluation of active substances used in pesticides, which is carried out Rapporteur Member States and peer reviewed by EFSA staff.

- Scientific Committee. Develops harmonised risk assessment methodologies on scientific matters of a horizontal nature in the fields within EFSA's remit where EU-wide approaches are not already defined. It provides general co-ordination to ensure consistency in the scientific opinions prepared by EFSA's Scientific Panels. It also provides strategic scientific advice to EFSA’s management.

2. EUROPEAN CHEMICALS AGENCY

The European Chemicals Agency (ECHA) implements the EU's chemicals legislation to protect human health and the environment. ECHA's core competence, is to deliver scientifically sound and consistent regulatory outcomes that meet EU chemicals policy objectives in a transparent, professional, independent and efficient manner.

ECHA's scientific competences cover the areas of chemical hazard and risk assessment, identifying the most effective risk management option(s), assessing alternative substances and socio-economic consequences of risk management decisions. ECHA covers the area of hazard assessment for industrial chemicals, pesticides and biocides; risk assessment of industrial chemicals; use and exposure to chemicals other than food and medicines.

ECHA's specific competences include:

- Chemistry, including substance identification and phys chem properties
- Hazard assessment – toxicology, ecotoxicology and environmental fate
- Derivation of limit values
- Alternative methods to animal testing (for example, QSARs)
- Exposure and risk assessment
- Risk management
- Data and information management in relation to chemicals management
- Consensus building and delivery of scientific opinions
- Delivery of regulatory decisions
- Support duty holders with regulatory obligations

ECHA has four committees and the enforcement forum:

- Committee for Risk Assessment. Prepares the opinions of ECHA related to the hazards and risks of substances to human health and the environment for the harmonised classification under CLP, for restrictions and authorisations under REACH and for the occupational exposure limits under worker protection legislation.

- Committee for Socio-Economic Analysis. Prepares the opinions of ECHA related to the socio-economic impact of possible legislative actions on chemicals in restriction and authorisation processes under REACH. The final decisions are taken by the European Commission.

- Member State Committee. The Member State Committee (MSC) participates in several REACH processes such as evaluation and authorisation. The MSC is responsible for resolving divergences of opinions among Member States and on proposals for the identification of Substances of Very High Concern (SVHCs). The Committee provides opinions on ECHA's draft recommendation for the authorisation list (Annex XIV) and draft Community Rolling Action Plan (CoRAP) for the substance evaluation process. If an agreement is not reached within the MSC, the matter is referred to the European Commission for decision-making.

- Biocidal Product Committee. Prepares the opinions of ECHA related to the following processes under biocidal product regulation:
    - Applications for approval and renewal of approval of active substances
    - Review of approval of active substances
    - Applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 and review of the inclusion of such active substances in Annex I
    - Identification of active substances which are candidates for substitution
    - Applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations, except where the applications are for administrative changes
    - Scientific and technical matters concerning mutual recognition in accordance with Article 38

- At the request of the Commission or of the Member States, the BPC is also responsible for preparing an opinion on any other questions that may arise from the operation of the BPR relating to risks to human or animal health or the environment, or to technical guidance.

- Enforcement Forum. A network of authorities responsible for the enforcement of the REACH, CLP, and PIC, POP and Biocidal Product regulations in the EU, Norway, Iceland and Liechtenstein. It coordinates enforcement strategies, proposes, coordinates and evaluates harmonised enforcement projects and joint inspections, it provides advice on enforceability of regulatory measures and provides harmonised practices and training.

3. EUROPEAN MEDICINES AGENCY

The European Medicine Agency (EMA) is responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and monitoring of medicinal products.

The Agency's specific competences include:

- providing scientific advice to medicine developers;
- evaluating applications for orphan designation (medicines for rare diseases);
- assessing paediatric investigation plans, which determine the studies that medicines developers must carry out in children;
- coordinating the scientific evaluation of applications for centralised marketing authorisations of human and veterinary medicinal products in the European Union, based on an evaluation of their quality, safety and efficacy;
- advising on maximum allowed concentrations for residues of veterinary medicinal products or biocidal products for use in animal husbandry which may be accepted in foodstuffs of animal origin (MRLs)
- coordinating inspection for the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice and pharmacovigilance obligations;
- publishing information on authorised medicinal products and potential adverse reactions;
- coordinating pharmacovigilance monitoring systems on all authorised medicines in the EU;
- assisting EU countries with communication to healthcare professionals and patients;
- creating and maintaining a web-portal on medicinal products and their approved uses accessible to the general public; and ensuring that it is updated, and managed independently of pharmaceutical companies; the database facilitates the search for information already authorised for package leaflets;
- development of scientific guidelines on the requirements for quality, safety and efficacy testing of medicines;
- promotion of alternative methods to animal testing;
- environmental risk assessment (ERA) of active pharmaceutical ingredients;
- supporting the development of new medicines and treatment approaches to respond to antimicrobial resistance; promoting responsible use of existing antibiotics; collecting antimicrobial consumption data to guide policy and research;
- managing shortages medicines and medical devices and supporting medicine development, approval and monitoring in preparation for and during public health emergencies.

EMA has seven scientific committees and a number of working parties and related groups which conduct the scientific work of the Agency:

- Committee for Medicinal Products for Human Use (CHMP). Responsible for preparing the opinions of the Agency on any question relating to the evaluation of medicinal products for human use;
- Pharmacovigilance Risk Assessment Committee (PRAC). Responsible for assessing and monitoring the safety of human medicines.
- Committee for Veterinary Medicinal Products (CVMP). Responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for veterinary use.
- Committee for Orphan Medicinal Products (COMP). Responsible for recommending orphan designations of medicines for rare diseases.

- Committee on Herbal Medicinal Products (HMPC). Responsible for compiling and assessing scientific data on the recommended use and safe conditions of use of herbal substances, preparations and combinations, to support the harmonisation of the European market.
- Committee for Advanced Therapies (CAT). Responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and following scientific developments in the field.
- Paediatric Committee (PDCO). Responsible for activities on medicines for children and to support the development of such medicines in the European Union by providing scientific expertise and defining paediatric needs.

4. EUROPEAN ENVIRONMENT AGENCY

The European Environment Agency (EEA) is mandated to provide the Community and the Member States with the objective, reliable and comparable information at European level and with the necessary technical and scientific support, enabling them to take the requisite measures to protect the environment, to assess the results of such measures and to ensure that the public is properly informed about the state of the environment. For these purposes, the Agency:

- maintains the network of national information networks, the national focal points and the topic centres;
- collects, processes and analyses data used in the implementation of EU environmental policy including chemicals emission data to water and air, and chemical monitoring data in surface waters, groundwater and ambient air;
- assists the monitoring of environmental measures through appropriate support for reporting requirements;
- records, collates and assesses data on the state of the environment; draws up expert reports on the quality, sensitivity and pressures on the environment within the territory of the Community, provides uniform assessment criteria for environmental data to be applied in all Member States; develops further and maintain a reference centre of information on the environment;
- helps ensuring that environmental data at European level are comparable and encourages improved harmonisation of methods of measurement;
- promotes the incorporation of European environmental information into international environment monitoring programmes such as those established by the United Nations and its specialised agencies;
- stimulates the development and application of environmental forecasting techniques so that adequate preventive measures can be taken in good time;
- stimulates the development of methods of assessing the cost of damage to the environment and the costs of environmental preventive, protection and restoration policies;
- stimulates the exchange of information on the best technologies available for preventing or reducing damage to the environment;
- ensures the broad dissemination of reliable and comparable environmental information, in particular on the state of the environment, to the general public and, to this end, to promote the use of new telematics technology for this purpose;
- supports the Commission in the process of exchange of information on the development of environmental assessment methodologies and best practice;
- assists the Commission in the diffusion of information on the results of relevant environmental research and in a form which can best assist policy development

EEA's specific competences include:

- collecting, processing and analysis of environmental data at European level;
- providing and maintaining an efficient reporting infrastructure for data flows and supporting members countries in reporting data;
- Collecting, maintaining and making publicly available datasets on emissions of pollutants to air and water, and on pollutants in ambient air, surface waters, groundwater and drinking water. Collecting data reported by companies on the production, import, export, destruction and feedstock use of F-gases in the EU assessing the state of the European environment, and climate, including assessments of the overall impact of chemical pollution on the environment and human health in Europe;
- Communicating environmental and climate change information to citizens;

- Producing evidence-based knowledge to support policy implementation and development of new initiatives to accelerate and scale up the transition to sustainability. Delivering targeted inputs to inform policy and public discussions, by organising and communicating knowledge on responses, including innovative solutions to societal challenges.

EEA coordinates at EU level the European Environment Information and Observation Network (EIONET). It consists of the EEA's member countries (27 EU Member States plus Iceland, Liechtenstein, Norway, Switzerland and Türkiye) and cooperating countries (Albania, Bosnia and Herzegovina, North Macedonia, Montenegro, Serbia and Kosovo). The network brings together around 2000 experts from more than 400 national institutions that have expertise in environmental issues. The EIONET network has the following roles and functions:

- **National Focal points** – nominated and funded by countries to act as primary links between the EEA and their country. NFPs organise and develop their country's Eionet network, as well as facilitate and coordinate contacts, requests and information delivery at national and EU levels.
- **National Data Flow Coordination** – ensures a coherent and coordinated overview of collecting, collating and sharing data between the country and the EEA to respond efficiently to the needs of the Agency's work programme.
- **EIONET groups** – work with the EEA and European Topic Centres to assess Europe's environment and climate, and any related impacts on health and ecosystems. Currently there are 13 Eionet Groups, several of them supported by Thematic Groups:
    - Biodiversity and ecosystems - integration of knowledge for policies
    - Biodiversity and ecosystems - cumulative pressures and solutions
    - Circular economy and resource use
    - Climate change impacts, vulnerability and adaptation
    - Climate change mitigation and energy systems
    - Communications
    - Data, technologies and digitalisation
    - Food systems
    - Foresight
    - Human health and the environment
    - Land systems
    - Mobility systems
    - State of the environment
- **European Topic Centres (ETC)** – are thematic expertise centres contracted and funded by the EEA for tasks identified in the EEA-EIONET Strategy. These are designated by the EEA management board following a European-wide competitive selection process. The topic centres support the EEA in the processing and analysis of the data received from Member Countries. As of 2023, there are 7 topic centres working with EEA and national EIONET partners:
    - ETC on Biodiversity and Ecosystems
    - ETC in Circular Economy and Resource Use
    - ETC on Climate Change Adaptation and LULUCF
    - ETC on Climate Change Mitigation
    - ETC on Data Integration and Digitalisation
    - ETC on Human Health and the Environment
    - ETC on Sustainability Transitions

5. EUROPEAN AGENCY FOR SAFETY AND HEALTH AT WORK

The European Agency for Safety and Health at Work (EU-OSHA) provides the Union institutions and bodies, the Member States, the social partners and other actors involved in the field of safety and health at work with relevant technical, scientific and economic information and qualified expertise in the field of safety and health at work in order to improve the working environment as regards the protection of the safety and health of workers.

To that end, EU-OSHA enhances and disseminates knowledge, provides evidence and services for the purpose of policy making, including research-based conclusions, and facilitates knowledge sharing among and between Union and national actors.

The EU-OSHA does this by developing, gathering and providing reliable and relevant information, analysis and tools to advance knowledge, raise awareness and exchange occupational safety and health (OSH) information and good practice which will serve the needs of those involved in OSH. Concretely, the EU-OSHA:

- collects and analyses technical, scientific and economic information on safety and health at work in the Member States in order to:
    - identify risks and good practices as well as existing national priorities and programmes;
    - provide the necessary input to Union priorities and programmes; and
    - disseminate that information to the Union institutions and bodies, the Member States, the social partners and other actors involved in the field of safety and health at work;
- collects and analyses technical, scientific and economic information on research into safety and health at work and on other research activities which involve aspects connected with safety and health at work and disseminate the results of the research and research activities;
- promotes and supports cooperation and exchange of information and experience amongst the Member States in the field of safety and health at work, including information on training programmes;
- organises conferences and seminars and exchanges of expertise from the Member States in the field of safety and health at work;
- supplies the Union institutions and bodies and the Member States with the objective technical, scientific and economic information available and the qualified expertise they require to formulate and implement judicious and effective policies designed to protect the safety and health of workers;
- provides forums for exchange of experiences and information between the governments, the social partners and other stakeholders at national level;
- contributes, including through evidence-based information and analyses, to the implementation of reforms and policies at national level;
- collects and makes available information on safety and health matters from and to third countries and international organisations;
- provides technical, scientific and economic information on methods and tools for implementing preventive activities, identify good practices and promote preventive actions, paying particular attention to the specific problems of MSMEs and, with regard to good practices, focuses, in particular, on practices which constitute practical tools to be used in drawing up an assessment of the risks to safety and health at work, and identifying the measures to be taken to tackle those risks;
- contributes to the development of Union strategies and action programmes relating to the protection of safety and health at work,
- establishes a strategy for relations with third countries and international organisations;

- carries out awareness raising and communication activities and campaigns on safety and health at work issues.

EU-OSHA's specific competences include:

- Competence in occupational safety and health as regards the workplace management of dangerous substances (this includes registered chemicals and process-generated substances and mixtures (e.g. silica dust, welding fumes, diesel motor emissions or wood dust))
- Development of tools for the management of dangerous substances at the workplace level and sectoral workplace risk assessment tools (OiRA)
- Collecting information on national tools and guidance and examples of good practice regarding the management of dangerous substances at work.
- Development of information and awareness-raising campaigns in the area of dangerous substances at work
- Collecting and analysing technical and scientific information in the area of dangerous substances at work and related health problems and publishing the results
- Development of surveys targeting exposures at workplaces, e.g. the Workers´ exposure survey on cancer risk factors in Europe
- Supporting the European Commission, for instance through the development of guidance in the area of dangerous substances management and OSH

The EU-OSHA maintains a network that comprises the main components of the national information networks, including the national employers' and employees' organisations and the national focal points.

- Network of national **Focal Points and Member State tripartite networks**: in accordance with the founding regulation of EU-OSHA, the national authorities or a national institution designated by the Member State as a national focal point coordinates and transmits the information to be supplied at national level to EU-OSHA within the framework of an agreement between each focal point and EU-OSHA on the basis of the work programme adopted by EU-OSHA. The national authorities or national institution shall consult the national employers' and employees' organisations and shall take into account their point of view in accordance with national law or practice. The Member States regularly inform EU OSHA of the main components of their national safety and health at work systems and strategies. This network provides input to EU-OSHA's work and the mechanism to disseminate products and information to national stakeholders. In addition, the focal points are active in the planning and implementation of EU-OSHA campaigns as well as nominating national experts to the Agency's groups and seminars.
- Close functional links with the **Advisory Committee on Safety and Health at Work** and its working parties and the **Senior Labour Inspectors Committee** and its working groups

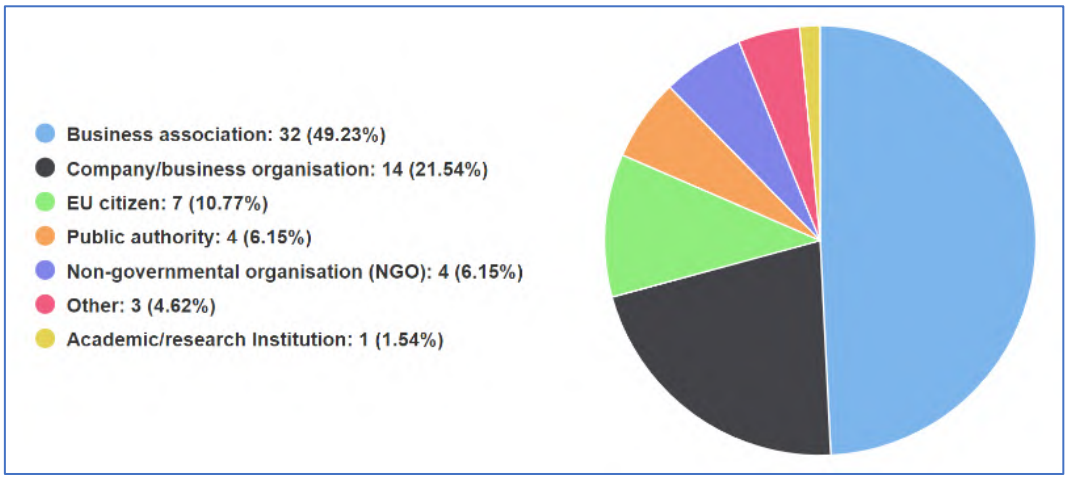
ANNEX II: SUMMARY OF THE FEEDBACK RECEIVED THROUGH THE PUBLIC CONSULTATION ON THE CALL FOR EVIDENCE FOR THE INITIATIVE ON (RE-)ATTRIBUTION OF SCIENTIFIC AND TECHNICAL WORK ON CHEMICALS TO THE EU AGENCIES

The call for evidence was published on the Commission's website 'Have your say' on 15 March 2022 and the feedback period lasted 30 days, until 12 April 2022.

1. RESPONDENTS

In total, 65 submissions were received (61 unique submissions and 4 replicative submissions by the same respondent), majority being from business associations and companies (in total around 70% of submissions), followed by submissions from EU citizens (11%), non-governmental organisations (6%), public authorities (6%), others (5 %) and academic/research institutions (1.5%).

Proportions of number of feedbacks received by category of respondents



As regards geographical variation, the majority of feedback was received from respondents from Belgium (49%), followed by Germany (17%), Poland (8%), France (6%), Spain and Denmark (3% each) and UK, Sweden, Slovakia, Portugal, Norway, Japan, Italy, Finland and Austria (2% each).

2. TYPE OF RESPONSES

Large majority of responses were relevant to the topic of the call for evidence. Only 3 responses were assessed as not relevant to the 1S1A. They provided specific comments on the ongoing revisions of some pieces of legislation but without relevance to the 1S1A or just a general critisism of the EU legal framework.

As this has been the first public consultation on an initiative under the 1S1A, a lot of feedback received was not specific about the consulted initiative on the reattribution of task to the EU Agencies but about the general scope of the 1S1A approach as well as other initiatives announced under the 1S1A. All feedback received is however useful for the upcoming discussions, therefore, the text below summarises all relevant input received.

3. SUPPORT TO THE INITIATIVE ON 1S1A

Generally, there is a large support of the initiative among the respondents, whether of the 1S1A approach as a whole or of the specific initiative on the reattribution of tasks. 67% of respondents expressed their explicit support, 23% did not expressed explicitely their opinion but provided relevant advices on how to develop the 1S1A approach and about 10% expressed doubts about usefulness of the initiative or opposition to the initiative.

The well-implemented 1S1A initiative is seen by respondents as beneficial for both industry and regulators. The respondents supporting the initiative identified the following benefits of the initiative:

- More uniform risk assessment across relevant chemical legislation; enhanced consistency of assessments and their outcomes, carried out on the same dataset;
- Improved robustness of the assessments;
- Involvement of the right expertise at the right place at the right time;
- Provision of tailored assessments under specific legislations/uses if relevant;
- Optimal use of resources;
- Increased efficiency and predictability;
- Making use of synergies (phys/chem/tox data available at different EU agencies);
- Elimination of duplication of animal testing in the EU and a driver for both improved sustainability and better protection of animals;
- Strengthening trust between society and industry, whilst improving efficiency, and sound science-based regulatory and political decision-making; achieving a robust and consistent approach to chemical regulation;

Some respondent identified concrete past and on-going discrepancies and ineficiencies as regards the safety assessment of chemicals that they hope to be avoided by the implementation of the 1S1A initiative. These are:

- Past discrepancy in assessments of phthalates and bisphenols between ECHA and EFSA and between REACH and Food Contact Materials;
- On-going discrepancy in risk management measures on silicon dioxide under the biocidal product regulation (where there is a low limit on its presence in biocidal products) and REACH (where this substance is exempted from information requirements and can be sold in products at much higher concentrations than in the biocidal products);
- Currently no link exists between the REACH and Food Contact Material legal framework as regards the re-use of data, although the same substances are being regulated under both frameworks. On the chemical side, over ten years of REACH implementation led to the generation of a very comprehensive (eco)toxicological dataset on a wide number of substances, which is available to ECHA. It would be very efficient and avoid unnecessary test and the repetition of studies, especially in vivo (animal studies), if this data could be used for the risk assessment in the FCM framework by EFSA. Although the robust study summaries provide some publicly available data, like toxicological end points, this is often not accepted by authorities as the original studies behind the end points are requested, which cannot be accessed by the authorities. Therefore, the link needs to be established between these two legislation and the legal framework around the usage of such data should be modified and broadened to facilitate the reuse of already available data and to allow other Agencies to access the REACH data.
- There is a need for an improved vertical coordination and collaboration between the expert panels of EFSA evaluating the same substance. Challenges have previously been seen for e.g. fluoride, evaluated by the EFSA nutrition panel but where the contaminants panel is also relevant. For chemical substances like fluoride it is important that an evaluation covers both aspects of nutrition and toxicology. For some contaminants we have also seen that JECFA and EFSA have evaluated the same substance with different output/result. It would improve the use of resources if it were not necessary to have two different bodies evaluating the same substance. However, as Codex Alimentarius refer to JECFA evaluations and EU Commission to EFSA evaluations it will be challenging to accept/adopt the evaluation made by the other Committee.
- Currently, there is no central searchable database on environmental impacts of pharmaceuticals available. Therefore, it is proposed to integrate the validated environmental information on pharmaceuticals held by EMA in data platforms already used on a European level. The central database would also be a valuable tool for endpoints of monograph systems for human and veterinary pharmaceuticals.

The respondents opposing or doubting the initiative provided the following arguments:

- Did not observe problems with 'duplication' or 'inconsistent outcomes', although the substances they produce/use fall within various regulatory domains;
- The initiative is likely to create more complexity, as well as a transition period which will considerably affect substance evaluation and authorization processes and timelines, as well as the burden placed on applicants. The latter will come on top of the increased complexity created by the recent implementation of the Transparency Regulation and its requirements related to confidentiality justification and the new IT tools to be used for notification and submission of dossiers to EFSA and the Commission.
- Several product specific regulations require special product qualities like e.g. a high purity and consider very specific exposure possibilities. The general goal of true "one substance, one assessment" is highly difficult to implement, taking into account all possible applications and the various grades of a substance on the market. The assessment of a substance requires a high level of expertise and detailed considerations.
- It is important that chemicals used in the EU are assessed by several independent research teams, which will reduce the risk of lobbying and increase the possibility of comparing test results.

Some confusions or misunderstandings could be observed in some of the responses provided. The most common ones are:

- Some respondents considers that ECHA does only hazard assessment while EFSA does risk assessment. The true is that both agencies do both, hazard and risk assessment. The confusion might originates from the fact that ECHA does also harmonised classification of hazards under the CLP regulation, which is pure hazard assessment, and respondents are not aware of their risk assessment work as part of the REACH restriction process or implementation of the biocidal product regulation, POPs regulation or drinking water directive.
- Some respondents fear that moving some assessments to ECHA will automatically result in hazard-based regulation, omitting the use of exposure information. The true is that reattribution of tasks on safety assessment will not change the risk management measures. In addition, as explained above, ECHA is also doing risk assessments and has experience in doing so.
- Some respondents fear of the ambition to create one new 'risk assessment' agency and consolidating all risk assessments into such agency. There is no such intention. The objective of 1S1A initiative is to improve cooperation between agencies and clearly distribute the relevant tasks among them with the objective to improve coherence, efficiency and effectiveness of safety assessments.

4. SCOPE AND OBJECTIVES OF 1S1A

Number of respondents provided their views and expectations regarding the scope and objectives of 1S1A.

The expectations and views expressed by the respondents regarding the general scope and objective of the 1S1A are as follows:

- 1S1A should ensure that the level of protection for the human health and the environment is not jeopardised and remains high.
- 1S1A should work towards a coherent protection goals by developping a new EU Human Health Directive that aims to achieve 'good public health', protecting humans from the combined action of chemicals and combined action of chemicals and non-chemical environmental stressors.
- 1S1A should be limited to one substance, one hazard assessment. The hazard assessment – the basic evaluation of substance properties – should be grounded in a single set of agreed scientific principles, as it is independent of the area of application or legislation. Risk assessments and potential socio-economic assessment however should remain tailored to their different purposes and legislation, taking into account the use of, the exposure to the substance and particularities of the sector. Risk management measures should be also specific and tailor-made.
- 1S1A should ensure that for a specific use there is only one risk assessment performed across legislation valuing existing expertise.
- 1S1A should ensure that all relevant assessments are updated if new data and new assessment lead to a new TDI or PNEC value to ensure that all regulations rely on limit values derived from the latest knowledge. It

should be considered in the new omnibus regulation to require updates in all sector specific regulations within a given timeframe when a new TDI or PNEC value is derived by an EU scientific committee.

- The actions of 1S1A initiative should be focused on where duplication really appears, i.e. to
    - hazard assessment and classification, identification of acute concentration limits ATEs, local effects specific concentration limits SCLs and NOAELs/LOAELs for human health, ECxx/LCxx/NOECs for acute aquatic toxicity and other wildlife. Based on these endpoints, the derivation of DNEL/OEL/TDI/ADI/PNECs/EQs, etc. may differ between legislations (REACH, OSH, PPR, BPR, FCM, WFD) due to different methodologies to carry out their safety assessment.
    - substances used in different applications covered by different legislation.
- Although 1S1A is targeting on 'chemicals', it should be expanded also to microbials, natural substances and semiochemicals used as biocontrol. Biocontrol products themselves may be used for more than one purpose; for example, micro-organisms are used in the area of crop protection, but also as fertiliser or biostimulant under Fertilizer Product Regulation. The same micro-organism are used in agriculture and are subject to different regulatory frameworks and thus to different sets of data requirements and procedures. Ultimately this may lead to different and even contrary decisions, based on the same data package the same micro-organism may be authorised for one area of use (e.g. as a biostimulant), but may not be approved for another area of use (e.g. crop protection). Establishing within the EU a group of biocontrol experts is recommended. To start, the group should consist of microbial experts from Member States, EFSA, ECHA, and other relevant EU institutions that, in close cooperation with COM, will be responsible for all evaluations and assessments of microbial active substances submitted in the EU for approval. This would guarantee a consistent and scientifically sound approach that would considerably simplify and speed up procedures. This should then be extended to cover experts in natural substances and semiochemicals.
- 1S1A should also aim to improve comparability of monitoring data across Member States in the area of food contaminants. Pursuant to Commission Regulation (EC) No 1881/2006, Member States are requested to examine samples and provide necessary data that could lead to a comprehensive risk assessment. Despite the European scope of the risk assessment, means to support such data collection is still largely maintained at a Member State level, manpower and the financial means of Member States for this varies, which all together may lead to national authorities providing data with high variability. This initiative on streamlining scientific assessments is an opportunity for the Commission to support the integral role that national authorities and European Reference Laboratories do to ensure the conclusions taken from these studies and guidance documents are as robust as possible.
- Some respondents argued that veterinary medicinal product should be exlcuded from the scope of 1S1A, while others were arguing for importnace to include also medicinal products, in particular as regards the environmental data on medicinal and veterinary products.

The expectations and views expressed regarding the five specific areas of the 1S1A initiative identified in the chemicals strategy for sustainability are as follows:

Coordination and initiation of the assessments

- Upfront close coordination of assessments should be established across different DG's, Scientific committees (including Scientific Panels), Agencies as well as Member States at European level, to decide what is required, and who does what and when;
- A central coordination mechanism should be established, including a coordinated problem formulation phase (i.e. identifying the correct scientific question that needs to be answered) which would enhance predictability for industry;
- Mechanisms needs to be created to integrate assessments that specify the health and environmental endpoints used by the different agencies;
- Different bodies active in the assessment of chemicals must ensure proper coordination of their work, especially when they are assessing the same substance. This includes an exchange of information such as results of previous assessments.
- Also the national authorities of each EU member state that should be active in the assessment of chemicals, e.g. under REACH, are included in the "one substance, one assessment" initiative in order to prevent diverging views between member states and/or EU authorities regarding the assessment of (groups of) chemicals.

- It is vital that the implementation of the "one substance, one assessment" approach contains provisions for supporting greater interagency cooperation;
- To make this system work it is recommended that evaluators/risk assessors from different regulatory bodies attend each other meetings thus ensuring consistency and avoiding duplication of work;
- Cooperation between EU and national agencies is crucial for a better usage of resources.
- It shall be avoided that overlapping evaluations and assessments are taking place in parallel within the same regulatory context. Risk management measure processes should not be started during an on-going substance evaluation, where data gaps may be identified and therefore pre-empting the step in the substance evaluations that identifies the most appropriate risk management measures to be identified or data to be gathered to be available;

Allocation of responsibilities

- Tasks should be reattributed amongst the agencies to ensure efficiency, by assigning the relevant responsibilities to the pertinent agency rather than reshuffling already established responsibilities;
- Each body (i.e. authority, agency, working group, etc.) that is carrying out an assessment of (groups of) chemicals should be equipped with sufficient expertise necessary for the specific assessment, e.g. in the field of toxicology, ecotoxicology, occupational safety and health, exposure assessment, etc
- Cooperation between EU and national authorities should be also optimized. Synergies and overlaps must be clearly identified. This area is not left out and there is a clear division of tasks.

Data

- Data exchange across Committees and Agencies should be ensured to avoid duplication of data submission; a common information base needs to be created to avoid duplication of assessments, for example with an open data platform on chemicals and tools for accessing relevant academic data;
- Exposure assessment tools and methodology could also be centralised on a common data platform;
- Access to all available data in the same structured format should be provided for all EU authorities. Equal transparency regimes are applied across all sectors.
- Academic data has a role to play in science-based policy making, however, there needs to be a process to ensure that data is reliable and robust. There are 1000's of studies related to titanium dioxide that are published each year and the titanium dioxide industry has a comprehensive screening process in place including regular updates of the REACH dossier. A lot of the academic data related to titanium dioxide is not reliable or robust enough with basic information such as the identity of the substance unknown. The other concern is the inherent bias as non-adverse outcome are less likely to be published. The OECD Guidelines for the Testing of Chemicals were developed for this reason, and it is important that they remain the key benchmark.
- We strongly support the proposal to introduce new tools for the 1S1A approach, which would further improve the work of the industry and scientific committees in ensuring consumer safety by:
    - extending the use of the public activities coordination tool to other legislation
    - establishing an EU repository of human and environmental health-based limit values; and
    - establishing a common, open data platform on chemicals and tools for accessing relevant academic data
- We support the principle of harmonizing the format in which data is reported to enable data to be shared between agencies. A harmonized data format will in our opinion lead to efficiencies and greater transparency. To us a harmonized data format does not equal harmonized data requirements between agencies since adequate data required for a risk assessment depends on the sector considered. It would be important to have a systematic mechanism supported by the authorities to organize the request of data to the manufactures to avoid duplication of efforts/resources and to guarantee a good agreement among the interested parties. The format of all data collected should be developed in close collaboration with the industry to ensure it is fit for purpose.
- We are in favour of promoting the environmental biomonitoring and check how the establishment of that limit values could benefit from this biomonitoring.

- The legal framework around the usage of REACH registration data should be modified and broadened to allow other Agencies to access such information, in order to prevent double work, but above all the repetition of studies, especially in-vivo, for the same substances. With specific reference to evaluations concerning food contact materials, we believe that EFSA would greatly benefit from access to registration dossier data, with due consideration of data protection. Similarly, we believe that also MSCA should also have access to the existing data. For instance with regards to FCM evaluations, this would enable them to make evaluation on the same dataset used by EFSA, uniformizing the petitioning process by avoiding divergence in the approach.
- Environmental safety data already assessed by one of the European agencies should be available for procedures under different EU regulations. This should also apply to environmental data from the veterinary and human pharmaceutical legislation. Therefore, including EMA as agency responsible for the environmental impacts of pharmaceuticals is highly welcome. Currently, there is no central searchable database on environmental impacts of pharmaceuticals available. Therefore, it is proposed to integrate the validated environmental information on pharmaceuticals in data platforms already used on a European level. The central database would also be a valuable tool for endpoints of monograph systems for human and veterinary pharmaceuticals.

Methodologies

- Clear, standardised approaches/protocols on hazard and risk assessments must be developed to ensure consistency and predictability, while acknowledging the different needs of the different regulatory frameworks. For example, in food safety related matters it is crucial to define health-based guidance values from the context of food exposure only, and therefore the ways of assessing the hazard might divert from other legislative areas where other routes of exposure are more prominent.
- The assessment of chemicals must be science-based.
- Harmonisation of the methodologies for the assessment of chemicals should incorporate and expand the use of non-animal New Approach Methods and next generation risk assessment tools (based on the knolwdge acquired by SCCS), making this a default 'one assessment' framework applicable to all chemicals.
- Harmonisation of evaluation methodologies is needed. For example, the AOEL (acceptable operator exposure level), DNEL (derived no-effect level), the MOS (margin of safety) and the OEL (occupational exposure limit) are four different ways to set a threshold limit under Pesticides, REACH, the Cosmetics Regulation and workplace regulation, respectively. Another example is the methodology used under the Water Framework Directive to set environmental quality criteria with the purpose of protecting humans from consumption of polluted fish and shellfish. This methodology differs from the methodology used by EFSA and national food safety authorities to set limit values for edible fish, thereby resulting in different limit values for the same substance.

Transparency rules

- Transparency on the decisions and processes is increased;
- All information regarding the evaluating authority, the process and status of the assessment as well as all relevant documentation should be available to all stakeholders.
- Transparency rules should be also harmonized.

5. REATTRIBUTION OF TASKS TO EU AGENCIES

Number of respondents provided their views on how the reattribution of tasks to the EU agencies should be done. These are:

- Reattribution of work must not result in a single agency being responsible for the risk evaluations of all chemicals. A clear demarcation of responsibilities between relevant EU agencies and regulations is needed.
- The role, tasks and expertise of each agency should be clearly defined and exploited in a targeted manner. Agencies should stay within their assigned areas of duty and abstain from political interventions.

Expertise

- It is strongly suggested that expertise for risk assessment under the different regulations should stay with the existing responsible agencies. Each Agency is best positioned to lead and provide specific assessments due to their extensive experience in product specific related matters, e.g., EFSA for food use, EMA for medicines use.
- It shall be ensured that whatever body carries out the risk evaluation tasks it shall have available the necessary and adequate expertise within the application domain of the use of the chemicals.
- We strongly encourage the Commission to review the functioning of the existing scientific committees, agencies, consultants, etc. supporting scientific assessments to ensure that they have the relevant expertise (both quantitatively and qualitatively) and always strive for opinions of the highest scientific excellence and integrity
- Not all hazard endpoints are covered by all regulations. For the environment, the Plant Protection Regulation is probably the most advanced as requiring testing on species not covered by other regulations such as honeybees, earthworms, plants, beneficial arthropods, birds. Therefore, the derivation of these endpoints should stay with the Agency having the expertise, *i.e.* EFSA.
- The reattribution should ensure that valuable expertise gathered by existing entities is preserved. The knowledge of SCCS to perform risk assessment without animal use has to be preserved and cosmetics have to continue use only data from non-animal tests. Transparent safety assessment process for cosmetics should continue to be underpinned by the use and further development of the current Notes of Guidance from SCCS.

Resources

- The necessary resources must accompany new tasks to the agencies.
- Re-attribution of work should not lead to the situation that the Agency or committee is not able to handle the workload and hence would jeopardise the quality of the work or result in the use of scientifically unsound decisions/approaches.

Organisation of scientific committees

- Agencies might need to be reorganised to deal with increased workload. RAC in ECHA has already now immense workload; In ECHA, MSC could be turned into the hazard assessment committee to deal with CLP classification, RAC could focus only on risk assessments. It would be useful to also align panels in EFSA as the same substance is evaluated by two panels.
- Instead of creating new scientific panels, the agencies should be supported to be able to reinforce the expert independent committees and working groups that already exist, with a certain level of flexibility and openness in terms of reaching the best assessment.
- The safety assessment for consumer products should be performed by an independent commitee which has equal status to hazard assessment committee (i.e. a safety assessment committee for consumer product should not report into a hazard assessment committee).

Tasks to re-attribute

- For substances used in food contact materials the process should involve EFSA and ECHA. The process should start with the hazard identification and characterization of substances, followed by an FCM specific risk assessment. We recommend ECHA play a central role in the hazard assessment of chemicals, while EFSA assess risks linked to their use in FCMs (which are highly specific compared to those for other uses of chemicals).
- So far, a number of tasks have been distributed to ECHA, or are foreseen to be distributed to ECHA. This includes e.g. opinions on health based limit values under OSH, derivation of limit values under the Drinking Water Directive, evaluation of cosmetic ingredients under the Cosmetic Products Regulation, etc. However, other areas have not been addressed such as e.g. derivation of environmental quality standards under the Water Framework Directive, or opinions on chemical substances in e.g. toys by the scientific committee SCHEER. It should be considered how to achieve harmonization in these areas as well, including if tasks should be redistributed to one of the agencies (EFSA or ECHA)
- The proposal should include as many substance regulations as possible within the EU legislative framework, e.g. Toys directive, food and feed additives, environmental quality standards (EQS).

Impact assessment

- Few respondents suggested to perform an impact assessment for the 1S1A initiative to make sure that potential impacts on business operators are adequately considered and to make sure that businesses are involved in the development of the initiative.

ANNEX III: DETAILED IMPACT ANALYSIS OF THE (RE-)ATTRIBUTION OF SCIENTIFIC AND TECHNICAL WORK RELATED TO CHEMICALS TO EU AGENCIES

1. DRINKING WATER DIRECTIVE (2020/2184)

Responsible body:

Currently: N/A, no current process exists at EU level

(Re-)attribution planned to: ECHA

Legal basis for reattribution: Revision of drinking water directive

Type of task: New

Brief task overview: Establishing and maintaining four EU positive lists for substances and compositions authorised to be used for the manufacture of materials in contact with water intended for human consumption.

Detailed process description:

Current process:

N/A, no process exists at EU level

New process:

1. *From national lists to the first EU positive lists (review programme)*

The Commission, supported by ECHA, compiles the first EU positive lists for substances and compositions used in the manufacture of organic, cementitious, metallic and inorganic materials in contact with water intended for human consumption. These first positive lists are based on national positive lists notified to ECHA by July 2021; in addition, the positive list for organic materials will incorporate the plastic FCM positive list of Regulation (EU) No. 10/2011. All entries in the EU positive lists will be subject to a review. To this end, each entry will be accompanied by an expiry date by which industry needs to submit an (review) application to ECHA. The burden of proof is with industry: if industry wishes to keep a substance or composition on the EU positive list, they need to submit an application by a specified deadline. If no application is received by the deadline, the substance or composition is removed from the positive list.

It is estimated that the first EU positive lists will contain approximately 2000 entries with assigned expiry dates of 2028, 2031, 2034 and 2037 depending on the hazard of each entry and the availability of past risk assessments. The first European positive list will be adopted by January 2024, the first review applications can be submitted as from January 2026 and the whole review programme shall be finished within 15 years by end December 2039.

2. *Updating the EU positive list*

Once established, ECHA will need to manage the EU positive lists through the addition, removal and updating of entries in the lists. The process can be triggered by:

a. An economic operator who wishes to add a substance or composition to an EU positive list or has to submit a review application for an existing entry;

b. An authority that has a reason to propose removing a substance or composition from an EU positive list or to update an entry;
c. ECHA, that may submit an application on the Commission's request.

Once an application is received, the process at ECHA contains the following main steps:

- Automated and manual checks of the application to verify completeness and accordance with the information requirements which will be set out in implementing legislation;
- Dissemination of information and consultation of interested parties;
- Opinion development via the RAC committee;
- Support to applicants and Member State Competent Authorities;
- Technical and scientific support to the Commission.

The first review applications can be submitted as from January 2026.

Proximity to ECHA mandate:

The work is close to the ECHA core mandate of assessing the risk of chemical substances based on industry applications and many of the core competences are already present in the Agency.

Projected synergies and added value of (re-)attribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already supports similar work on substance risk assessment under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk and exposure assessment - Committee opinion development - Existing IT capabilities for industry dossier submission, stakeholder consultation and dissemination
Re-use of data	Medium	Reuse of substance identification and hazard data collected under other chemical legislation. Currently low availability of data on substances in products and no data available on migration of substances to water.
Workload balancing	Low	With an estimated workload of developing 50-150 RAC opinions annually, there is little room for workload balancing.
IT tools: automation and economies of scale	High	Industry actors can submit their applications reusing existing ECHA submission tools, which will be adapted to the needs of the EU positive lists, at the same time automating the existing process. In addition, reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value

Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology at EU level to improve equal EU market access and coherence in the scientific advice provided to the Commission. Reuse of assessment insights developed under other chemical legislation. Opportunities to put into practice the One Substance-One Assessment for substances of interest to both drinking water (ECHA) and food contact materials (EFSA).
Robustness of assessment and acceptance	High	Harmonising market access and scientific work from Member State level to EU level. Additional involvement of RAC committee adds more scientific robustness to the process.
Independence	High	Moving scientific work from Member State level to EU agency experts and committees. ECHA and its committees work under strict conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will ensure transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities and application submission intentions improves predictability for all stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: The high impact of the work on the RAC committee needs to be addressed.

Projected impact on ECHA:

- ECHA Committees/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to significant additional workload

	RAC			**SEAC**		
Process	**# of opinions per year**	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Assessment of applications and dossiers	50-150	RAC member		0		

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on existing expert competencies which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks, as well as new competencies which ECHA should acquire (e.g. migration assessment and materials science)

Workload and resource implications:

Current workload and resource use:

N/A, no current process exists at EU level

Future workload and resource needs:

The Directive is in force since 2021. Industry can notify their intention to submit an application from January 2025 with the first industry applications expected from January 2026 onwards.

A total of 3 new full-time equivalent temporary agent staff (AD 5-7) (average cost EUR 136 000/year, during 4 years) and 2 full-time equivalent contract agent staff (CA FG III, average cost EUR 65 000/year), have been allocated to ECHA to set up the system. After 4 years, the review process will necessitate additional resources, i.e. 10 FTE on average for the next 4 years (7 temporary agent staff and 3 contract agent staff). A new assessment of the needs will be completed at the end of the period on the basis of the experience gained during the first years of functioning of the system. According to first estimates, additional staff (around 3 FTE, i.e. bringing the total to 13 FTEs) might be needed to complete the review of all substances on the positive lists in a reasonable deadline (15 years).

In addition to staff costs, EUR 1 000 000 is reserved for the first 3 years annually to set up the IT systems, whereas roughly half of this amount will be needed for maintenance work after the set-up period. Infrastructure expenditure has been estimated at 24% of the staff expenditure.

The aforementioned resources have been estimated using a calculation model which takes account of relevant experience from tasks executed by ECHA under other regulatory frameworks (e.g. REACH, CLP, BPR) and from the implementation of the existing national approaches where relevant. It sets out the resources that will be needed by ECHA over a time window of 20 years, including a review programme running over 15 years, in order to handle the foreseen tasks.

The estimated resources for the process to review and update the EU positive lists are application/dossier driven. The number of applications/dossiers have been estimated on the basis of substances on lists currently in use by the Member States and that have been registered under REACH. Member States' forecasts were used to estimate the flux of incoming applications/dossiers. The key tasks involve examination of the applications/dossiers, opinion development and decision process. The estimated resources for the initial setup, ICT process infrastructure and development of methodologies, for the process from national lists to the first EU positive lists as well as the resources involved in other tasks such as helpdesk, legal support are task driven regardless of the number of dossiers.

Once the routine phase for dealing with the tasks under the proposed recast of the Directive has been approached (from the tenth year onwards), about 70 % of the resources will be involved in the operational work (dossier and opinion related efforts).

Additional limited resources might be necessary for EFSA in case the existing system of FCM (under evaluation) is still in place when the review will start (after 2025) to ensure coordination on the review of the plastic lists. These potential additional resources are not included in the present estimate.

Summary of additional resource needs for the drinking water directive regulation:

Agency	**Summary of tasks**	**Resource needs**	
ECHA	- Establishing and maintaining four EU positive lists for substances and compositions authorized to be used for the manufacturing of materials in contact with water intended for human consumption	Financial resource needs:	2021: **EUR 1 000 000** 2022: **EUR 1 000 000** 2023: **EUR 1 000 000** 2024: **EUR 510 000** 2025: **EUR 520 000** 2026: **EUR 530 000** 2027: **EUR 540 000**
		Human resource needs:	2021: **3 TA, 2 CA** 2022: **3 TA, 2 CA** 2023: **3 TA, 2 CA** 2024: **3 TA, 2 CA** 2025: **6 TA, 3 CA** 2026: **7 TA, 3 CA** 2027: **8 TA, 3 CA**

Future budget line: DG Environment

Candidate for fees: Yes - for authorisations, No - for others

2. REGULATION ON SERIOUS CROSS-BORDER THREATS TO HEALTH (2022/2371)

Responsible body:

Currently: Commission with the support of the SCHEER Committee

(Re-)attribution planned to: ECHA, EEA, EFSA, EMA

Legal basis for reattribution: proposal for regulation on serious cross-border threats to health.

Type of task: existing

Brief task overview: ECHA, EEA, EFSA, EMA, ECDC, EMCDDA are tasked, on the request of the Commission, to carry out "a risk assessment of the potential severity of the threat to public health, including possible public health measures" when there is an alert of a cross-border threat of chemical origin (see draft article 20.1(c)).

Detailed process description:

Current process:

Decision 1082/2013/EU on serious cross border threats to health (the Decision) layed down rules on combating serious cross border threats to health. Where there is an incident or alert of an actual or potential serious cross-border threat to health that fulfils the criteria detailed in Article 9 of the Decision (Box 1), the Commission shall, where necessary for the coordination of the response at Union level and upon request of the Health Security Committee (HSC) or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the Early Warning Response System (EWRS), a public health risk assessment of the potential severity of the threat to public health, including possible public health measures.

In operational terms, the Commission and the HSC may request the SCHEER to undertake rapid risk assessments (within 72h) in case of chemical cross border public health threats from both manmade and naturally occurring events (e.g. chemicals released during an incident or during a volcanic eruption) that may have an impact on health (hereafter chemical health threats). The assessment did not cover the wider effects on the environment which are outside the scope of addressing the effects on human health (e.g. biological effects on ecosystems) as these were outside of the remit of the Decision and would therefore have to be taken forward through other existing mechanisms, e.g. through a separate mandate or different body.

To implement this obligation, SCHEER has developed a guidance in ad hoc rapid risk assessment of serious cross-border chemical health threats. SCHEER set up and maintained a continuous readiness to provide rapid risk assessments (within 72h) where urgently needed by setting up a SCHEER permanent working group on rapid risk assessment. The committee held on average 10 meetings per year and performed regular crisis exercises.

Changes in the process:

The responsibility for rapid risk assessment for risks of a cross-border threat that is linked to medicinal products and medical devices is assigned to EMA, for risks of a cross-border threat of chemical origin is shared between ECHA and EFSA based on their mandate and for risk of a cross border threat of threats of environmental origin, including those due to the climate, are shared among ECHA, EFSA and EEA based on their mandate.

Proximity to Agencies (ECHA, EEA, EFSA and EMA) mandate: EFSA has been already involved in the rapid risk assessment based on the old system, in parallel with SCHEER, and thus have developed expertise and procedures. For ECHA and EMA this is a new task. While they have certain expertise in the area of chemical or environmental risks, they do not have dedicated expertise related to risk management of chemical incidents, nor do they hold data on emissions into the environment.

For EEA is a new task too but EEA holds data on emissions into the environment and there are some synergies with (re-)attribution of SEVESO III work on chemical accidents.

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	Medium	Process and expertise: ECHA, EFSA and EMA already provides scientific advice on chemical substances under their mandate. Therefore, the existing capacities on hazard, risk and exposure assessment can be reused/reinforced. EEA is to be responsible also for SEVESO directive dealing with chemical accidents and this expertise can be partly reused.
Re-use of data	Medium	ECHA, EFSA, EMA and EEA can reuse of data collected under other legislation within their mandate.
Workload balancing	Medium	With only sporadic requests for advice, the workload of Agency experts can be balanced.
IT tools: automation and economies of scale	Medium	Not an IT-intensive process, but reuse of IT capabilities for case management, interaction with Member States and external experts.
Support services: economies of scale	Medium	Reuse of scientific support services (e.g. data management and coordination with Member States and external experts). Reuse of administrative services.

Type	Added value	
Scientific consistency	Medium	Opportunity to align process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under other legislation.
Robustness of assessment and acceptance	Medium	Centralising scientific work from dispersed Commission services and committees to EU Agencies and their experts.
Independence	Medium	Agencies are independent of the Commission and their experts have to fulfil strict non-conflict rules.
Transparency	Medium	Agencies involvement will bring additional transparency to the process: - Overall process transparency - Dissemination of opinions and outcomes

Main risks and opportunities: It might be challenging for Agencies to set up and maintain a continuous readiness to provide rapid risk assessments (within 72h) where urgently needed, similar to what is currently available through the DG SANTE secretariat and members of the SCHEER committee.

Projected impact on Agencies (ECHA, EFSA, EMA, EEA):

- Agencies Committees/bodies: **no impact**. The task does not require involvement of ECHA Committees/bodies
- Agencies data model and IT infrastructure: **no impact**. The task does not require adjustment

of data structures and IT systems

- Agencies key experts: **medium impact**. The task partly relies on expert competencies that are currently not present within the Agencies and will therefore need to be acquired and developed

Workload and resource implications:

Current workload and resource use

DG SANTE Health Security unit leads this process (resources spent unknown), but the main work is carried out by the SCHEER Committee dedicated working group (on average 10 meetings / year + regular crisis exercises, etc.). With this level of activity this work is estimated to take up at least 20% of the work time of the DG SANTE SCHEER secretariat (= ca. 0.6 FTE/year) and require significant time from the SCHEER members. In addition, the operational budget for the reimbursement of members is at least EUR 48 000 (20% of EUR 240 000/year)

DG SANTE (Health Security unit)	
DG SANTE (SCHEER secretariat)	Ca. 0.6 FTE (ca. 20% of SCHEER capacity) EUR 48 000 operational SCHEER budget (at peak EUR 68 000)
Total	*Ca.* 0.6 FTE

Current budget line: DG SANTE

Future workload and resource needs:

The work performed by SCHEER will be shared among several agencies based on their expertise and mandate. The requests for rapid risk assessments are made on ad hoc basis and are not very frequent. Considering the existing expertise in the agencies, the existing network of experts, low abundancy of the requests, it is expected that the Agencies can absorb the tasks without additional resources.

Summary of additional resource needs for the regulation on cross-border threats to health:

Agency	Summary of tasks	Resource needs	
ECHA, EEA, EFSA, EMA, ECDC, EMCDDA	- contribution to the public health risk assessment	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0**
		Human resource needs:	2024: **0 FTE** 2025: **0 FTE** 2026: **0 FTE** 2027: **0 FTE**

Future budget line: None – no resources allocated

Candidate for fees: No

3. EUROPEAN PARTNERSHIP FOR THE ASSESSMENT OF RISKS FROM CHEMICALS (PARC)

Responsible body:

Currently: N/A, no current process exists at EU level

(Re-)attribution planned to: ECHA, EEA, EFSA

Legal basis for reattribution: None, voluntary (ECHA and EFSA) or grant (EEA) agreement to participate in the project

Type of task: new

Brief task overview: Participate in and provide input and support to the European Partnership for the Assessment of Risks from Chemicals

Detailed process description:

PARC is one of the projects selected for funding by the European Union's "Horizon Europe" framework programme for the 2021-2027 period. It is a 7-year partnership that started on 1st May 2022 and that consists of 200 partners in 28 countries and at EU level, national agencies and research organisations working in the areas of the environment or public health, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environment Agency (EEA).

PARC aims to advance research, share knowledge and improve skills in chemical risk assessment. By doing so, it will help support the European Union's Chemicals Strategy for Sustainability, paving the way for the "zero pollution" ambition announced in the European Green Deal.

PARC represents a campaign of unprecedented scale, since it brings together about 200 European players, involving national and European health and safety agencies as well as research organisations. The partnership encompasses all aspects of chemical risk assessment, aiming in particular to: better anticipate emerging risks, better account for combined risks, and underpin the concrete implementation of new orientations in European public policies to safeguard health and the environment in response to important issues for health, the ecology and citizens' expectations.

The partnership builds on work undertaken as part of the European Joint Programme on human biomonitoring, HBM4EU (Human Biomonitoring for Europe), which came to an end in the summer of 2022, and broadens the scope of its interests specifically to the assessment of environmental risks.

Main objectives of the PARC are:

- Develop the scientific skills needed to address current and future challenges in chemical safety
- Provide new data, methods and innovative tools to those responsible for assessing and managing the risks of chemical exposure
- Strengthen the networks which bring together actors specialised in the different scientific fields contributing to risk assessment

The EU Agencies (ECHA, EFSA and EEA) are to contribute to, participate in and support various workpackages of PARC.

Proximity to mandate: The task is close to EEA, EFSA and ECHA mandate and key competences regarding risk assessment of chemicals, management and interpretation of data related to chemicals.

Projected synergies and added value of (re-)attribution: PARC consortium will benefit greatly from invlovement of EU Agencies that hold experience in performing regulatory risk assessment and hold knowledge and data for such assessments. Through their experience they can identify gaps and needs requiring scientific development and steer such development in a direction that provides the highest value for the regulatory risk assessment. The EU Agencies will benefit from the participation as well. They can uptake immediately in the regulatory risk assessment any innovation in risk assessment that PARC will deliver.

Projected impact on Agencies:

- Committees/bodies: **no impact**. The task does not require involvement of Agencies' Committees/bodies
- Data model and IT infrastructure: **no impact**. The task does not require any new data structures and IT systems/capabilities
- Key experts: **medium impact**. The task will require experts in the field to participate in the

projects.

Projected workload and resource implications:

Future workload and resource needs:

ECHA participates fully in the project (i.e. as a signatory of the consortium agreement) but without (co-)financing from the foreseen Horizon Europe subsidy to PARC and without requesting an increase of its EU contribution. To compensate for the workload that PARC will generate, ECHA will increase its allocation of Contract Agents by two and will finance them from economies of scale and efficiency gains. This solution will be temporary until the Commission revises the founding regulation of ECHA. This revision will be an opportunity to adjust and clarify the future mandate of ECHA in the light of the existing and new tasks and assess its resources needs. The role of ECHA in the research projects under Horizon Europe will also be clarified in the proposal.

EFSA participates fully in the project (i.e. as a signatory of the consortium agreement) but without (co-)financing from the foreseen Horizon Europe subsidy to PARC and without requesting an increase of its EU contribution. EFSA has dedicated resources for involvement and follow up of relevant EU funded research projects.

EEA participates fully in the project with (co-)financing from the Horizon Europe subsidy to PARC. EEA will finance from the subsidy 2 additional FTEs (2 CAs).

Summary of additional resource needs for PARC:

Agency	**Summary of tasks**	**Resource needs**	
EEA		Financial resource needs:	2022: **EUR 289 000** 2023: **EUR 289 000** 2024: **EUR 289 000** 2025: **EUR 289 000** 2026: **EUR 289 000** 2027: **EUR 0**
		Human resource needs:	2022: **2 CA** 2023: **2 CA** 2024: **2 CA** 2025: **2 CA** 2026: **2 CA** 2027: **0 CA**
ECHA		Financial resource needs:	2022: **EUR 0** 2023: **EUR 0** 2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0**
		Human resource needs:	2022: **2 CA** 2023: **2 CA** 2024: **2 CA** 2025: **2 CA** 2026: **2 CA** 2027: **0 CA**
EFSA		Financial resource needs:	2022: **EUR 0** 2023: **EUR 0** 2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0**
		Human resource needs:	2022: **0 TA, 0 CA** 2023: **0 TA, 0 CA** 2024: **0 TA, 0 CA** 2025: **0 TA, 0 CA**

			2026: **0 TA, 0 CA** 2027: **0 TA, 0 CA**

Future budget line: DG Environment, DG GROW, DG RTD

Candidate for fees: No

4. COMMISSION IMPLEMENTING DECISION 2022/1979 UNDER SEVESO DIRECTIVE

Responsible body:

Currently: Commission (DG JRC)

(Re-)attribution planned to: EEA

Legal basis for reattribution: Commission Implementing Decision

Type of task: existing tasks plus some improvements

Brief task overview: Redevelopment of databases (eMARS and eSPIRS) by the EEA for the reporting of information on industrial major accidents and for reporting of the location of Seveso establishments. It will integrate some improvements in the reporting format, the workflow and the set of reporting tools.

Detailed process description: The process is described in detail below in the section on projected workload

Proximity to mandate: The task is close to EEA key competence on receiving and processing reporting information. The agency has the IT and networking infrastructure that is similar to the tasks, such as operation of the European pollutant release and transfer register, reporting under the industrial emission directive, the F-gas regulation or ozone depleting substances regulation.

Projected synergies and added value of (re-)attribution:

Main risks and opportunities:

Projected impact on EEA:

- EEA Committees/bodies: **no impact**. The task does not require involvement of EEA Committees/bodies
- EEA data model and IT infrastructure: **high impact**. The task requires investment in a new data structures and IT systems/capabilities
- EEA key experts: **high impact**. The task will require a new dedicated expertise

Projected workload and resource implications

Current workload and resource use:

The development and operation of databases (eMARS and eSPIRS) for the reporting of information on industrial major accidents and for reporting of the location of Seveso establishments and providing supporting services was performed by DG JRC. The work was performed by 4 FTEs, 1 FTE was an official of DG JRC, and 3 FTEs were external consultants.

Current budget line: DG JRC (core staff) + DG Environment (contractual support)

Future workload and resource needs:

A/ During the redevelopment phase of eSPIRS and eMARS (2023-2025)

IT infrastruture

One-off cost:

- EUR 275 000 and then EUR 200 000 are reserved for the two first years to set up the IT eSPIRS systems and the support of Member States to facilitate their reporting within the new platform, which will be developed by the EEA.
- EUR 60 000 is reserved for the two first years to set up the IT eMARS systems. This amount is lower compared to eSPIRS because some tasks will be mutualised between eSPIRS and eMARS.

Yearly cost:

- From 2024, the running costs of the two databases require 70 000 EUR per year (hosting of tools, maintenance of software, infrastructure and support for the quality assurance of data deliveries).

Staff, 4 agents are needed for the period 2023-2025 for the following roles:

- **2 IT staff agents :** thanks to the mutualisation of tasks related to the IT deployment, continuous improvment and support to Member States for the the future eSPIRS and eMARS databases, the need of staff is limited to: one full-time equivalent temporary agent (AD TA) (average cost EUR 199 576/year) and one full-time equivalent contract agent staff (CA) (average cost EUR 107 666/year) at the EEA:
  - **1 AD TA"IT expert – database systems redevelopment". Objective**: to support the implementation of the new IT information system necessary for the eSPIRS and eMARS reporting:
    - IT project management of the redevelopment of new tools and reporting system, ensuring design of alignment and complementarity with the existing EEA software used for the reporting of industrial information to the EU Registry on Industrial Sites. As part of the redevelopment and implementation of the new tools, the agent will lead on the following:
      - Update the data model. This consists in the design and proposal of UML model, feature descriptions and deployment and updating the code lists.
      - Support on updating the technical guidance.
      - Integration of the data model changes across the reporting infrastracture. This includes, among others:
        - Update of the XML schema and EEA dictionary: the existing schemas and code lists in the EEA data dictionary have to be updated according to the agreed data model version.
        - Update of Quality Assurance (QA) scripts: with support from Member State Competentent Authorities, stakeholders and thematic experts (see below), the agent will assess the need of new automated Quality Assurance/Quality Control (QA/QC) in view of the newly included reporting requirements. Should this be required, the agent will also integrate these in the reporting infrastructure. Changes in the logic of the data model may also need adjustments of existing QA/QC.
        - Update of conversion services: this refers to a service of converting an user-friendly template into EU Registry-compliant XML reports. This service will need to be updated.
        - Update of harvesting routines: this relates to updating the systems used to incorporate the data reported by Member States into the EEA databases.
        - Support for the update of the manual for reporters.
      - Design and run tests for the future reporting tools.

- Launch and if necessary revise/adjust reporting tools: according to experience with the design and deployment of the EU Registry of indutrial sites, a period of around two reporting cycles is needed for all countries to fully succeed in sending high-quality data. The IT speecialist's role will be to incorporate possible changes/adjustments to the reporting tools if necessary, as well as provide technical support to possible IT queries from Member States. It is expected that these will be more numerous and complex during this early period and will stabilise once all systems are in place.
- Adjustment of public-facing products (IT):
  - Generation of EU datasets.
  - European Industrial Emissions Portal.
- Whereas the data currently reported to eSPIRS could be integrated in the existing IT infrastructure (with the required changes outlined above), it is possible that eMARS will require its own database/IT infrastructure. This is mainly related to the nature of the data currently reported to eMARS and the specific legal requirements related to the rapid reporting of industrial accidents. The agent will evaluate the possible options and work on the design and development of such dedicated IT environment if necessary, as well as contribute to the development of its support documentation (e.g. manuals, guidance). Also, the agent will provide their IT expertise in the process of amending Commission Implementing Decision (CID) 2014/895/EU establishing the format for communicating the information referred to in Article 21(3) of Directive 2012/18/EU (i.e. implementing the reporting of accidents, i.e. the eMARS dataflow). This will ensure the language and structure of the Decision are suitable, clear and compatible with the fture IT requirements.

- Performing the internal EEA function of "data custodian" involving the maintenance of databases, developing and updating automated quality assurance scripts, data harvesting scripts and IT dimensions of updating the website European Industrial Emission Portal.
- Ensuring that confidentiality, data protection and IT security protocols are maintained to the standards required by the EU Institutions, from the design phase throughout the pre-operational and operational phases.
- Ensuring a secure access and use of the data that are marked as confidential, in accordance with Article 4 of Directive 2003/4/EC[49]. These data shall neither be publically available nor accessible (directly or indirectly).

- **1 CA "Member State and stakeholder support". Objective**: to support the transition to the future tools with the following tasks:
  - Support to the development of the technical guidance for reporters. This support will focus on coordinating the stakeholder validation of the technical materials by the reporters' community and incorporate their feedback in the materials. The agent will engage with the current community of Seveso reporters and will also coordinate contacts with EU registry reporters, who will also be affected by the changes and who will have to liaise with their colleagues reporting on Seveso for the submission of data.

[49] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information

The agent's role early on in the process is crucial for ensuring that the system is fit for purpose and incorporates the realities of all EU Member States.

- Support on Member State validation of new automated QA/QC checks and on obtaining feedback during the necessary testing phase/s for the tools.
- Support on Member State validation of manual for reporters.
- From a strategic point of view and in view of the experience with the EU Registry, building the foundation of a efficient relationship with the Seveso community of reporters requires time. Starting this at the development phase is also relevant for a smooth run of the process once implemented and ensures dedicated support and validation to minimise the risk of unnecessary changes and issues later in the process.

- **2 thematic staff agents for for eSPIRS and eMARS:** 2 full-time equivalent temporary agents (AD TA) at the EEA (average cost EUR 199 576/year) for the thematic and analytic tasks linked to eSPIRS and eMARS:
  - **1 AD TA "Subject matter expert – eSPIRS Seveso reporting". Objective**: to lead the EEA activities relating to eSPIRS reporting redevelopment and ensure close links with other EEA activities on zero pollution and reporting streams under environment law on industrial emissions. It will fulfill the following tasks:
    - Supervising the redevelopment of the eSPIRS reporting tools by providing the necessary thematic (expert) perspective. Among others, the agent will ensure that the changes to the data model and XML schema are compliant with the reporting requirements and are fit for purpose, design and test automated and manual QA that is suitable for this dataflow, lead the update of the technical guidance and manual for reporters, and interpretation of the legal requirements for their implementation into the data model, with support with IT expert and Member State support expert (see above).
    - Capacity building and support to the reporters in countries to define the requirements of the new eSPIRS reporting tools, train them in their use and assist the interpretation of the requirements.
    - During the redevelopment phase, liaising with the European Commission services to support Member States when designing their reporting systems and tools, including agreeing ad-hoc adjustments relevant to each Member State legal and operational frameworks.
    - During the redevelopment phase, liasing with the JRC as necessary on historical issues and topics that may be of relevance for the new tools.
    - Work is ongoing for the design of the Zero Pollution monitoring indicators framework and indicators for the Chemicals Strategy for Sustainability. The agent will participate in the process to assess how this dataflow can support and design possible indicators.
    - Work is ongoing for the design of the Zero Pollution monitoring indicators framework and indicators for the Chemicals Strategy for Sustainability. The agent will participate in the process to assess how this dataflow can support and design possible indicators.
    - Adjustment of public-facing products (thematic perspective):
      - Generation of EU datasets.
      - European Industrial Emissions Portal.

  - **1 AD TA "Subject matter expert – eMARS Seveso reporting". Objective**: to lead the EEA activities relating to eMARS reporting redevelopment and ensure close links with other EEA activities on zero pollution and reporting streams under environment law on industrial emissions. It will fulfill the following tasks:
    - Supervising the redevelopment of reporting tools by providing the necessary thematic (expert) perspective. Among others, the agent will ensure that the changes to the data

model and XML schema (or design of new IT tool if necessary) comply with the reporting requirements and are fit for purpose, design and test automated and manual QA that is suitable for this dataflow, lead the update of the technical guidance and manual for reporters, including the interpretation of the legal requirements for their implementation into the data model, with support with IT expert and Member State support expert (see above).

- CID 2014/895/EU would most likely need amendments and adapting to either the existing IT infrastructure or a tailored infrastructure compliant with the INSPIRE Directive and other requirements on data quality, security and transparency. The thematic expert will support the Commission in the identification of current and possible future requirements to design the data structure required in the future tools. The expert will also assist the Commission during the adoption of the proposed legal act through Committee deliberation. To ensure that the outcome is workable for the EEA, the expert will be involved as observer throughout the process to advise on consequences of the potential changes that the comitology process may bring.
- During the redevelopment phase and beyond, capacity building and support to the reporters in countries to define the requirements of the tools, train them in their use and assist the interpretation of the requirements.
- During the redevelopment phase, liaising with the European Commission services to support Member States when designing their reporting systems and tools, including agreeing ad-hoc adjustments relevant to each Member State's reality.
- During the redevelopment phase, liasing with the JRC as necessary on historical issues and topics that may be of relevance for the new tools.
- Work is ongoing for the design of the Zero Pollution monitoring indicators framework and indicators for the Chemicals Strategy for Sustainability. The agent will participate in the process to assess how this dataflow can support and design possible indicators.
- Adjustment of public-facing products (thematic perspective):
  - Generation of EU datasets.
  - European Industrial Emissions Portal.
- To ensure confidentiality, personal data protection and IT security standards are met given the sensitive character of these information exchanges and thus keeping systems at a state-of-the art level.
- To ensure a secure access and use of the data that are marked as confidential, in accordance with Article 4 of Directive 2003/4/EC[50]. These data shall neither be publically available nor accessible (directly or indirectly).

B/ After the redevelopment phase of eSPIRS and eMARS (2026 and beyond)

IT Infrastructure

Yearly cost:

- The running costs of the two databases require 70 000 EUR per year (hosting of tools, maintenance of software, infrastructure and support for the quality assurance of data deliveries).

Staff, 4 agents are needed from 2026 for the following roles:

- **IT staff agents :** thanks to the mutualisation of tasks related to the IT deployment, continuous improvment and support to Member States for the the future eSPIRS and eMARS databases, the

[50] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information

need of staff is limited to one full-time equivalent temporary agent (AD TA) (average cost EUR 199 576/year) and one full-time equivalent contract agent staff (CA) (average cost EUR 107 666/year) at the EEA:

- **1 AD TA"IT expert – database systems development and maintenance ". Objective**: to support the implementation of short-term IT development priorities and long-term system maintenance. The agent will address all aspects relating to the IT dimensions of the reporting flows and the storage and use of the databases generated by this exchange of information between Member States and the EEA:
  - IT support to Member States following the redevelopment phase: According to experience with the design and deployment of the EU registry of indutrial sites, a period of around two reporting cycles is needed for all countries to fully succeed in sending high-quality data. The IT speecialist's role will be to incorporate possible changes/adjustments to the reporting tools if necessary, as well as provide technical support to possible IT queries from Member States.
  - IT project management of improved tools and reporting system, ensuring alignment and complentarity with the existing EEA software used for the reporting of industrial information to the EU Registry on Industrial Sites. As part of the development and implementation of improvmements, the agent will lead on the following:
    - Identify improvements.
    - Update the data model.
    - Support on update of the technical guidance.
    - Integrate the improved data model across the reporting infrastracture.
    - Support for the update of the manual for reporters.
    - Design and run tests for the future reporting tools.
    - Possible revisions/adjustments to the improved reporting tools.

  - Performing the internal EEA function of "data custodian" involving the maintenance of databases, developing and updating automated QA scripts, data harvesting scripts and IT dimensions of updating the website European Industrial Emission Portal.
  - Ensuring that confidentiality, data protection and IT security protocols are maintained to the standards required by the EU Institutions.
  - Ensuring a secure access and use of the data that are marked as confidential, in accordance with Article 4 of Directive 2003/4/EC[51]. These data shall neither be publically available nor accessible (directly or indirectly).

- **1 CA "Member State and stakeholder support". Objective**: to support Member States on the day-to-day proceedings of data submission, quality checking of systematic aspects and validation of submissions and other assitance functions to reporters and the general public. The agent would achieve the following tasks:
  - Performing the Seveso helpdesk function to assist Member States in their reporting.
  - Complement automated quality checks by also manually checking reports before their harvesting into the master database to systematically ensure basic data quality.
  - Production of extracts and basic database analysis upon demand by the European Commission's services, the Member States and other stakeholders.
  - Assistance to feeding content from Seveso eSPIRS into the European Industrial Emission Portal through its Content Management System (CMS).
  - Supporting publications and strategic communication, dissemination and outreach activities (webinars, web visibility) on its practical/technical aspects.

[51] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information

- **<u>Thematic staff agents for for eSPIRS and eMARS:</u>** 2 full-time equivalent temporary agents (AD TA) at the EEA (average cost EUR 199 576/year) for the thematic and analytic tasks linked to eSPIRS and eMARS:
  - **1 AD TA "Subject matter expert – eSPIRS Seveso reporting". Objective**: to lead the EEA activities relating to eSPIRS and ensure close links with other EEA activities on zero pollution and reporting streams under environment law on industrial emissions. It will fulfill the following tasks:
    - Overall coordination for the eSPIRS dataflow between Member States (function defined at the EEA as "reporters") and the EEA (function defined in EEA as "data steward"). These duties include:
      - Supervising the development of improvement on the eSPIRS reporting tools by providing the necessary thematic (expert) perspective.
      - Capacity building and support to the reporters in countries.
      - Quality assuring reports from countries.
    - Analysing country data and the resulting European dataset to extract intelligence on the distribution of establishments relevant in terms of industrial accidents, cross-checking those with other aspects of industrial activities regulated by EU law (e.g. Industrial Emission Directive, greenhouse gas emission trading scheme).
    - Contributing to the dissemination of the reported information in the European Industrial Emission Portal, and ensuring relevant information is also used for assessment activities in line with the Agency's support to the European Commission on Zero Pollution.
    - Liaising with the European Commission services and the Expert Groups and Committees relevant to the Seveso Directive.
    - Attending scientific meetings related to the subject matter and other networking activities that can contribute to the uptake and use of the reported information in relevant Fora.
  - **1 AD TA "Subject matter expert – eMARS Seveso reporting". Objective**: to lead the EEA activities relating to eMARS and ensure close links with other EEA activities on zero pollution and reporting streams under environment law on industrial emissions. It will fulfill the following tasks:
    - Overall coordination for the eMARS dataflow between Member States (function defined at EEA as "reporters"), the JRC and the EEA (function defined in EEA as "data steward"). These duties include:
      - Supervising the development of improvement on the eMARS reporting tools by providing the necessary thematic (expert) perspective.
      - Capacity building and support to the reporters in countries to define the requirements of the improved tools, train them in their use and assist the interpretation of the requirements.
      - Quality assuring reports from countries.
    - Analysing country data and the resulting European dataset to extract intelligence and lessons learned on industrial accidents covered by the Seveso Directive, cross-checking those with other aspects of industrial activities regulated by EU law (e.g. Industrial Emission Directive, greenhouse gas emission trading scheme) .
    - To follow up on reported accidents throught the life cycle of their cases, improving the information stored in the database until the conclusion of the case.
    - To ensure confidentiality, personal data protection and IT security standards are met given the sensitive character of these information exchanges and thus keeping systems at a state-of-the art level.

- To ensure a secure access and use of the data that are marked as confidential, in accordance with Article 4 of Directive 2003/4/EC[52]. These data shall neither be publically available nor accessible (directly or indirectly).
- Contributing to the dissemination of the reported information in the European Industrial Emission Portal, and ensuring relevant information is also used for assessment activities in line with the Agency's support to the European Commission on Zero Pollution.
- Liaising with the European Commission services and the Expert Groups and Committees relevant to the Seveso Directive.
- Attending scientific meetings related to the subject matter and other networking activities that can contribute to the uptake and use of the reported information in relevant Fora.

Summary of additional resource needs for the Commission implementing decision (EU) 2022/1979 under the SEVESO directive:

Agency	Summary of tasks	Resource needs	
EEA	Operation of database of industrial plants falling under the scope of Seveso III Directive Operation of database of industrial major accidents	Financial resource needs:	2023: **EUR 335 000** 2024: **EUR 330 000** 2025: **EUR 70 000** 2026: **EUR 70 000** 2027: **EUR 70 000**
		Human resource needs:	2023: **3 TA, 1 CA** 2024: **3 TA, 1 CA** 2025: **3 TA, 1 CA** 2026: **3 TA, 1 CA** 2027: **3 TA, 1 CA**

Future budget line: DG Environment

Candidate for fees: No

5. BATTERIES REGULATION (PROPOSAL)

Responsible body:

Currently: N/A, no current process for hazardous substances

(Re-)attribution planned to: ECHA

Legal basis for reattribution: proposal for a Battery Regulation (revision of Battery Directive).

Type of task: New

Brief task overview: Under the proposal for a new Batteries Regulation, a task to prepare, on the request of the Commission, a restriction dossiers for substances in batteries and for the RAC and SEAC committees to provide an opinion would be given to ECHA. In addition, ECHA would prepare a mapping study by 31/12/2026 on substances of concern present in batteries or used in their manufacturing, in order to assist the Commission to prepare such report to the European Parliament and Council by 31/12/2027.

Detailed process description:

Current process:

N/A, no process exists at EU level

[52] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information

New process:

1. If the Commission considers that the use of a substance in the manufacture of batteries, or the presence of a substance in the batteries when they are placed on the market, or during their subsequent life cycle stages, including the waste phase, poses a risk to human health or the environment that is not adequately controlled and needs to be addressed on a Union-wide basis, it shall request the European Chemicals Agency (the 'Agency') to prepare a dossier that conforms to the requirements of point (3) of Part II of Annex XV to Regulation (EC) No 1907/2006 ('restriction dossier'). The restriction dossier shall include a socio-economic assessment, including an analysis of alternatives.
2. The Agency shall publish without delay the intention of the Commission to initiate such restriction process life cycle for a substance, and shall inform stakeholders concerned.
3. Within 12 months of the receipt of the request from the Commission in paragraph 1 and if the restriction dossier prepared by the Agency pursuant to that paragraph demonstrates that action is necessary on a Union-wide basis, the Agency shall suggest restrictions in order to initiate the restriction process described in paragraphs 4 to 14.
4. The Agency shall make publicly available on its website the restriction dossier, including the restrictions suggested pursuant to paragraph 3, without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly, within four months of the date of publication, comments on the restriction dossier.
5. Within 12 months of the date of publication referred to in paragraph 4, the Committee for Risk Assessment (RAC), set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006, shall adopt an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the restriction dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in paragraph 4.
6. Within 15 months of the date of publication referred to in paragraph 4, the Committee for Socio-economic Analysis (SEAC), set up pursuant to Article 76(1)(d) of Regulation (EC) No 1907/2006, shall adopt an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to paragraph 4, if there are any.
7. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from the publication of that draft opinion.
8. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 7. This opinion shall take account of the comments of interested parties submitted under paragraphs 4 and 7.
9. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions suggested, the Agency shall postpone the deadline for the opinion of the Committee for Socio-economic Analysis by a maximum of 90 days.
10. The Agency shall submit to the Commission without delay the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to the request made by the Commission under paragraph 1. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested pursuant to paragraph 3, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both

of the Committees do not adopt an opinion by the deadline set in paragraphs 5 and 6 the Agency shall inform the Commission accordingly, stating the reasons.

11. The Agency shall publish the opinions of the two Committees on its website without delay.
12. The Agency shall provide the Commission on request with all documents and evidence submitted to or considered by it.
13. If the Commission concludes that the conditions laid down in Article 6(2) are fulfilled, it shall adopt a delegated act pursuant to Article 6(2). This delegated act shall be adopted without undue delay following the receipt of the opinion of the Committee for Socio-economic Analysis referred to in paragraph 8 or after the deadline set out under paragraphs 6 and 9, as applicable, if that Committee does not adopt an opinion.
14. Where the Committees for Risk Assessment and Socio-economic Analysis provide an opinion pursuant to paragraphs 5 and 6, they shall make use of rapporteurs as specified in Article 87 of Regulation (EC) No 1907/2006. The rapporteurs or co-rapporteurs concerned, or their employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements related to restrictions established by the Management Board, set up pursuant to Article 76(1)(a) of Regulation (EC) No 1907/2006. Where the persons concerned fail to fulfil their duties, the Executive Director of the Agency has the right to terminate or suspend the contract or withhold remuneration

Proximity to ECHA mandate: The battery restriction process, although not identical, is very similar to the REACH restriction process and the same scientific methodologies can be applied. The substances under scrutiny are the same or similar to those under REACH and REACH (and other ECHA) data and processes can be reused for battery restriction dossier development and opinion forming. ECHA holds the right competences to manage the battery restriction process, however, does not have sufficient information on the exact use of substances in batteries, which is to be remedied with a study to be commissioned.

Projected synergies and added value of reattribution:

Type	Synergy	
Reuse of capabilities	High	Process and expertise: ECHA already supports similar work on substance restrictions under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk, exposure and socio-economic assessment - Committee opinion development - Existing IT capabilities for authority dossier submission, stakeholder consultation and dissemination
Re-use of data	Medium	Reuse of substance identification and hazard data collected under other chemical legislation. Currently low availability of data on substances in products and waste streams.
Workload balancing	Medium	With an estimated workload of one new restriction every year, the workload of Agency experts and Committee experts can be spread and balanced over the years (although resource estimates are already annualised).
IT tools: automation	High	Reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory

and economies of scale		intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	**Added value**	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of assessment insights developed under other chemical legislation.
Robustness of assessment and acceptance	High	Centralising the scientific assessments on chemicals in one EU agency and stricter separation between policy and scientific advice adds more scientific robustness to the process.
Independence	High	ECHA and its committees work under strict conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: No major concerns and there are certainly opportunities to find synergies with the REACH restriction process.

Projected impact on ECHA

- ECHA Committees/bodies: **medium impact**. The task generates medium impact on the setup / organisation / staffing of Committees/bodies due to the additional workload.

	RAC			**SEAC**		
	# of opinions per year	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Restriction dossier	1	RAC member		1	SEAC member	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems

- ECHA key experts: **medium impact**. The task partly relies on existing expert competencies which are limited within ECHA and also critical to REACH/CLP/BPR *regulatory tasks*

Projected workload and resource implications:

Current workload and resource use:

N/A, no current process exists at EU level

Future workload and resource needs:

A total of 2 new full-time equivalent temporary agent staff (AD 5-7) at ECHA (average cost EUR 171 000/year with coefficient for FI and annual indexation over 4 years and beyond) will be needed to make sure that sufficient resources would be earmarked for regulating the necessary battery related substances without competing with REACH priorities. This covers an average of one additional restriction (or other risk management measure) yearly, including risk assessment of lead in lead-acid batteries, and of mercury and cadmium used in electric vehicle batteries.

In addition, 1 full-time equivalent contract agent staff for 3 years (CA FG III, average cost EUR 91 000/year with coefficient for FI and annual indexation over 3 years), will be necessary to increase the knowledge base and carry out a mapping of substances of concerns used in batteries, facilitating an informed priority setting and work plan establishment. This will be based on a mapping study to build ECHA's current knowledge on how the battery industry manages its hazardous chemicals to identify relevant substances for regulatory risk management in the future. The study is estimted at EUR 400 000 (over 3 years) to outsource part of such research needs.

A sum of EUR 22 000 is also required to cover the cost of the rapporteurs (Member State experts guiding the dossiers through the opinion-making in the RAC and SEAC committees) for each restriction, as well as EUR 43 000 over 4 years for covering a proportionate part of the full cost of organising the RAC and SEAC meetings (travel, accommodation and daily allowance costs: cost calculated based on the average time/effort needed for a restriction dossier in both committees).

The aforementioned resources have been estimated using a calculation model which takes account of relevant experience from tasks executed by ECHA under other regulatory frameworks (e.g. REACH, CLP, BPR) and from the implementation of the existing national approaches where relevant. It sets out the resources that will be needed by ECHA over 2024-2027 and beyond, in order to handle the foreseen tasks.

Summary of additional resource needs for the batteries regulation:

Agency	Summary of tasks	Resource needs	
ECHA	Assessment underlying the restriction of hazardous substances in batteries (1 restriction / year) - Substance prioritisation and data analytics - Restriction dossier development - RAC opinion development - SEAC opinion development - Dissemination	Financial resource needs:	2023: **EUR 158 000** 2024: **EUR 158 000** 2025: **EUR 158 000** 2026: **EUR 25 000** 2027: **EUR 25 000** 2028: **EUR 25 000**
		Human resource needs:	2023: **2 TA, 1 CA** 2024: **2 TA, 1 CA** 2025: **2 TA, 1 CA** 2026: **2 TA, 0 CA** 2027: **2 TA, 0 CA** 2028: **2 TA, 0 CA**

Future budget line: DG Environment

Candidate for funding from fees: No

6. E-PRTR REGULATION (2006/166)

Responsible body :

Currently: N/A, no current process as it is expansion of the existing task performed by EEA

(Re-)attribution planned to: EEA

Legal basis for reattribution: Revision of the EPRTR regulation (166/2006)

Type of task: new (extension of the existing one)

Brief task overview: EEA currently operates the European Pollutant Release and Transfer Register. The existing EPRTR is replaced by an Industrial Emissions Portal that should be operated by EEA too. The new Portal should contain more data and provide more functionalities as compared to the old EPRTR. The Portal should provide information on emission for more substances, for more installations and for more activities. It should also provides information on the use of water, energy and raw materials by the concerned installations to allow monitoring of progress towards a circular, highly resource-efficient economy.

Proximity to EEA mandate: The operation of the Industrial Emission Portal fits well within the mandate of EEA. EEA already operates the existing EPRTR and the new Portal has evolved from the EPRTR.

Projected synergies and added value of (re-)attribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: EEA already operates EPRTR, manages reporting flows from installations and Member States and manages related environmental information on air quality and water quality. Several key capacities can be reused and further developed.
Re-use of data	High	Reuse of data collected under other environmental legislation (air and water) can be combined.
IT tools: automation and economies of scale	High	The existing IT capabilities can be partly reused.
Support services: economies of scale	High	Reuse of support services for reporting and data management. Reuse of administrative services.

Main risks and opportunities: N/A

Projected impact on EEA:

- EEA Committees/bodies: **no impact**. The task does not require involvement of EEA Committees/bodies
- EEA data model and IT infrastructure: **high impact**. The task requires adjustment of data structures and IT systems and their long term operation

- EEA key experts: **low impact**. The task can utilise existing expert competences.

Projected workload and resource implications

Current workload and resource use:

N/A, no current process as it is an extension of the existing one.

Future workload and resource needs:

EEA costs include cost of 2 additional FTE (2 TAs) who will establish the IT infrastructure for collecting new data fields (on resource use and additional pollutants), modify and expand the XML schema to enable reporting at installation level and for newly captured agro-industrial activities, update the Manual for Reporters to ensure consistent returns by operators/MS, run training sessions for MS reporters to introduce these new requirements, and subsequently manage the reporting and related dataflow. Costs of developing IT infrastructure will go down in the 3rd year, as only the IT infrastructure maintenance costs will remain. It's assumed that for the first two years EEA will need more financial resources to revamp the existing tools as a result of the legal proposal.

EEA staff will establish the IT infrastructure that will be required to implement the proposed revisions and subsequently manage the reporting and related dataflow. These IT enhancements relate to the physical capacity of the reporting stream (i.e. number and nature of reports) and the supporting systems (guidance, training etc.) to ensure their consistent application by industrial operators and Member States.

Summary of additional resource needs for E-PRTR regulation:

Agency	Summary of tasks	Resource needs	
EEA	• Establishing and operating the IT infrastructure for collecting new data fields • Updating the manual for reporters • Run training sessions for MS reporters	Operational resource needs:	2024: **EUR 170 000** 2025: **EUR 70 000** 2026: **EUR 30 000** 2027: **EUR 30 000**
		Human resource needs:	2024: **2 TAs, 0 CA** 2025: **2 TAs, 0 CA** 2026: **2 TAs, 0 CA** 2027: **2 TAs, 0 CA**

Budget line: DG Environment

Candidate for fees: No

7. INDUSTRIAL EMISSIONS DIRECTIVE (2010/75/EU)

Responsible body:

Currently: N/A, no current process

(Re-)attribution planned to: ECHA

Legal basis for reattribution: Revision of the Industrial Emissions Directive (2010/75/EU)

Type of task: new

Brief task overview: ECHA has already for some time provided input to the Commission to the review of the Best Available Techniques Reference documents (BREF). Now ECHA's role has been formalised as part of this revised proposal. Overall, ECHA's role would include routine support to BREF/BAT and support to design/ implementation of the Chemicals Management System (CMS) methodology.

Detailed process description:

Current process:

N/A, no process exists at EU level

New process:

While ECHA has already done some work in this area, the Commission has now proposed giving ECHA a formal role in drawing up BAT reference documents (BREFs).

The role of ECHA would be to ensure that:

- An appropriate identification (and if necessary selection) of relevant substances for each sector/BREF is made. This will include a characterisation of the uses of those substances by sectors covered by BREFs including definition of best practices to use the safest alternatives on the market. This will improve clarity and consistency of the various legislations (IED, REACH, CLP)
- The correct terminology is used in the BREF processes (e.g. substance, process chemical, raw material)
- The chemicals-related BATs (such as substitution techniques) are technically sound
- Background documents, for Kick off Meeting and final meeting, drafted by the EIPPCB are relevant regarding chemicals issue
- Assistance is provided to the EIPPCB to access the information on ECHA's database
- Assistance is provided to answer stakeholders questions or comments where a chemicals expertise is needed

The Commission would facilitate this work by organising an exchange of information between the concerned industries, Member States, NGOs and ECHA. In addition, by 2024, ECHA should start building a methodology for on-site risk assessment to actively manage input chemicals and resulting emissions.

In short ECHA's new tasks would include the following:

- Data mining of ECHA databases and generating a list of hazardous substances potentially used in BREF sectors; extract substance-related information (regulatory status, classification, substance identity), characterise the uses of those substances by sectors covered by BREFs including definition of best practices to use the safest alternatives on the market, and provide technical support to BREF revisions (TWG meetings, review, other technical inputs).
- Develop guiding principles for the Chemicals Management System focussing on data structure and methodologies for a site inventory of chemicals (substances and mixtures) associated with further development of a site-level risk assessment methodology and contribute to the development of guiding principles on how to conduct a comparative risk assessment between the substances an operator uses for his processes/products and potential alternatives.

Proximity to ECHA mandate: This new task would mainly be the formalisation of a task already performed by ECHA on an ad hoc basis, with the addition of support to design/ implement the CMS methodology.

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already provides scientific advice on chemical substances and as it has supported related ad hoc advice requests in the past, it already has the needed expertise. Several key

		capacities can be reused/reinforced: - Hazard, risk and exposure assessment - IT capabilities for stakeholder consultation and dissemination
Re-use of data	High	Reuse of data collected under other chemical legislation, especially also on substances in products via the SCIP database.
Workload balancing	Medium	With occasional requests, the workload of Agency experts can be balanced (although resource estimates are already annualised).
IT tools: automation and economies of scale	High	Not an IT-intensive process, but reuse of IT capabilities for case management, public consultation, interaction with Member States and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	**Added value**	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under other chemical legislation.
Robustness of assessment and acceptance	High	Centralising scientific work from dispersed Commission services to one central EU Agency and its experts.
Independence	High	Moving scientific work from dispersed Commission services to experts in the European Chemicals Agency with a stricter separation between science and policy. ECHA experts work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process: - Overall process transparency - Public consultation/call for evidence - Stakeholder involvement - Dissemination of scientific data and outcomes

Main risks and opportunities: N/A

Projected impact on ECHA:

- ECHA Committees/bodies: **no impact**. The task does not require involvement of ECHA Committees/bodies

- ECHA data model and IT infrastructure: **no impact**. The task does not require adjustment of data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Workload and resource implications:

Current workload and resource use:

N/A, no current process

Future workload and resource needs:

ECHA costs include cost of new 3 FTEs, who

- will do the data mining of ECHA databases and generate a list of hazardous substances potentially used in BREF sectors; extract substance-related information (regulatory status, classification, substance identity), characterise the uses of those substances by sectors covered by BREFs including definition of best practices to use the safest alternatives on the market, and provide technical support to BREF revisions (TWG meetings, review, other technical inputs) – 2 FTE
- Develop guiding principles for the Chemicals Management System focussing on data structure for a site inventory of chemicals (substances and mixtures) associated with further development of a site-level risk assessment methodology and contribute to the development of guiding principles on how to conduct a comparative risk assessment between the substances an operator uses for his processes/products and potential alternatives - 1 FTE

In total, 3 TA posts

Summary of additional resource needs for industrial emissions directive:

Agency	Summary of tasks	Resource needs	
ECHA	• Mining of ECHA databases and generate a list of hazardous substance potentially used in BREF; • Extract substance-related information, characterise the uses • Technical support to BREF revisions • Develop guiding principles for the Chemicals Management System • Contribute to the development of guiding principles on how to conduct a comparative risk assessment	Operational resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0**
		Human resource needs:	2024: **3 TAs, 0 CA** 2025: **3 TAs, 0 CA** 2026: **3 TAs, 0 CA** 2027: **3 TAs, 0 CA**

Future budget line: DG Environment

Candidate for fees: No

8. ENVIRONMENTAL QUALITY STANDARD DIRECTIVE (2008/105/EC) + WATER FRAMEWORK DIRECTIVE (2000/60/EC) + GROUNDWATER DIRECTIVE (2006/118/EC)

Responsible body:

Currently: Commission with the support of the SCHEER committee, JRC and consultants

(Re-)attribution planned to: ECHA and EEA

Legal basis for reattribution: revision of Environmental Quality Standard Directive (2008/105/EC), Ground Water Directive (2006/118/EC) and Water Framework Directive (2000/60/EC) + Omnibus regulation.

Type of task: Existing + new

Brief task overview

1. Assessments underpinning amendment of priority list of substances and derivation of Environmental Quality Standards under EQS Directive;
2. New legal task: EU-wide EQS for substances listed in a (new) Annex II of the EQSD including the so-called 'River Basin Specific Pollutants' (two per year); EU-wide threshold values for groundwater pollutants (one per year) to be included in Annex II GWD
3. Assessment underpinning review of Annexes I and II of the Groundwater Directive;
4. Technical and scientific work related to amendment of 'watch list' and coordination of 'watch list' activities both under EQS and Groundwater Directives.

Detailed process description:

Current process

Summary process description

Surface water:

Watchlist and priority list work currently done by JRC and after that a SCHEER opinion. IA of EQS proposals for new substances on the Priority Substance (PS) list outsourced to contractor. For future: Risk Assessment Committee (RAC) not needed for identification of substances for monitoring (watch list). ECHA involvement lighter, but heavier for 6y priority setting, including RAC.

- Watch List: identifying new substances for and removing substances from the Watch List (amendment needed every 2 years (EQSD Article 8b(2)). The Commission is considering moving to a three-year review cycle)
    - Proposals for adding and removing substances (including mixtures): usually ca. 10 substances / mixtures on watch list (based on literature overviews, information resulting from other legislation)
    - Establishment/identification of the related PNECs. No RAC involvement.
    - Verification of the suitability and availability of monitoring and analytical methods not entailing significant costs, and compilation of information on these for Member States;
      Issue is often absence of monitoring methods, otherwise nothing can be monitored. ECHA to check availability and suitability of tests. This work we haven't done much in the past. Registrants have to supply appropriate analytical methods for their substances, follow-up more now. ECHA could run a consultation to identify available analytical methods. However, ECHA does not have the expertise to also test their suitability, so it would preferably outsource such task to a scientific institute.
    - Assessment of monitoring results in view of identifying the need for setting EU wide or national EQS (based on importance, frequency, impact of exceedances)
- Priority List: technical work on reviewing the PS list (six-year review cycle; through delegated acts)
    - Prioritisation work
    - Establishment of EQSs for new (groups of) PS or trigger values for (effect-based) groups of PS

    - Development of a final proposal (on new and revised PS/PHS, EQS), supported by an opinion from the Risk Assessment Committee (RAC) and from the Committee for Socio-Economic Assessment
    - Regular discussion and presentation in the WG Chemicals or related subgroup

- New 1 (similar to current task 2 under GWD): EU-wide EQS for substances listed in a (new) Annex II of the EQSD including the so-called 'River Basin Specific Pollutants' (RBSP) formerly part of the 'ecological status' component of surface water status. The intention is that MS will apply the listed EQS (rather than national EQS) if they identify the substances as posing a risk; MS will be asked to upload/send these national EQS for uploading in the EU wide Repository to be established by ECHA; this will enable ECHA to assist EC in prioritising RBSPs for which the largest divergences have been identified without those being justified; and develop the EU-wide EQS; the latter would be adopted through delegated acts; timeline: one EQS per year, adoption by delegated act every six years. Difference with EU EQS for priority substances apply in all cases, i.e. the substances are prioritised because of their overall EU concern; for EQS for RBSPs, MS should in principle establish themselves EQS whenever an RBSP is of national/local concern; but even for these, where it appears that divergences are too wide between MS without this being justified; there is a need to set EU wide EQS, to be applied however only when there is a national or local issuer

- New 2: identification of suitable monitoring methods for monitoring and analysis of PFAS, by 2 years after entry into force and for microplastics (2 years) and Antimicrobiotical resistance genes (AMR) (2 years).

Groundwater:

Groundwater: no JRC involvement currently, most work done by Member State expert group and contractor and outcome sent to SCHEER

- Specific technical work on six-yearly reviewing the pollutants and quality standards in Annex I
- New: Six yearly review of list of pollutants in Annex II for which MS must consider setting national thresholds if there is a local/regional/national problem (difference with Annex I which relates to pollutants of EU wide concern)
- New: develop/identify EU wide threshold values for pollutants currently covered by a national threshold value (in Annex II), where necessary to ensure better and more harmonised implementation: one per year, threshold values to be adopted by delegated act once every six years
- In summary, review of the pollutants listed in the two annexes and of the quality standards in Annex I and development of EU wide threshold values for pollutants listed in Annex II. proposals for the amendment of Annexes I and II, based on scientific and technical evidence; Development of proposals for the amendment of Annexes I and II, based on scientific and technical evidence; Opinion development via the RAC and SEAC committee; regular presentation and discussion in the WG Groundwater.
- New: mandatory Watch List:
    - Proposals for adding and removing substances
    - Verification of the suitability and availability of monitoring and analytical methods not entailing significant costs, and compilation of information on these for MS
    - Development of the related PNECs. No RAC involvement
- New: identification of suitable monitoring methods for monitoring and analysis of PFAS, by 2 years after entry into force and for microplastics (2 years) and Antimicrobiotical resistance genes (AMR) [2 years].

Detailed description of current process

Amendment of the list of priority substances for surface waters and development of Environmental Quality Standards (EQS), including designation of Priority Hazardous Substances (from Water Framework Directive (2000/60/EC) and its daughter directive EQS Directive (2008/105/EC) as amended by 2013/39/EU):

- The amendment (and associated technical and scientific work) is initiated by the Commission.
- Consultant and/or JRC prioritises substances to be included in the list of priority substance (PS-list) using a combination of monitoring-based approach and modelling-based approach, including the results of the watch-list monitoring. Their work is regularly discussed in a sub-group of the CIS WG Chemicals known as the Sub-Group on Review (SG-R) of the PS list. The outcome is a ranking of substances based on their potential risks. (~ REACH prioritisation of candidate substances for further risk management)
- Consultant and/or JRC reviews the existing PS-list with a view to determine whether some should be taken off the PS-list. A document has been drafted identifying potential criteria for removing substances, considering that even if existing PS no longer pose a risk, removing them could result in them again becoming a risk, unless their use has been banned.
- Commission (DG ENV) in consultation with WG Chemicals selects substances for which EQS are derived and which of the listed substances should be designated as priority hazardous substances.
- Commission (consultants, JRC) or volunteer Member States derive EQS for newly selected PS (groups of PS), and review EQS for existing PS if new data are available. The work is organised in subgroups for specific substances, led by the consultants, JRC or volunteer Member State experts and are also discussed in WG Chemicals, subject to public open and targeted consultation and specific technical workshops with experts under the IA support contract. (~derivation of/proposal for Exposure Limits) (~stakeholder and public consultation) (~Adaptation to Technical Progress)
- Commission consults SCHEER on EQS derivation. (~RAC opinions)
- Consultants prepare an impact assessment study of listing of a substance in the PS-list. (~Socio-economic Assessment – SEAC opinion)
- Commission makes a proposal for listing the substances in the PS-list and for setting EQS values. The proposal goes through the ordinary legislative procedure.
- Updated Annexes are published by the Commission.

Review and amendment of the surface-water watch-list (from EQS Directive (2008/105/EC) as amended by 2013/39/EU):

- The amendment (and associated technical and scientific work) is initiated by the Commission.
- Consultant and/or JRC performs prioritisation exercise. EQSD Article 8b(1) specifies the information to be taken into account. It is important to have an estimate of the PNEC (~derivation of PNEC) and to ensure that an adequately sensitive analytical method is available.
- JRC reviews the existing watch-list with a view to taking substances off the list. The substances can only stay on for up to 4 years, but if sufficient high-quality monitoring data are obtained sooner, they should be removed (~hazard assessment?) (~proposal for identification of candidate substances).
- The review of the watch-list is carried out in consultation with WG Chemicals.
- The Commission adopts a new watch-list in the form of an Implementing Act subject to agreement in the WFD Regulatory Committee.
- Member States performs the monitoring and report data to EEA.

- JRC analyses the monitoring data whether there is an EU-wide risk.

Review of Annexes I and II and Voluntary groundwater watch-list (from Ground water directive (2006/118/EC)):

- The amendment (and associated technical and scientific work) is initiated by the Commission under its legal obligation (GWD art. 10). This was initiated after the WFD fitness check conclusions (2019), but technical works of the watch list started already in 2015.
- Commission and CIS WG Groundwater consultant with the technical and scientific support of the specific subgroup collects data and prioritises substances to be included in the annexes using an agreed methodology (2018). These are included in a 'List facilitating the review'. (When there are insufficient monitoring data, substances are proposed for the voluntary watch-list). Prioritization and selection process involves several steps, and relies upon aggregate data from national entities across Europe on substance occurrence in groundwater, as well as available data on substance persistence, mobility, toxicity, and bioaccumulation behaviour. The work is regularly shared with CIS WG Chemicals and JRC.
- Based on updated monitoring data, the consultant reviews the existing voluntary watch-list and list facilitating the review with a view of adding substances to the lists. Outcomes are provided to Commission and shared/discussed with WG Groundwater experts.
- Commission proposes substances for potential inclusion in the two annexes. These are also considered in the Impact Assessment (IA) Support Study policy options and corresponding economic analysis (consultants).
- Commission (JRC or consultant) propose potential quality standards for newly proposed substances for Annex I and II. These are also shared with WG Groundwater experts, subject to public open and targeted consultation and specific technical workshop with groundwater experts under the IA support contract.
- The Commission consults the SCHEER on selection of substances and the derivation of EU quality standards (also consulting whether any of the proposed substances should be considered for Annex II, in which case MS are to derive threshold values).
- Consultants carry out an impact assessment support study of policy options that consider listing substances in Annex I (with EU quality standard) or Annex II.
- Commission makes a proposal for listing the substances in Annex I of the Groundwater Directive (and EU quality standards if proposed for Annex I) or for adding substances in Annex II. The proposal for Annex I goes through the ordinary legislative procedure; the proposal for Annex II goes through 'comitology: regulatory procedure with scrutiny' (last review took place in 2014).
- Updated Annexes are published by the Commission.

Additional details for the voluntary groundwater watch list mechanism (progresses and outcomes regularly shared with WG Chemicals and JRC).

- Consultant and group of volunteers within CIS WG Groundwater performs prioritisation exercise (groups of substances), collects data and runs agreed methodology.
- Consultant reviews the existing voluntary watch list and list facilitating (substances with enough monitoring information that can be proposed for the GWD Annexes review) with a view adding substances to the lists.
- The review of the voluntary WL list and list facilitating is carried out in consultation with the group of volunteers (within WG Groundwater).
- The Commission agrees (Water Directors acknowledge) on a new voluntary watch list. The Commission considers list facilitating for the formal process of the GWD Annexes review.
- Member States perform monitoring on voluntary basis for the watch list and list facilitating substances and report data to consultant. For quality standards and threshold values MS report on

pollutants causing failure and risk, exceedances and trends (among other) though established WFD reporting system.

- Consultant assesses data provided on voluntary basis. EEA analyses the reported monitoring data under WFD scheme.

Changes envisaged as part of reattribution: Yes

- In the past only voluntary watch list under groundwater directive. Obligatory watch list would be new.
- New legal task: EU-wide EQS for substances listed in a (new) Annex II of the EQSD including the so-called 'River Basin Specific Pollutants';
- New legal task: EU wide threshold values for pollutants listed in Annex II GWD (where too wide divergences exist between national standards);
- Explicit identification, within 2 years of entry into force, of suitable monitoring methods for monitoring and analysis of PFAS, and for microplastics and Antimicrobiotical resistance genes (AMR)[2 years], for both SW and GW (in addition to the regular verification of the suitability and availability of monitoring and analytical methods not entailing significant costs for substances proposed to be listed in the Watch Lists under both directives)
- Groundwater Directive: verification of the suitability and availability of monitoring and analytical methods not entailing significant costs, and compilation of information on these for MS. This task existed, but was never performed.

Proximity to ECHA mandate: The works seems close to the ECHA core mandate, especially for the EQSD / priority setting. ECHA already has the required expertise/competence for deriving EQSD (PNECs).

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already supports similar work on substance restrictions, including safe limit value setting under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk, exposure and socio-economic assessment - Committee opinion development - IT capabilities for stakeholder consultation and dissemination (including regulatory intentions)
Re-use of data	High	Reuse of data collected under other chemical legislation.
Workload balancing	Medium	With work culminating in 3 and 6-year cycles, the workload of Agency experts and Committee experts can be balanced (although work will be permanently ongoing and resource estimates are already annualised).
IT tools: automation and economies of scale	High	Not an IT-intensive process, but reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination. ECHA is also requested to build an EU repository of health limit values, including EU and national EQS, building further on existing tools.

Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	**Added value**	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under other chemical legislation.
Robustness of assessment and acceptance	High	Insourcing of scientific work from consultants and dispersed Commission services to one central EU Agency and its experts. Involvement of RAC and SEAC committees adds more scientific robustness to the process. *(See also European Court of Auditors: External consultants at the European Commission - Scope for reform).*
Independence	High	Moving scientific work from consultants and dispersed Commission committees to Agency experts and well-established committees in the European Chemicals Agency with a stricter separation between science and policy. ECHA and its committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: The scope of EQSD / priority setting includes all chemicals, also pesticides, pharmaceuticals, etc. ECHA will need to see how it collects data on pesticides and pharmaceuticals in practice.

Projected impact on ECHA:

- ECHA Committees/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to the additional workload. The committees expertise is adequate. No new expertise of the committee is needed.

	RAC			**SEAC**		
	# of opinions per year	**rapportuer**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**

GWD Annex I	1	ECHA		1	ECHA	
GWD Annex II	1	ECHA		1	ECHA	
EQSD Annex I	4	ECHA		4	ECHA	
EQSD Annex II	1	ECHA		1	ECHA	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task relies on existing expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Projected workload and resource implications

Financial resource needs	
Human resource needs	Approximately: 11 FTEs
Candidate for funding from fees?	No

Current workload volume and resources spent in Commission

In summary the current resources spent are:

Current budget line	*Budget line of DG ENV (+JRC) + budget line of DG SANTE*
JRC + JRC consultants for EQS surface water and Watch List surface water	Ca. 4.5 FTE (1 FTE regular JRC staff + 3.5 FTE contracted by EUR 232 030 per year)
DG ENV consultants for impact assessment for EQS surface water	Ca. 0.25 FTE (contracted by EUR 16 700 per year)
DG ENV consultants for voluntary watch list groundwater	Ca. 0.16 FTE (contracted by EUR 10 560 per year)
SCHEER Committee members + external experts	Ca. 30% of work time (average over all the years) of SCHEER membership • EUR 79 200 for reimbursement (30% of EUR 240 000) or up to EUR 93 134 for the year at the peak
DG SANTE SCHEER Committee secretariat	Ca. 1.00 FTE (ca. 30% of work time (average over all the years) of 2 + 1 FTE)
Total	**Ca. 6.00 FTE**

(to convert the cost of consultants into FTEs, the cost of 1 FTE consultant is estimated at ca. EUR 66 000 EUR annually)

Such Commission resources do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.).

Past workload for EQSD (surface water) (Budget line of ENV and SANTE)

Watchlist surface water:

- Review of ca. 10 substances / every 2 years

Prioritisation and EQS derivation

The Priority List went from 33 to 45 substances in 2013 and will grow with an additional 22 substances in 2022. From that list the SCHEER provided opinions on a total of 45 EQS during the last 10-12 years (average of 4 EQS per year) as follows:

- 2022: EQS for 14 priority substances + 4 pending + groundwater standards pending for several substances
- 2021: EQS for 3 priority substances
- 2012: EQS for 1 substance
- 2011: EQS for 23 substances

Also, if one looks at the last 6-year review cycle in 2022 when 22 substances were added to the Priority List, one comes to an average of 4 substances per year if the workload needs to be annualised.

Past workload for groundwater:

In the past only voluntary watch list under groundwater directive. Obligatory watch list would be new, align two directives. Currently only 2 pharmaceuticals for EU standard and 1 for MS monitoring. A few substances will be added in 2022.

Resources used currently for EQSD (surface water):

Watchlist and derivation of EQS for new Priority (hazardous) substances is currently led by JRC (in house and contractors) and the list of P(H)S and related EQS are submitted to a SCHEER opinion. SCHEER has delivered 45 opinions in the period between 2011 – 2022 (average of 4/year). IA of EQS proposals for new substances on the PS list outsourced to contractor; regular discussion and presentation in Working Group Chemicals.

JRC staff permanent+ JRC consultant work Watch List and Annex I EQS list PS and EQS = EUR 1 392 181 (AAs with JRC) over 6 years, i.e. EUR 232 030 per year; if we calculate yearly consultant cost at EUR 66 000, this would make **ca 3.5 FTE plus 1 FTE** (one permanent staff)/year.

In addition, part of the impact assessment was carried out under IA contract DG ENV = relevant part of IA contract was about EUR 100 000; i.e. Ca. 1.5 FTE over six years = **0.25 FTE** per year

The SCHEER Committee serves water legislation for approximately 1/3rd of its capacity (17 opinions out of 51 during 2016-2022). SCHEER has 17 (external) scientists per mandate that are remunerated for their work. DG SANTE provides the secretariat to the SCCS and SCHEER that consists of 4 FTE + 2 FTE for technical and administrative support (literature search, editing and proofreading of opinions, website mastering, assistance for the Health-EU newsletter, dissemination activities). **Costs for renumeration of members of the committee are ca. EUR 93 134 per year** (30% of 310 447,08 (the total cost of SCHEER activities in 2019 consisting of indemnities, travel cost and daily allowances for the members).

The total resources used: **6.1 FTEs** (4.5 FTE/year (Scientific work) + 1.35 FTE/year (committee secretariat) + 0.25 FTE/year (impact assessment via contract)) + **costs of renumeration of members of the committee of ca. EUR 93 134 per year**

Resources used currently for GWD (ground water)

No JRC involvement currently, most work on voluntary watch list mechanism is done by MS expert group and contractor; outcome of that work is sent to SCHEER for updating of Annex I; for the current proposal of additional 4 groups of substances one single opinion was provided (one file covering all pollutants).

DG ENV consultants for voluntary watch list groundwater = 4 low volume contracts at cost of EUR 57 000 = approximately 1 FTE over six years = **0.16 FTE** per year

In addition: contributions from MS; EC and JRC permanent staff (already estimated under 'Surface water' and SCHEER opinion (one opinion on total amount of substances proposed for Annex I).

<u>Future policy trends, workload drivers and ECHA resource needs</u>

Commission's calculation method:

If we estimate the additional cost of the new tasks introduced under the proposal, i.e. additional 2 EQS per year for Annex II EQSD and GWD and additional 1,5 substances/pollutants to be identified per year for Watch List GW (proposed 5 substances every 3 years, i.e. 10 over six years i.e. approximately 1.5 per year): so this would add up to approximately 35% of the current 6.26 FTE (4 opinions per year, plus Watch List with double amount of substances), i.e. in total 6.26 FTE plus 2.25 FTE which **would make approximately 8.5 FTE**.

To compare this estimate of current expenditure with the proposal from ECHA we would need to add the estimated amount for the development and/or identification of monitoring and analysis methods for total PFAS (note that for microplastics and for AMR, since these will be part of the 'normal' Watch list mechanism, the identification of methodologies would supposedly be covered by the normal 'Watch list support');

For JRC is currently working on a methodology for measuring microplastics in drinking water (budget of EUR 300 000), to be adopted by delegated act in Jan 2024. A contract is being launched for the development of technical guidelines on analytical methods for PFAS (mainly 'PFAS Total') in drinking water (budget EUR 200 000); also to be established by Jan 2024. It is likely that the work required for developing or identifying methodologies for microplastics and total PFAS in surface and in groundwater bodies will benefit from the work carried out under the drinking water directive, possibly resulting in slightly lower estimates.

ECHA's calculation method:

The priority setting process is similar work to REACH Annex XIV prioritisation, while the setting of EQS as well as reviewing the substances and quality standards in Annexes I and II to the GWD) is assumed similar to deriving Occupational Exposure Limits (OELs), with an average cost in ECHA of 0.7 FTE / substance. This however does not yet include the provision of a socio-economic analysis / impact assessment via the SEAC committee, which would add an additional 0.3-0.5 FTE (estimate made in the past for possible socio-economic assessment work for OELs).

Also, the surface water and groundwater watchlist process, and especially the setting of PNECs, is assumed similar to deriving OELs, with an average cost in ECHA of 0.7 FTE / substance. However, this process would potentially not include committee opinion forming, so the cost is estimated to be half lighter at 0.35 FTE / substance.

Annual ECHA resource needs:

- The following resource estimates correspond to the "ECHA way", i.e. implementing similar processes and similar level of digitalisation to what is in place for ECHA's current tasks. Such examples would be the creation of registries of intentions and the dissemination of lists (watch lists, priority lists) as structured data. The benefit of this approach is to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability.
- **Both for Groundwater and surface water**: verification of the suitability and availability of monitoring and analytical methods not entailing significant costs, and compilation of information on these for MS: **0.5 FTE** for running a public consultation on available methods, scientific support and contract management of the second part of the task to assess suitability of analytical methods which would be outsourced to a scientific institute at ca. EUR 70 000 annually;
- Identification of suitable monitoring and analytical methods for microplastics, PFAS and AMR within two years after entry into force: resource needs covered under the bullet point above;
- Identifying and setting PNECs for 5 **groundwater** watch list substances every 3 years: **0.5 FTE annually** (~unit cost of 1 'light' OEL without committee involvement = 0.35 FTE);
- **Groundwater**: Specific technical work on six-yearly review of the pollutants and quality standards in Annex I and possible updating of Annex II (listing pollutants for which MS must set national thresholds) to the GWD: six year cycle review of the pollutants listed in the two annexes and of the quality standards in Annex I. Development of proposals for the amendment of Annexes I and II, based on scientific and technical evidence: review 1 substance annually: **1 FTE annually** (~unit cost of 1 OEL, incl. RAC + SEAC = 1 FTE);
- Priority setting process **groundwater**, identifying substances where national thresholds apply but wide divergences exist, identification of EU wide thresholds for pollutants in Annex II; one per year, to be included in a delegated act every six years: **1 FTE annually** (~unit cost of 1 OEL, incl. RAC + SEAC = 1 FTE);
- Identifying and setting PNECs for 10 **surface water** watch list substances every 3 years: **1.05 FTE annually** (~unit cost of 1 'light' OEL without committee involvement = 0.35 FTE);
- Setting of EQS for Priority List substances for ca. 4 **surface water** substances annually + RAC committee opinion forming + SEAC committee opinion forming: **4 FTE annually** (~unit cost of 1 OEL, incl. RAC + SEAC = 1 FTE);
- Technical work under **surface water** on establishing EU-wide EQS for substances listed in a (new) Annex II of the EQSD including the so-called 'River Basin Specific Pollutants' formerly part of the 'ecological status' component of surface water status: assumption of setting EQS for 1 substance per year: **1 FTE annually** (~unit cost of 1 OEL, including RAC + SEAC = 1 FTE);
- IT tools and infrastructure development and run cost (data submission, processing, output): contribution of 10% for common components and customisations;
- Horizontal support (governance & enablers / administrative overhead): contribution of 15%.

Ca. 2.5 FTE for groundwater

Ca. 6.05 FTE for surface water

+ 0.5 FTE + 70k EUR for analytical methods for both groundwater and surface water

+ 10% IT tools and infrastructure (would be approximately 1 FTE)

+ 15% administrative overhead (would be approximately 1.5 FTE)

Total: ca. 11 FTEs plus EUR 70 000 for outsourcing of identification of monitoring methodologies

Summary of additional resource needs for Environmental Quality Standard Directive (2008/105/EC) + Water Framework Directive (2000/60/EC) + Groundwater Directive (2006/118/EC):

Agency	Summary of tasks	Resource needs	
EEA		Operational resource needs:	2024: **EUR 130 000** 2025: **EUR 80 000** 2026: **EUR 80 000** 2027: **EUR 80 000**
		Human resource needs:	2024: **3 TAs, 0 CA** 2025: **3 TAs, 0 CA** 2026: **3 TAs, 0 CA** 2027: **3 TAs, 0 CA**
ECHA		Operational resource needs:	2024: **EUR 673 000** 2025: **EUR 686 000** 2026: **EUR 702 000** 2027: **EUR 718 000**
		Human resource needs:	2024: **7 TAs, 4 CA** 2025: **7 TAs, 4 CA** 2026: **7 TAs, 4 CA** 2027: **7 TAs, 4 CA**

Future budget line: DG Environment

Candidate for fees: No

9. CLP REGULATION (1272/2008)

Responsible body:

Currently: N/A

(Re-)attribution planned to: ECHA, EFSA

Legal basis for reattribution: Revision of the CLP Regulation

Type of task: New

Brief task overview:

1. Developing a proposal for harmonised classification
2. Opinion on a proposal for harmonised classification

Detailed process description:

Current process:

For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH). Harmonised classifications are listed in Annex VI to the CLP Regulation.

The process for harmonised classification is as follows:

i. Member State (or industry under certain conditions) submits proposal for harmonised classification to ECHA. There is no legal obligation to do this; it is at the MS' (or industry's) discretion.

ii. RAC provides an opinion on harmonised classification.
iii. ECHA sends opinion to COM
iv. 'Where appropriate', COM formalises classification through addition of substance to Annex VI to CLP

Future process:

ECHA or EFSA, on the request of the Commission, will be obliged to develop a proposal for harmonised classification.

Proximity to Agency mandate: The task fits well with the mandates of ECHA and EFSA. Both agencies are already involved in hazard and risk assessment of chemicals. ECHA already manages the process of RAC opinion making on proposals for harmonised classification and other provisions of CLP regulation.

Projected synergies and added value of reattribution: Higher capacity to agree on harmonised classification for substances and the possibility to solve divergent opinions among agencies as regards hazard assessment is the key added value.

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already supports work under the CLP regulation including opinion making on harmonised classification and performs risk and hazard assessment under other pieces of legislation. Several key capacities can be reused/reinforced: - Hazard assessment - Committee opinion development - Existing IT capabilities for dossier submission, stakeholder consultation and dissemination
Re-use of data	Medium	Reuse of substance identification and hazard data collected under other chemical legislation.
Workload balancing	Low	With an estimated workload of developing 5 proposals annually, there is little room for workload balancing.
IT tools: automation and economies of scale	High	Reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value	
Scientific	High	Opportunity to solve divergent opinions among agencies as regards

consistency		hazard assessment.

Projected impact on ECHA and EFSA:

- ECHA Committees/bodies: **high impact**. The task requires involvement of ECHA committee RAC. EFSA Committees/bodies: **no impact**. No involvement of EFSA's committees

	RAC			**SEAC**		
	# of opinions per year	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Harmonised classification	6	ECHA staff		0		

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems; EFSA data model and IT infrastructure: **no impact**. The task does not require use of IT infrastructure.
- ECHA key experts: **high impact**. The task relies on expert competencies, which are limited in ECHA and also critical to other regulatory tasks. EFSA key experts: **high impact.** The task relies on expert competencies, which are limited in EFSA and also critical to other regulatory tasks.

Workload and resource implications:

Current workload and resource use:

Number of RAC opinions on harmonised classifications managed by ECHA varies per year, with an average of 47 opinions per year:

	Number of opinions per year					
Opinions on	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Classification (CLH)	35	33	61	51	49	53

Based on the analysis provided by ECHA (which was based on the analysis of ECHA and MSs spending on preparation of classification dossiers), the dossier for harmonised classification which is of average complexity requires 0,5 FTE and 95k EUR:

ECHA's estimate of resources for supporting the preparation of a CLH dossier of medium complexity	
	estimate for CLH
Dossier development	0.35 FTE
RAC opinion making	0.1 FTE
Support services	0.05 FTE
Total FTE	0.5

95K EUR:

- Title 1 Staff expenditure: EUR 85 000, including 19% overhead cost
- Title 2 Infrastructure: included under Title 1 above
- Title 3 Operational costs: EUR 10 000

The dossier of high complexity, requires 0.65 FTE and EUR 120 000:

ECHA's estimate of resources for supporting the preparation of a complex CLH dossier	
	ECHA estimate for CLH
Dossier development	0.5 FTE

RAC opinion making	0.1 FTE
Support services	0.05 FTE
Total FTE	0.65

EUR 120 500:

- Title 1 Staff expenditure: EUR 110 500, including 19% overhead cost
- Title 2 Infrastructure: included under Title 1 above
- Title 3 Operational costs: EUR 10 000

The CLH dossier of low complexity requires 0.35 FTE and EUR 69 500

ECHA's estimate of resources for supporting the preparation of a CLH dossier of low complexity	
	estimate for CLH
Dossier development	0.2 FTE
RAC opinion making	0.1 FTE
Support services	0.05 FTE
Total FTE	0.35

EUR 69 500:

- Title 1 Staff expenditure: EUR 59 500, including 19% overhead cost
- Title 2 Infrastructure: included under Title 1 above
- Title 3 Operational costs: EUR 10 000

ECHA and EFSA do not prepare any proposals for harmonised classifications.

Future workload and resource needs:

Based on the impact assessment, it is expected that additional 250 dossiers will have to be prepared over the next 20 years, i.e. 12.5 dossiers per year. It is expected that the dossiers to be prepared are to be of lower complexity than medium, but higher than low complexity dossiers, i.e. having an average resource requirement of 0.4 FTE per dossier. This would result in the need of 5 FTEs per year to process 12.5 dossiers/year. Normally, there is a need for the contribution of 15% for the development and maintenance of common IT components (0.75 FTE) and for the contribution of 15% for the horizontal support (governance & enablers / administrative overhead) (0.75 FTE per year). However, as this is an extension of existing CLH process in the agency and the process and structures are fully in place, there is no need for these additional overhead contributions. Therefore, in total, there is a need of **5 FTEs per year**.

EFSA will need to prepare up to 1 dossier per year, which is possible to be absorbed by its resources for the plant protection products.

Summary of additional resource needs for the CLP regulation:

Agency	**Summary of tasks**	**Resource needs**	
ECHA	- Preparing classification dossiers (12.5 per year) - Assessing classification dossiers (13.5 per year)	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0**
		Human resource needs:	2024: **3 TA, 2 CA** 2025: **3 TA, 2 CA** 2026: **3 TA, 2 CA** 2027: **3 TA, 2 CA**
EFSA	- Preparing classification dossier (1 per year)	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0**
		Human resource needs:	2024: **0 FTE** 2025: **0 FTE** 2026: **0 FTE**

			2027: **0 FTE**

Future budget line: DG GROW

Candidate for fees: No

10. PACKAGING AND PACKAGING WASTE DIRECTIVE

Responsible body:

Currently: N/A, no current process for hazardous substances

(Re-)attribution planned to: ECHA

Legal basis for reattribution: revision of the Packaging and Packaging Waste Directive (94/62/EC)

Type of task: New – expanding the existing REACH restriction process and

Brief task overview: Assessments underpinning restrictions of substances in packaging and performing a scoping study for substances in packaging that would be candidates for restriction.

Detailed process description:

New process:

If there is a need to restrict a substance in packaging, restriction process under REACH shall be used for that purpose.

The study will aim at collecting, identifying and prioritising relevant substances of concern in packaging for which potential limitations or restrictions could be envisaged. This study will draw on available information and registers covering substances of concern to enable an initial prioritisation for swift further restriction action, as appropriate. This study, will determine the conditions under which the concentration level of certain substances of concern, do not apply to recycled materials and to product loops which are in a closed and controlled chain. It will also detail the reasoning of setting exemptions from the requirements of the proposed regulation for certain types of packaging.

Proximity to ECHA mandate: This task fits very well with the ECHA's core mandate, as it is a REACH restriction. ECHA holds the right competences to manage the packaging restriction process, however, does not have sufficient information on the exact use of substances in packaging.

Projected synergies and added value of reattribution:

This reattribution ensures maximal synergies and coherence of scientific opinions. The same process and the same scientific methodologies as in REACH will be used. The substances under scrutiny are the same or similar to those under REACH (and other legislation supported by ECHA) and REACH (and other ECHA) data and processes can be reused for packaging restriction dossier development and opinion forming. All needed competencies for the task exist in ECHA.

Projected impact on ECHA

- ECHA Committees/bodies: **medium impact**. The task generates medium impact on the setup / organisation / staffing of Committees/bodies due to the additional use to be considered in the restriction

	RAC			**SEAC**		
	# of opinions per year	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**

Restriction in packaging and packaging waste	0	RAC member		0	SEAC member	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **medium impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Projected workload and resource implications

Current workload and resource use:

N/A, no current process for hazardous substances.

Future workload and resource needs:

It can be expected that at most 1 restriction of a substance will be needed once per two years, i.e. 0.5 restriction per year. This would require 0.5 FTE per year. In addition, there is a need for the contribution of 15% for the development and maintenance of common IT components (0.1 FTE per year) and for the contribution of 15% for the horizontal support (governance & enablers / administrative overhead): (0.1 FTE per year). In total, there is a need of 0.7 FTE per year. Considering the fact that these restrictions will be performed as REACH restrictions, possibly merging restriction in packaging with restriction of the same substance in another uses, the work resources can be covered by the available resources for REACH restriction.

The performing of the scoping study will require a dedicated person for 3 years to compile and analyse the necessary information leading to the identification and prioritisation of substances that need to be considered for the restriction in packaging. The work is the best to be performed by the large part by the internal ECHA staff as the access to all information on chemicals and materials is needed. It is estimated that 1 FTE for 3 years would be necessary to perform such study. Some subcontracting may be possible to get more information on the insight of the use of chemicals in packaging.

Summary of additional resource needs for packaging and packaging waste directive:

Agency	Summary of tasks	Resource needs	
ECHA	- Processing at most 0.5 restriction dossiers per year (including RAC and SEAC opinion) as part of REACH restriction - Performing a scoping exercise related to presence of chemicals in packaging	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 TA, 0 CA** 2025: **1 TA, 0 CA** 2026: **1 TA, 0 CA** 2027: **1 TA, 0 CA** 2028: **0 TA, 0 CA**

Future budget line: DG Environment

Candidate for fees: No

11. LEGISLATION ON MEDICINAL PRODUCTS FOR HUMAN USE (726/2004)

Responsible body:

Currently: EMA

(Re-)attribution planned to: EMA, expanding and modifying the existing tasks and adding new tasks

Legal basis for reattribution:

Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM (2023) 192 final)

Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM (2023) 193 final)

Type of task: New and modified existing ones

Process description:

New/modified processes:

The details of the new and modified tasks are provided in the proposal for the directive[53], the regulation with accompanying legislative financial statement[54] and the accompanying staff working documents[55,56,57].

In short:

Specific objectives of the legislative proposals are:

1. Promote innovation, in particular for unmet medical needs, including for rare disease patients and children.
2. Create a balanced system for pharmaceuticals in the EU that promotes affordability for health systems while rewarding innovation.
3. Ensure access to innovative and established medicines for patients, with special attention to enhancing security of the supply across the EU.
4. Reduce the environmental impact of the pharmaceutical product life cycle.
5. Reduce the regulatory burden and provide a flexible regulatory framework.

The main requirements of the proposals to be met in the short and long term are:

- Upon the entry into force of the Regulation, the Agency should put in place the framework which will be used to enhance regulatory support and accelerated assessment, to address medicine shortages and supply chain challenges and to strengthen the environmental risk assessment under the marketing authorisation.
- Regarding the enhanced regulatory support, the Agency shall set up within 6 months of adoption a coordination mechanism to enable parallel scientific advice with health technology assessment and regulatory bodies for medical devices. Within the same period, the Agency shall create an

[53] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM (2023) 192 final).
[54] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM (2023) 193 final).
[55] EUR-Lex - 52023SC0191 - EN - EUR-Lex (europa.eu)
[56] EUR-Lex - 52023SC0192 - EN - EUR-Lex (europa.eu)
[57] EUR-Lex - 52023SC0193 - EN - EUR-Lex (europa.eu)

Academia Office, a secretariat to support not-for-profit entities by providing them free of charge early scientific advice. Furthermore, the Agency shall establish an EU inspectorate within the Agency, to strengthen the network's inspection capacity and deal with emergencies, similar what was needed during the pandemic.

- For addressing medicine shortages the Agency shall extend the monitoring and management capacity for all shortages, with a focus on critical shortages, and extend the EMA capacity to support would facilitate availability of critical medicinal products. This appropriate availability and access to medicinal products which may have a serious impact on public health.
- The Agency shall also extend its capacity to support the enhanced environmental risk assessments.

The modified or new tasks that are related to the one substance, one assessment approach are:

- developing coherent scientific assessment methodologies in the fields falling within EMA mission;
- cooperating with EU decentralised agencies and other scientific authorities and bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, taking into account the specificities of the assessment of medicinal products;
- take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other Union bodies and agencies carrying out similar tasks in relation to issues of common concern. Where the Agency identifies a potential source of divergence, it shall contact the body or agency in question to ensure that all relevant scientific or technical information is shared and in order to identify potentially contentious scientific or technical issues. Where a substantive divergence over scientific or technical issues is identified and the body concerned is a Union Agency or a scientific committee, the Agency and the body concerned shall cooperate to resolve the divergence, and inform the Commission without undue delay.
- to enable coherence between scientific opinions and to avoid duplication of tests, EMA shall make arrangements with other bodies or agencies established under Union law for cooperation on scientific assessments and methodologies. EMA shall also make arrangements for the exchange of data and information on relevant substances with the Commission, Member States' authorities and other Union Agencies, in particular for environmental risk assessments, non-clinical studies and maximum residue limits. These arrangements shall seek to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection.
- electronic applications for marketing authorisations and for variations to the terms of the marketing authorisations shall be introduced to avoid unnecessary administrative and financial burden both for the pharmaceutical industry and the competent authorities and EMA shall make available such electronic formats.
- EMA shall set-up an active substance based review system of environmental risk assessments ('ERA monographs') for authorised medicinal products. An ERA monograph shall include a comprehensive set of physicochemical data, fate data and effect data based on an assessment of active substances.

Proximity to Agency mandate: The tasks fit well with the mandate of EMA as all three tasks target the areas of the EMA mandate, and they are either an expansion of existing tasks or addition of new tasks related to medicines.

Projected synergies and added value of reattribution: Improving coherence, consistency and interoperability among the Agencies work is the key added value.

Workload and resource implications:

Future workload and resource needs:

The new tasks require additional resources for EMA. The additional resource needs are mainly related to additional tasks to be carried out by EMA in terms of providing scientific, administrative and IT support in the following main areas:

- enhanced pre-authorisation scientific and regulatory support;
- decision-making on orphan designations and management of the Union Register of designated orphan medicinal products;
- active substance master file assessment and certification;
- inspection capacities for inspections in third countries and support to Member States;
- environmental risk assessment strengthening;
- shortage management and security of supply.

As described in the legislative financial statement accompanying the proposals, the following resources are needed:

- 6 FTEs (4 AD and 2 AST TAs) are necessary to set up the Academia Office at EMA that will be managing the procedures. The tasks of the office will be similar to the tasks of the SME office and will include procedural and administrative assistance to "not-for-profit" entities, including direct assistance and briefing meetings on regulatory strategy, providing fee waivers and reductions to eligible entities, provide free-of-charge translations of the product information in all EU languages for initial EU marketing authorisations, provide training and education to "not-for-profit" entities, etc
- 54 FTEs:
    - managing (AD profiles) and providing support (AST profiles) to operational expert groups in the area of the Environmental Risk Assessment (ERA);
    - with a scientific and regulatory profile to work in the shortages management and security of supply;
    - Good Manufacturing Practice and Good Clinical Practice inspectors (AD) necessary to establish an EU inspectorate resourced by EMA staff that would provide help to the inspections done by Member States (lacking resources), and deal with emergency situations which require dedicated and dependable intervention (e.g., similar to inspections required during the pandemic);
    - Legal officers (AD profiles), needed in the field of orphan designations that are already today a litigious topic and so it is assumed the proposed changes in the decision making on orphan designation would generate an increased in workload for even more legal queries and litigations;
    - defining business requirements for the data register, following up on the implementation and perform the related scientific activities when the register is live;, develop trainings on ERA, etc.;

- providing administrative support to the operational expert groups;
- working in the area of inspection planning;
- general assistants, assistants, supporting on procedural aspects or working on document creation.

Summary of additional resource needs for Medicinal Products Regulation:

Agency	Summary of tasks		
EMA	See above	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **19 FTE** 2025: **37 FTE** 2026: **52 FTE** 2027: **60 FTE** 2028: **60 FTE**

Future budget line: DG SANTE (EU4Health programme) + EMA fees

12. END-OF LIFE VEHICLES (ELV) DIRECTIVE

Responsible body:

Currently: Commission with the support of consultants

(Re-)attribution planned to: ECHA

Legal basis for reattribution: revision of the Directive on end-of-life vehicles (2000/53/EC)

Type of task: Existing

Brief task overview:

1. Restriction of hazardous substances in end-of-life vehicles
2. Assessments underpinning review of exemptions from restriction on lead, mercury, cadmium, or hexavalent chromium.

Detailed process description:

Current process:

The End-of-life Vehicle Directive bans the use of four heavy metals (lead, mercury, hexavalent chromium and cadmium) in vehicles put on the EU market after 1 July 2003. More substances could be prohibited, but in practice no substances have been added since the start of the directive. Annex II to the Directive lists the exemptions which allow the use of one of these heavy metals in specific applications where their use is "unavoidable". The only criteria used is availability of alternatives. Environmental and socio-economic aspects are not considered. The Commission reviews the exemptions on a regular basis based on technical and scientific progress and as the dates of exemption validity expire.

1. Restricting (uses of) hazardous substances in vehicles: (~ REACH restriction):

- Has not happened since the initial four heavy metals were placed on Annex II.

2. Review of exemptions from the restrictions (~ REACH authorisation)

- Two years before the expiry date of an exemption, the Commission contracts a consultant to

review the existing exemptions. The contractor is used also for new exemptions. Next review is in 2025.

- Contractor makes a review of the exemption needs (example). The assessment focuses on determining whether the use of the substances in applications listed in Annex II is avoidable. The assessment includes stakeholder consultation.
- Contractor concludes on whether the use of substances is avoidable and makes recommendation to the Commission.
- The Commission consults a Commission expert group on the proposal, including MS and stakeholders.
- The Commission drafts a delegated act, which is open for a 4-week commenting period, after which it adopts the delegated act amending Annex II.

Changes in the process: Yes

As part of the revision of the directive, the following changes are envisaged.

The scope of the Directive will be extended (from passengers' cars and light commercial vehicles) to include also motorbikes, buses, lorries, etc. As a result, higher workload is expected in terms of exemption requests.

Restricting (uses of) new hazardous substances in vehicles will be done via REACH regulation, similarly as proposed for packaging and packaging waste directive.

ECHA will be tasked to assess the need for exemptions for existing restrictions (4 heavy metals).

The criteria for exemptions from restriction of 4 heavy metals will be amended to be similar to the socio-economic assessment and analysis of alternatives performed under REACH. The only criterion currently used is availability of alternatives. Environmental and socio-economic aspects are not considered. This is criticised, so better alignment with assessments as done under REACH is envisaged.

Restrictions of use of chemicals in batteries used in vehicles will not be within the scope of the directive. This is to be addressed under the Batteries Regulation (as lex specialis).

Proximity to ECHA mandate: All new restrictions of substances in vehicles will be done via the restriction process under REACH and the existing scientific methodologies used for REACH restrictions can be applied. The ELV exemption process will become very similar to the authorisation process under REACH, including the criteria for assessment. The substances under scrutiny are the same or similar to those under REACH and existing ECHA data and processes can be reused for ELV restriction dossier development, exemption process and opinion forming. ECHA holds the appropriate competences to manage the process, however, does not have sufficient information on the exact use of substances in end-of-life vehicles.

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already supports similar work on substance restrictions and exemptions under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk, exposure and socio-economic assessment - Committee opinion development - Existing IT capabilities for industry dossier submission, stakeholder consultation and dissemination
Re-use of data	Medium	Reuse of data collected under other chemical legislation, but low

		availability of data on substances in products and waste streams.
Workload balancing	Medium	With an estimated workload of processing 5 exemption requests annually, while developing one new restriction every 5 years, the workload of Agency experts and Committee experts can be spread and balanced over the years (although resource estimates are already annualised).
IT tools: automation and economies of scale	High	Industry actors can submit their exemption requests reusing existing ECHA submission tools, at the same time automating the existing process. In addition, reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under other chemical legislation.
Robustness of assessment and acceptance	High	Insourcing of scientific work from consultants to Agency experts. Additional involvement of RAC and SEAC committees adds more scientific robustness to the process. *(See also European Court of Auditors: External consultants at the European Commission - Scope for reform).*
Independence	High	Moving scientific work from consultants to Agency experts and committees. ECHA and its committees work under strict conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: No major concerns and there are certainly opportunities to find synergies with the REACH restriction process.

Projected impact on Agency:

- ECHA Committees/bodies: **medium impact**. The task generates medium impact on the setup / organisation / staffing of Committees/bodies due to the additional workload

	RAC			**SEAC**		
	# of opinions per year	**rapportuer**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Restriction (as part of REACH)	0	RAC member		0	SEAC member	
Review of exemption	0	-		5	SEAC member	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **medium impact**. The task partly relies on existing expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Projected workload and resource implications:

Current workload and resource use:

No new substances were restricted since the adoption of the Directive (end 2000). 4 substances are currently restricted. They were restricted as part of the adoption of the legal text end 2000.

There were 41 valid exemptions in May 2022. The number of exemptions assessed varies across the years, with average 2.14 exemption assessment per year:

11th adaptation 2021 reviewed	3 exemption requests reviewed
9th and 10th adaptation 2019	5 exemptions reviewed
8th adaptation 2016	3 exemptions reviewed
7th adaptation 2015	6 exemptions reviewed
6th adaptation 2012	1 exemption reviewed
4th and 5th adaptation 2010	12 exemptions reviewed
3rd adaptation 2008	1 new exemption
2nd adaptation 2007	11 exemptions reviewed
1st adaptation 2004	5 exemptions reviewed
Total	**47 assessments** (average of 2.14 assessments annually over 22 years)

The Commission spends ca. 0,1 FTE within DG ENV for the hazardous substances in the ELV Directive, plus a contract of 60.000 EUR every 2,5 years on average.

The summary of current resources spent is:

	Ca. 0.1 FTE (dedicated to the work on

DG ENV	hazardous substances)
DG ENV consultants	*Ca.* 0.36 FTE (a contract of EUR 60 000 every 2.5 years for reviewing exemptions)
Total	***Ca.* 0.46 FTE**

(to convert the cost of consultants into FTEs, the cost of 1 FTE consultant is estimated at ca. EUR 66 000 annually)

Such Commission resources do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.).

Current budget line: DG Environment

Future workload and resource needs:

New restrictions of substances in vehicles will be done in the future via restriction process under REACH. The number of restrictions can be expected to be approximately 1 restriction per 5 years, i.e. 0.2 restriction per year.

Assessment of the exemptions under the new REACH restriction will be done as part of the REACH process and review of REACH restrictions.

Assessment and review of exemptions from existing restrictions for 4 metals (cadmium, mercury, led and chromium VI) will be in the future done by ECHA with involvement of SEAC committee. The assessment criteria will be extended as compared to today to be aligned with the criteria used under the REACH authorisation process. The scope of the directive will be extended to cover more types of vehicles, which will result in higher number of exemption requests as compared to today. The number of assessments of exemption is expected to be double as compared to today, i.e. 4.28 assessments per year.

The ELV restriction process is to be similar to REACH restrictions, with an average cost in ECHA of 1 (light) – 1.5 (complex) FTE per restriction dossier. The ELV restrictions are expected to be light dossiers.

The exemption review process is assumed similar to REACH applications for authorisations (AfA = 0.15 (light dossier) – 0.3 (complex dossier) FTE per application. The ELV assessments are expected to be light dossiers.

The resources needed for ECHA are as follow:

- Development of 1 restriction dossier every 5 years (scope extension to new vehicle types)+ opinion forming: 0.2 FTE (~1 light REACH restriction = 1 FTE). However, considering that these restrictions will be performed as REACH restrictions, these resources can be covered by the available resources for REACH restriction. Therefore, for this part of work it is 0 FTE.
- Review of up to 5 existing exemptions annually + SEAC opinion forming: 0.75 FTE (~unit cost of 1 light REACH application for authorisation = 0.15 FTE)
- Scientific support services: substance identification and prioritisation, data management and dissemination: can be absorbed by the agency
- IT tool development cost (data submission, processing, output): contribution of 15% for common components (0.11 FTE)
- Horizontal support (governance & enablers / administrative overhead): contribution of 15% (0.11 FTE)

Total: 0.97 FTE

Summary of resource needs for end-of-life vehicle directive:

Agency	Summary of tasks		
ECHA	Preparation of 1 restriction dossier every 5 years Assessment of up to 5 exemptions per year	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 TA, 0 CAs** 2025: **1 TA, 0 CAs** 2026: **1 TA, 0 CAs** 2027: **1 TA, 0 CAs** 2028: **1 TA, 0 CAs**

Future budget line: DG Environment

Candidate for funding from fees: Task 1 No, Task 2 yes

13. TOY SAFETY DIRECTIVE

Responsible body:

Currently: Commission with the support of the SCHEER Committee

(Re-)attribution planned to: ECHA

Legal basis for reattribution: revision of the Toy safety directive (2009/48/EC).

Type of task: existing

Brief task overview:

1. Assessment underpinning establishing or strengthening chemical limit values in toys for children under 36 months or toys for other children intended to be taken in the mouth;
2. Assessment underpinning amending the limit values for 'heavy metals' in toys;
3. Assessment underpinning amendments to the lists of allergenic fragrances that are prohibited in toys or that have to be labelled if present in toys;
4. Assessment underpinning a derogation for the use of CMR substances in toys.

Detailed process description:

Current process:

Tasks 1, 2 and 3:

The process can be triggered by an expert of the subgroup Chemicals (which is a subgroup of the Expert Group on Toys Safety (01360) consisting of experts from the Member States, EEA-EFTA countries, the toy industry, the European consumer organisations ANEC) suggesting that a new or strengthened limit value for a chemical substance is needed, for example due to new scientific knowledge. Also a Scientific Committee opinion, such as from the Scientific Committee on Consumer Safety (SCCS), may be a basis for the Commission services to propose a new/strengthened limit value;

Once the process is triggered, the subgroup Chemicals discusses the possible occurrence of the substance in toys, assesses the hazard, exposure and risk and recommends a limit value for toys below which the substance presents no risk. In case of conflicting views in the subgroup Chemicals that

cannot be resolved, the Commission asks the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to assess the hazard, exposure and risk, and to recommend a limit value for toys that presents no risk.

On the basis of the above recommendation, the Commission services draft a Directive amending the Toy Safety Directive, Appendix C. The draft Directive indicates in its recitals the occurrence of the chemical substance and suggests test methods for the substance in toys and toy materials. The Commission consults the proposal with the Expert Group on Toy Safety (consisting of experts from the Member States, EEA-EFTA countries, Candidate Countries, Switzerland, the toy industry, European consumer organisations (ANEC, BEUC), CEN, Cenelec, notified bodies). After the consultation, the Commission adopts the proposal via the comitology procedure.

Task 4:

The process is usually triggered by a toy industry expert, suggesting a derogation to allow the continued use of a CMR substance (Cat. 1A, 1B or 2) in toys. This occurs when a substance has been newly classified as being CMR.

The subgroup Chemicals briefly discusses the derogation and the Commission services requests the toy industry for an analysis of alternatives in the case substance is a CMR cat 1 A or 1B (no analysis is necessaryif the substance is Cat. 2).

The Commission services then mandate the SCHEER to assess the use of the CMR substance in toys. To allow the Commission to grant a derogation, the SCHEER has to assess the use of the CMR in toys as safe. The Commission services also check whether REACH does not prohibited the CMR substance in consumer articles.

If the use of the CMR substance in toys is concluded by SCHEER to be safe, there is no prohibition of the substance in the consumer articles under REACH and the industry provides the analusis of alternatives when necessary, the Commission services draft a Directive amending the Toy Safety Directive, Appendix A. Then the Commission consults with the Expert Group on Toy Safety and adopts the proposal.

Changes envisaged as part of reattribution: Yes

With the revision, the Commission intends to introduce the following changes:

- extending the generic assessment approach (automatic ban) to other hazard classes for the most harmful chemicals such as endocrine disrupting chemicals;
- the possibility to introduce specific limit values for new chemicals could be introduced in all toys, and not only in toys intended for children under 36 months or to be put in the mouth, as is the case today.
- Transfer the risk assessment tasks from SCHEER committee to ECHA's Committee for Risk Assessment (RAC).

Proximity to ECHA mandate: The task is closely related to ECHA's core mandate and ECHA has the needed data, competences and expertise to perform the task.

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already performs similar work on restrictions, derogations, setting of limit values and assessing socio-economic impacts under REACH and other legislation. Several key

		capacities can be reused/reinforced: - Hazard, risk, exposure and socio-economic assessment - Exposure limit value definition - Committee opinion development - Existing IT capabilities for industry dossier submission, stakeholder consultation and dissemination
Re-use of data	High	Reuse of data collected under other chemical legislation, especially REACH & CLP and via the SCIP database, with a focus on CMRs and Endocrine Disruptors.
Workload balancing	Medium	With an estimated workload of 2 derogation requests and setting limit values for 2 additional substances annually, the workload of Agency experts and Committee experts can be spread and balanced over the years (although resource estimates are already annualised).
IT tools: automation and economies of scale	High	Industry actors can submit their derogation requests reusing existing ECHA submission tools, at the same time automating the existing process. In addition, reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	**Added value**	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation. Reuse of data collected under other chemical legislation to improve coherence in the scientific advice provided to the Commission.
Robustness of assessment and acceptance	High	Insourcing of scientific work from consultants to Agency experts. Centralising the scientific committees for assessing chemicals in one EU agency and stricter separation between policy and scientific advice adds more scientific robustness to the process. *(See also European Court of Auditors: External consultants at the European Commission - Scope for reform).*
Independence	High	Moving scientific work from consultants to Agency experts and from dispersed Commission committees to well-established committees in the European Chemicals Agency with a stricter separation between science and policy. ECHA and its committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process:

		- Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: Methodologies would need to be aligned. Finally, the revision is an opportunity to also streamline the process and align with similar processes under REACH.

Projected impact on ECHA:

- ECHA Committees/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to the additional workload

	RAC			**SEAC**		
	# of opinions per year	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Assessments under Tasks 1,2,3 or 4	4.2	RAC member		4.2	SEAC member	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Projected workload and resource implications:

<u>Current workload and resource use:</u>

In 12 years (2010-2021), there were 10 opinions requested from SCHEER (and before from SCHER and SCENIHR). These opinions were about 17 substances and dealt with setting or reviewing limit values (3 opinions for 13 substances), 2 generic assessments and 2 derogations requests:

- 2021: limit values for 8 substances in squishy toys
- 2017: limit value for 1 substance
- 2016: 1 generic opinion
- 2015: limit value for 1 substance
- 2012: 3 opinions (including 2 limit values and 1 derogation)
- 2010: 3 opinions (including 1 limit value and 1 derogation request)

The secretariat of the scientific committees hosted by DG SANTE employs 4 FTE of DG SANTE and 2 additional FTEs of external interim staff (for technical and administrative support like literature search, editing and proofreading of opinions, website mastering, assistance for the Health-EU newsletter, dissemination activities). The staff of 6 FTEs is equally split over two committees, which means that 3 FTEs are used to support work of SCHEER. The workload of SCHEER dedicated to support of toys safety directive amounts to 10% of its time, which makes 0.3 FTE.

The operational costs for two committees (that includes special indemnities, accommodation, daily allowances, travel costs, reimbursement for rapporteurship, etc) operated by the Commission were EUR 2 883 030 for 6 years (2016-2021), which makes it approximately EUR 240 000 per year per committee. It must be noted that the operational costs in 2019 were EUR 340 000, which then went down because of the pandemic measures. The workload of SCHEER dedicated to support of toys

safety directive amounts to 10% of its time, which corresponds to operational costs of EUR 24 000 (or at higher level of 2019 to EUR 34 000).

The resource use can be summarized as follows:

DG GROW	Ca. 1 FTE (dedicated to the work on hazardous substances)
DG SANTE SCHEER secretariat	Ca. 0.3 FTE (10% of workload of SCHEER secretariat)
SCHEER committee	10% of membership capacity Operation costs EUR 24 000/ year
Total	***Ca.* 1.3 FTE**

(to convert the cost of consultants into FTEs, the cost of 1 FTE consultant is estimated at ca. EUR 66 000 annually)

Such Commission resources do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.).

Future workload and resource needs:

With the revision, the Commission intends to introduce the following changes:

- extending the generic assessment approach (automatic ban) to endocrine disrupting chemicals;
- the possibility to introduce specific limit values for new chemicals could be introduced in all toys, and not only in toys intended for children under 36 months or to be put in the mouth, as is the case today.

Furthermore, currently CMRs are still allowed in toys up to the relevant CLP concentration limits. Beyond those, derogations can be requested. Only a few derogations were requested by industry in the past. If the generic prohibition would be extended from CMRs to EDC (or maybe even other hazard classes), then also new derogation requests could be expected, especially in the early years when production processes have not yet been adapted and EDCs are still present in potentially quite large amounts. Due to this, it can be reasonably expected that the workload for derogations will multiply (assumption x10 in the first years), but still within reasonable limits (e.g. 2 requests annually vs 2 requests in 10-12 years).

The main work related to limit value setting can be best compared to CLH work, which is currently rated at 0.5 FTE per substance per year within ECHA.

The processing of derogation requests is assumed similar to REACH applications for authorisations (AfA = 0.15 – 0.3 FTE / application).

The resource needs for ECHA would then be as follow:

- Setting/reviewing limit values for 2 substances every year + scientific committee opinion forming: 1.0 FTE annually (~unit cost of 1 CLH opinion = 0.5 FTE)
- Restriction/prohibition of 1 substance or generic opinion development for 1 substance/subject every 5 years + scientific committee opinion forming: 0.3 FTE annually (~unit cost of 1 REACH restriction = 1 – 1.5 FTE)
- Review of 2 derogation requests annually + scientific committee opinion forming: 0.3 FTE (~unit cost of 1 REACH application for authorisation = 0.15 – 0.3 FTE)

- Scientific support services: substance identification and prioritisation, data management and dissemination: can be absorbed by the agency
- IT tool development cost (data submission, processing, output): contribution of 15% for common components (0.24 FTE)
- Horizontal support (governance & enablers / administrative overhead): contribution of 15% (0.26 FTE)

Total: 2 FTEs

Summary of resource needs for toy safety directive:

Agency	Summary of tasks		
ECHA	Assessment underpinning chemical limit values Assessment underpinning amending the limit values for 'heavy metals' in toys; Assessment underpinning amendments to the lists of allergenic fragrances that are prohibited in toys Assessment underpinning a derogation for the use of CMR and EDs substances in toys.	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 TAs, 0 CAs** 2025: **2 TAs, 0 CAs** 2026: **2 TAs, 0 CAs** 2027: **2 TAs, 0 CAs** 2028: **2 TAs, 0 CAs**

Future budget line: DG GROW

Candidate for fees: No

14. RESTRICTION OF HAZARDOUS SUBSTANCE (ROHS) DIRECTIVE (2011/65/EU)

Responsible body:

Currently: Commission with the support of consultants

(Re-)attribution planned to: ECHA

Legal basis for reattribution: Directive amending the RoHS Directive on reattribution of tasks to ECHA

Type of task: Existing

Brief task overview:

1. Assessments underpinning restrictions of hazardous substances in electrical and electronic equipment (currently 10 restricted substances)
2. Review of applications for exemptions from the restrictions.

Detailed process description:

Current process:

RoHS restricts the use of hazardous substances in Electrical and Electronic Equipment (EEE). It covers the placing on the market of articles. It does not cover the use of the substance during the manufacture of them. The restricted substances are included in Annex II to the Directive. They are identified in accordance with the criteria outlined in its Article 6(1) with priority given to substances included in Annexes XIV or XVII to REACH, Substances of Very High Concern (SVHC) and substances with detrimental effects on waste management. RoHS includes also provisions for granting temporary exemptions for specific applications under certain conditions pursuant to

Article 5. Applications exempted from the restrictions are included in Annex III and IV. The details of the processes are:

1. Restricting hazardous substances in electrical and electronic equipment (similar to REACH restriction):

- The process is initiated by the Commission on its own initiative or following submission of a proposal by MSs (Art 6(1)).
- Consultants perform a prioritisation to select substances.
- Consultants perform an in-depth assessment (determination of hazard profile + waste management issues + also some basic socio-economic assessment; it includes consultation of interested parties).
- Consultants make a recommendation whether the substance should be listed.
- The Commission drafts delegated act modifying Annex II (currently listing 10 substances with their maximum concentration values).

2. Reviewing exemptions from the restrictions (similar to REACH authorisation)

- Industry applies for the exemption (new, renewal or revocation). Exemptions are by technical application.
- Consultants evaluate the request for derogation and its justification vis-à-vis the conditions provided in Article 5(1)(a). It includes consultation of interested parties.
- Consultants make recommendation whether a derogation shall be granted (and for how long).
- The Commission adopts a delegated act modifying the Annexes III or IV.

Changes envisaged as part of reattribution: Yes

The Commission wishes to establish a Registry of intentions. It also wishes to address the current criticism on the process with regard to lack of transparency, predictability of duration of the processes and of the procedural steps, involvement of stakeholders, quality of the assessment process and required time. Alignment with other chemicals legislation is also desired.

Proximity to agency's mandate: The RoHS restriction process, although not identical, is similar to the REACH restriction process and the similar scientific methodologies can be applied. The RoHS exemption process, although not the same, resembles the authorisation process under REACH. The substances under scrutiny are the same or similar to those under REACH and existing ECHA data and processes can be reused for RoHS restriction dossier development, exemption process and opinion forming. ECHA holds the right competences to manage the process, however, does not yet have sufficient information on the exact use of substances in electronic equipment.

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already supports similar work on substance restrictions and exemptions under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk, exposure and socio-economic assessment - Committee opinion development - Existing IT capabilities for industry dossier submission, stakeholder consultation and dissemination
Re-use of	Medium	Reuse of substance identification and hazard data collected under

data		other chemical legislation. Currently low availability of data on substances in products and waste streams.
Workload balancing	Low	With an estimated workload of processing 27 exemption requests annually, while assessing one substance every year for the list of restricted substances, there is little room for workload balancing (and resource estimates are already annualised).
IT tools: automation and economies of scale	High	Industry actors can submit their exemption requests reusing existing ECHA submission tools, at the same time automating the existing process. In addition, reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	**Added value**	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of assessment insights developed under other chemical legislation.
Robustness of assessment and acceptance	High	Insourcing of scientific work from consultants to Agency experts. Additional involvement of RAC and SEAC committees adds more scientific robustness to the process. *(See also European Court of Auditors: External consultants at the European Commission - Scope for reform).*
Independence	High	Moving scientific work from consultants to Agency experts and committees. ECHA and its committees work under strict conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: No major concerns and there are certainly opportunities to find synergies with the REACH restriction/authorisation process.

Projected impact on agencies:

- ECHA Committees/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to the additional workload. The major impact is on SEAC committee.

	RAC			**SEAC**		
	# of opinions per year	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Restriction	1	RAC member		1	SEAC member	
Exemptions	3	RAC member		30	SEAC member	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks. The end of life of an electrical and electronic equipment is important in this work and the expertise will need to be built in this area.

Projected workload and resource implications:

Current workload and resource use:

Currently, there are 10 restricted substances. When the first directive was adopted in 2003, 6 substances were restricted. The 2011 revision of the directive introduced an obligation on the Commission to review and amend the list of restricted substances at the latest by July 2014 and periodically thereafter. In the first review, the Commission with the help of a consultant assessed 5 substances out of which four were added to the list of restricted substances in 2015 (Recital 10). The second review was launched in 2018 and assessed 7 substances (/groups), out of which 2 were recommended to be restricted. They have not been added to the list yet, as for one substance there is an assessment undergoing under the Stockholm Convention. Based on this information (12 substances (/groups) assessed in 12 years (2011 - 2023)), the current average workload can be estimated to be as 1 assessment of a chemical per year.

The second review which assessed 7 substances was supported by an external consultant contracted by DG ENV. The cost of the contract was ca. EUR 180 000 and it took 2 years. As the assessments are to be done ca. every 5 years, this indicates the current resources used for external support to be approximately 2.7 FTEs (EUR 180 000/66 000) for 7 substances for 5 years, i.e. 0.54 FTE annually.

There are 45 time-limited use exemptions (Annex III) and 48 exempted uses in medical devices or monitoring and control instruments (Annex IV) as current number entries. Each number entry however can cover several final applications, which can be categorised in different EEE categories (Annex I). Depending on the expiry date, exemptions can have up to four sub-entries for four groups of categories. By including these sub-entries, there are 238 valid exemptions (Status March 2023). In addition, a handful of exemption requests were assessed but no exemption was granted due to failure to meet the criteria.

The number of completed exemption evaluations, resulting in a published report, and the corresponding amount of resources required for external support varied depending on the year (see table below). Due to expiry dates of existing exemptions, there are many applications and evaluations

in certain years. On average, in the period between 2015 and 2022, there were 13.9 exemptions evaluated per year.

	2015	2016	2017	2018	2019	2020	2021	2022
Number of exemptions evaluated (date of publication of study)	2	38	4	11	2	9	0	45

The number and complexity of exemptions requests increased over the years and it created a backlog on evaluating exemption request and adopting respective individual delegated directives. The corresponding resources spent for external support for assessments of exemption requests in the years 2017-2022 were ca. EUR 145 000 per year (on average), or ca. EUR 12 000 per exemption assessment, or 2.2 FTEs per year (EUR 145 000/66 000) or 0.18 FTE per exemption assessment (EUR 12 000/66 000).

The current resources spent by the Commission can be summarized as follows:

DG ENV (for overall RoHS implementation)	Ca. 1.5 FTE (on average)
DG ENV consultants – support for restrictions	Ca. 0.54 FTE annually (a contract of EUR 180 000 on average each 5 years for reviewing restrictions)
DG ENV consultants – support for exemption evaluation	Ca. 2.2 FTE annually (contract for EUR 145 000 annually (average from 2017-2022) for outsourcing the technical evaluation of exemption requests)

(to convert the cost of consultants into FTEs, the cost of 1 FTE consultant is estimated at ca. EUR 66 000 annually)

It must be noted that these resource estimates do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.). It must be also noted that the resources spent by the Commission were not sufficient, leading to the accumulation of requests for exemptions without processing them to the legal drafting (currently 61 exemptions pending) and the revision of the restriction was delayed (the review not finalised although it has started in 2018). There were also complaints about the quality and robustness of the assessments, the transparency of the process and involvement of stakeholders.

Current budget line: DG Environment

Future workload and resource needs:

Restrictions can be proposed by Member States and Commission has a duty to periodically review the list of restricted substances. It is expected that the number of restrictions and underlying assessments will be the same as in the past, *i.e.* assessment of ca. 1 chemical per year.

Requests for exemptions are submitted by industry. As exemptions are time-bound, the workload volume is determined by the number of exemptions already in place and new requests coming in. When a new restriction is introduced, it leads temporarily to higher number of requests.

In the near future it is expected that the number of exemption requests will increase as compared to the past because in the past one exemption, which can be relevant for different final applications, had one expiry date regardless of their final application (e.g. in medical devices). With the introduction of splitting exemption entries depending on their final application, one previous exemption entry can

have now several different expiry dates. That means, the number of exemption requests can be multiplied provided there are different final applications and the industry is applying for renewal. In addition, in order to narrow down the scope of exemptions, exemptions are more and more split in more specified sub-exemptions, which should narrow down the covered applications and allow more specific decisions.

Not all exemptions are applied for renewal, but economic operators can submit also new exemption requests. It is expected that in the period of 2024-2025 there will be ca. 30 exemption requests per year to be evaluated – provided recommended exemptions with respective expiry date will be included.

For the future, the Commission (and stakeholders) also wishes to improve the procedure as regards transparency (establishment of a registry of intent), involvement of stakeholders, the level of scrutiny by the experts, robustness of the advice, independence of the advice and ensuring coherence with the assessments performed under the other pieces of legislation. This will increase the need for resources per exemption as compared to the past, but it is inevitable to address the concerns raised by the stakeholders and to ensure robustness and acceptance of the process.

To evaluate specific exemption requests, ECHA might still require external expertise from time to time (e.g. for assessing specific information about electronics). At the beginning, the need for external expertise may occur more frequently than at a later stage when experience has already been gained (e.g. with re-occurring renewal requests). However, it is expected that consulting external experts remains the exception. In addition, there will be a need to implement the procedure (e.g. by updating the guidance document for applications for an exemption). These irregular tasks depend on needs at that specific moment and they are predestined to be carried out by external consultants. In order to allow such ad-hoc tasks in the future, an operational budget is needed.

The future RoHS restriction process is assumed to be similar to REACH restrictions, with an average cost in ECHA of 1 (light dossier) – 1.5 (complex dossier) FTE / restriction dossier. As it is expected that in average there will be a need for 1 restriction dossier per year and the restriction dossiers will be likely light, it is estimated that there would be a need for additional 1 FTE per year.

The future process for assessing exemption requests is assumed to be similar to REACH applications for authorisations (~ AfA = 0.15 (light dossier) – 0.3 (complex dossier) FTE / application). It is expected that the RoHS exemption assessments are to require light assessment, thus 0.15 FTE per application. In addition, it is expected that RAC is consulted in 10% of the exemption applications and the work is estimated with 0.1 FTE per exemption. However, this additional resources for RAC can be absorbed by the Agency as part of the synergies with other work. In combination with the average of expected exemption requests (*i.e.* 30 exemptions per year), this would result in 4.5 FTEs per year.

The following resource estimates correspond to the "ECHA way", i.e. implementing similar processes and similar level of digitalisation to what is in place for ECHA's current tasks. Such examples would be the creation of registries of intentions and the dissemination of lists (exemptions, restrictions) as structured data.

- Development of 1 restriction dossier annually + opinion forming by RAC and SEAC: **1 FTE** (~ unit cost of 1 REACH restriction = 1 (light) to 1.5 FTE (complex))
- Review of 30 exemption applications annually + opinion forming of SEAC and for 10% of cases also by RAC: **4.5 FTEs**
- Scientific support services: substance identification and prioritisation of candidate substances, data management and dissemination: to be absorbed by the Agency
- IT tool development cost (industry and authority data submission, processing, output):

contribution of 15% for development and maintenance of common components (**0.8 FTE**)

- Horizontal support (governance & enablers / administrative overhead): contribution of 15% (**0.8 FTE**)
- Add-hoc support by external consultants (e.g. specific expertise): **EUR 66 000** in the first year and **EUR 33 000** in average in the following years.

Process	Tasks	Estimated workload volume	ECHA resource need
Restriction of substances in electronic appliances	- Substance prioritisation and data analytics - Restriction dossier development (ECHA secretariat) - Conformity check - Public/targeted consultation - Committee opinion development (incl. support by secretariat) - Data dissemination	1 additional restriction per year	**7 FTEs** (including IT tool development and administrative overhead)
Exemption requests	- Industry dossier intake - Completeness check - Public consultation - Committee opinion development (incl. support by secretariat) - Support COM during adoption of the IA - Data dissemination	30 exemption requests / year	

Summary of additional resource needs for restriction of hazardous substances (RoHS) directive:

Agency	**Summary of tasks**	**Resource needs**	
ECHA	- restriction of substances in electronic and electrical equipment (ca. 1 dossier per year) - assessment of exemption request (30 assessments per year)	Financial resource needs:	2024: **EUR 0** 2025: **EUR 66 000** 2026: **EUR 33 000** 2027: **EUR 33 000** 2028: **EUR 33 000**
		Human resource needs:	2024: **0 TA, 0 CA** 2025: **3 TA, 0 CA** 2026: **4 TA, 3 CA** 2027: **4 TA, 3 CA** 2028: **4 TA, 3 CA**

Future budget line: DG Environment

Candidate for fees: Yes, for assessment of exemptions

15. POPS REGULATION (2019/1021)

Responsible body:

Currently: Commission with the support of consultants

(Re-)attribution planned to: ECHA, EEA

Legal basis for reattribution: Omnibus regulation for reattribution of tasks

Type of task: existing

Brief task overview:

1. Assessments underpinning setting concentration limit values for substances subject to waste management provisions as part of the review of Annexes IV and V of the POPs regulation
2. Receiving chemical monitoring data of POPs as part of the regular reporting under the POPs regulation

Detailed process description:

Current process:

Task 1

For a substance added to Annex I (prohibition on manufacturing, placing on the market and use), Annex II (list of substances subject to restrictions) and as appropriate also for substances in Annex III (list of substances subject to release reduction provisions), limit values in Annex IV and V for these substances contained in waste need to be set, in order to ensure the environmentally sound management of waste consisting of or contaminated by this POP substance.

The concentration limit values set for waste containing POP substances directly affects the amounts of the concerned waste stream that can potentially be recycled, rather than being disposed of; a stricter limit value could even result in the cessation of recycling of the waste stream altogether. These limits are also very important in determing the possible disposal routes for waste (e.g. disposal in non-hazardous or hazardous waste landfills instead of incineration, admission in different types of incineration or co-incineration facilities. All these have relevant economic consequences for operators.

Two concentration limits are distinguished for POPs in waste:

- Low POP concentration limit (Annex IV): defines the concentration limit above which POPs content in waste shall be subject to destruction or irreversible transformation; this means the waste cannot be recycled and disposal options are limited to certain treatments (possible exceptions can be granted by Member States for certain wastes)
- Maximum POP concentration limit (Annex V): defines the threshold above which no derogation from the obligation to destroy or irreversibly transform the POP content can be granted

The need to act is triggered by inclusion of a substance in the Stockholm Convention, following which the process is initiated by the Commission: approx. 2-3 substances are identified as POPs under the Stockholm Convention every 2 years, but for the transposition into the POPs Regulation the Commission acts in five year cycles due to the heavy ordinary legislative procedure to add substances to Annexes IV and V of the POPs Regulation.

For existing limit values in Annex IV and V no standard review process exists, but the values need to be kept up to date in view of scientific and technical progress and revision clauses contained in the Regulation, for substances already listed, need to be observed.

Under the current practice, consultants perform a technical assessment (hazard, risk, socioeconomic aspects) for setting concentration limit values of the substance(s) in waste. This includes:

- Collection of data on hazard and risk of the substance: this is mostly taken from the Stockholm Convention listing exercise of the substance;
- Compilation of information for identification of presence and concentrations of the substance in different waste streams, and on recycling and other waste treatment activities involving waste containing this substance(s), followed by an analysis of the information. Starting from reported uses of this substance in products and articles and their material flows this includes a targeted

stakeholder consultation (Member States and other relevant stakeholders in particular waste operators and users of recycled materials)

- Application of an existing risk assessment methodology plus a socio economic assessment (no full socio-economic impact assessment) already developed by a consultant and applied in the past (not legally binding) regarding the implications on waste management of possible limit values for the substance in Annexes IV and V: different secenarios for delimination of the concentration range for a limit value are developed based on the application of lower and upper limitation criteria:
    - Lower limitation criteria:
        - Limit values must be controlable analytically,
        - Limit values should be above existing environmental background contaminations,
        - the new required capacities for waste recovery and disposal are realistically available, and
        - required additional waste management costs are economically reasonable
    - Upper limitation criteria:
        - Limit values should not conflict with existing limit values
        - Avoidance of adverse effects on HH (general population plus workers) and ENV
- Based on the analysis of the impacts for different options of the limit values provided by the contractor, the Commission (DG ENV) develops an impact assessment for the options of the limit values and decides on the preffered option. The impact assessemnt is scrutinised by the Regulatory Scrutiny Board;
- After the positive opinion of the regulatory scrutiny board, the Commission makes a proposal for amendment of Annexes IV or V
- The proposal is submitted to the ordinary legislative procedure that is followed from the Commission side by DG ENV.

Task 2

Article 10 requires the Commission, supported by ECHA, and Member States to establish or maintain, as appropriate, in close cooperation, appropriate programmes and mechanisms, consistent with the state of the art, for the regular provision of comparable monitoring data on the presence of substances as listed in Part A of Annex III in the environment. When establishing or maintaining such programmes and mechanisms, due account shall be taken of developments under the Protocol and the Convention. The Commission is also mandated to regularly assess the possible need for the mandatory monitoring of a substance listed in Part B of Annex III and empowered to move a substance form Part B of Annex III to Part A.

Annex III Part A currently contains polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and polychlorinated biphenyls (PCB). Part B currently contains hexachlorobenzene, polycyclic aromatic hydrocarbons, pentachlorobenzene, hezachlorobutadiene and polychlorinated naphthalenes.

Article 13(1)(e) requires Member States to draw up and publish a report containing information on the presence of substances listed in Part A of Annex III in the environment, as compiled pursuant to Article 10.

Article 13(2) states that where a Member State shares the information referred to in point (e) of paragraph 1 with the Information Platform for Chemical Monitoring, this shall be indicated by that Member State in its report and the Member State shall be considered to have fulfilled its reporting obligations under that point. Where the information referred to in point (e) of paragraph 1 is contained in the report of a Member State provided to ECHA, ECHA shall use the Information Platform for Chemical Monitoring for compiling, storing and sharing that information.

Changes in the process: Yes

Task 1

- It is expected that ECHA prepares a report with a technical assessment (hazard, risk, socioeconomic aspects) for setting concentration limit values of the substance(s) in waste and makes a proposal for the concentration limit values.
- Some detailed elements of the exising risk and socio-economic assessment methodology used so far, especially as regards risk assessment used to determine upper limitation criteir based on human and environmental health impacts, may need to be critically assessed and updated by ECHA.
- It is expected that ECHA's Committee for Socio-Economic Assessment (SEAC) provides an opinion on the report prepared by ECHA and on the concentration limit values proposed by ECHA.
- The report and the opinion of SEAC is then transmitted by ECHA to the Commission. If significant divergence exists between the ECHA report and the SEAC opinion, ECHA submits to the Commission an explanation of the divergence.
- Based on the ECHA report and SEAC opinion, the Commission drafts a proposal for a delegated act amending Annexes IV or V.
- The procedure would be triggered on request of the Commission to ECHA; the request is expected to come as a follow up to the Stockholm Convention amendments.

Task 2

As part of the legislative proposal on data, the operation of the Information Platform for Chemical Monitoring is to be incorporated into the operation of the Common Data Platform on Chemicals and hosting of the collected monitoring data shall be done by the Agencies according to their mandates. This means that EEA will host all monitoring data in the environment.

To reflect the change of the situation with hosting the data and operation of IPCHEM, there is a need to change the process in POPs regulation. Therefore, Member States can make the relevant data available to the European Envrionment Agency instead of the IPCHEM and when done so, the reproting obligatio under Article 13 (1)(e) shall be considered fulfilled. When ECHA receives such monitoring data, it shall provide it for hosting to EEA instead of IPCHEM.

It shoud be noted that proposal for revision of water legislation requires Member States to share with EEA all monitoring data in waters. When adopted and enforced, EEA would have practically all monitoring data in the environment and thus the reporting under POPs would be fulfilled.

Proximity to Agencies' mandate:

ECHA (Task 1): Some aspects could be quite similar to that performed by ECHA under REACH restrictions (environmental and human health risk assessment + socio-economic analysis), although technical waste-related aspects need to be considered more (e.g. recycling targets and technical limitations).

EEA (Task 2): The task of hosting chemical monitoring data in the environment is a key part of the EEA mandate and thus the new task fits very well with its mandate. The existing tools and practices can be reused.

Projected synergies and added value of the reattribution:

Task 1 (ECHA):

Type	Synergies

Reuse of capabilities	High	Process and expertise: ECHA already supports other work under the POPs Regulation and performs similar work on restrictions, setting of limit values and assessing socio-economic impacts under REACH and other legislation. Several key capacities can be reused/reinforced: – Hazard, risk, exposure and especially also socio-economic assessment – Exposure limit value definition – IT capabilities for stakeholder consultation and dissemination
Re-use of data	Low	Reuse of data collected under other chemical legislation, but low availability of data on substances in products and waste streams.
Workload balancing	Medium	In a 5-year cycle, the workload of Agency experts and Committee experts can be balanced (although resource estimates are already annualised).
IT tools: automation and economies of scale	Low	Not an IT-intensive process, but reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. , prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation. Reuse of data collected under other chemical legislation.
Robustness of assessment and acceptance	High	Insourcing of scientific work from consultants to Agency experts. *(See also European Court of Auditors: External consultants at the European Commission - Scope for reform).*
Independence	High	Moving scientific work from consultants to Agency experts . ECHA works under strict conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA works fully transparent: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status

		- Dissemination of scientific data and outcomes

Task 2 (EEA):

Type	Synergies	
Reuse of capabilities	High	Process and expertise: EEA already collects and host the chemical monitoring data in the environment. Several key capacities can be reused/reinforced: – Collection and reporting tools – Network of Member States experts on data in the environment
Re-use of data	High	Reuse of data collected under water and air legislation
Workload balancing	High	The workload can be integrated in the existing processes and can be spread over time as necessary.
IT tools: automation and economies of scale	High	The existing reporting tools and IT capabilities used for water and air legislation (Reportnet 3.0) can be fully reused after small adaptation.
Support services: economies of scale	High	Reuse of scientific support services and data dissemination. Reuse of administrative services.

Type	Added value	
Scientific consistency	High	Opportunity to align the formats and storing practices and thus ensure interoperability.

Main risks and opportunities:

Task 1: The risk assessment to be applied for the development of concentration limits is a mixture of hazard and socio-economic analysis with a strong focus on technical waste-related aspects, for which ECHA does not have a ready expertise. Commission and other stakeholders would benefit from ECHA's extensive knowledge on hazard and risk assessment as well as of socio-economic analysis; As production shifts from primary to secondary raw materials, it would be an opportunity for ECHA to better understand the related hazards and risks as substances/materials re-enter supply chains under REACH jurisdictions or, when this is not possible, are disposed of in an environmentally sound manner, as waste.

Task 2: If and when the legislative proposal on revision of water legislation made in October 2022 will be adopted, there is an opportunity to completely abandon the reporting of monitoring data under the POP regulation as the data will be reported under new provisions of water legislation. There is a clear opportunity from consolidating the chemical monitoring data in the environment and humans in EEA.

Projected impact on Agencies:

ECHA (Task 1):

- ECHA Committees/bodies: **medium impact.** The task generates medium impact on the setup / organisation / staffing of Committees/bodies due to the additional workload The task requires involvement of SEAC committee

	RAC			**SEAC**		
	# of opinions per year	**rapporteur**	**Type of opinion**	**# of opinions per year**	**rapporteur**	**Type of opinion**
Setting waste limit values in Annex IV and V	0			2	ECHA	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks. New expertise will need to be built to cover waste management.

EEA (Task 2):

- EEA Committees/bodies: **no impact**. The task does not require involvement of EEA Committees/bodies
- EEA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- EEA key experts: **low impact**. The task relies on the expertise that already exists in the agency.

Workload and resource implications:

<u>Current workload and resource use:</u>

Currently, there are 25 limit values for individual substances or groups of substances. The workload driver is adding substances to the Stockholm Convention (new POP is also new entry here). The experience shows that about 2 substances are added to Stockholm Convention every 2 years. Another workload driver are review clauses that are added to substances, usually to be reviewed after 5 years. This depends on the initiative of the Commission. Changes in exemptions may also influence the need for an Annex IV review (due to changes in Annex A or B of the Stockholm Convention), but not so often. For both, reviews and changes in exemptions, the workload is lower compared to developing limit values for new substances as all the basic work has already been done.

For the latest proposal to amend Annexes IV and V of the POP Regulation, COM (2021) 656 final, DG ENV used circa EUR 200 000 (but also relied on a preceding study of ca. EUR 100 000 covering hazard / risk aspects) for the support study for the impact assessment with proposals for limit values for 8 substances:

- 3 new and recently listed substances to the Stockholm Convention
- 1 substance that was under consideration by the POP Review Committee of the Convention as a candidate (and which was added to Annex I in June 2022)
- 2 substances already listed in the Annex IV POP Regulation for review
- 2 substances already listed in the Annex IV POP Regulation for adaptation to scientific

and technical progress

20 % of the budget for this support study was dedicated to the update of information on mass flows associated with the POP substances in question and their presence in waste (earlier reports already identified these mass flows). 60 % of the budget for this support study was dedicated to the (i) compilation of information in support of the IA, (ii) stakeholder consultation activities, (iii) comparative assessment of the impact for each concentration limit option and (iv) the proposal and justification of the low POP concentration limits for the 8 substances. One desk officer in DG ENV worked on this task 50% for 3 years, plus contractors 3 staff for 1 year. The final impact assessment was written by the DG ENV staff member. DG ENV staff involvement further includes process until adoption by the College (RSB submission, ISC, etc) and involvement in the co-decision process (multiple interactions with the Working Party for the Environment of the Council, interaction with MEPs and MEP assistants in the ENVI Committee and participation in trilogues).
The current resources spent by the Commission can be summarized as follows:

DG ENV	0.5 FTE per year
DG ENV consultants	4.5 FTEs (EUR 300 000 for consultants) every 3 years (i.e. 1.5 FTE per year)
Total	***Ca.* 2.0 FTEs annually**

(to convert the cost of consultants into FTEs, the cost of 1 FTE consultant is estimated at ca. EUR 66 000 annually)

It should be noted that such Commission resources do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.).

Current budget line: DG Environment

Future workload and resource needs:

Task 1

It is expected that the number of substances added to the Stockholm Convention will continue to be about 2 substances every 2 years, or 1 substance per year on average. Based on current review commitments established in review clauses in the POPs Regulation, it is expected that about 5 reviews of existing limit values will be necessary every 5 year, i.e. on average 1 review per year.

The Commission wishes to change the procedure for amendment of Annexes IV and V from ordinary legislative procedure to delegated act to reduce the administrative burden on the EU institutions and to make the procedure proportional to its impact.

In order to have a scrutiny of socio-economic impacts of the chosen limit values robust and of high quality, the Commission wishes to get an opinion of the Committee for Socio-Economic Analysis on the proposed limit values, based on a prior ECHA report.

The process would be to some extent similar to REACH restrictions with limit values or to the setting the Occupation Exposure Levels, with an average cost in ECHA of 1 (light dossier) – 1.5 (complex dossier) FTE / restriction dossier, but only with the scrutiny by SEAC and not by RAC. The detailed resource needs estimation for ECHA is as follows:

- On average there is a need to develop 1 new dossier every year + SEAC opinion forming: 1 FTE/year, as there is no involvement of RAC (because most of the hazard assessment work has been done already at the Stockholm Convention level and the unit cost of 1 REACH

restriction are approximately 1 (light dossier) to 1.5 (complex dossier) FTEs)

- Review of existing 5 substance limit values every 5 years, or on average 1 substance every year (at 50% effort of full new dossier) = 0.5 FTE / year
- Scientific support services: substance identification and prioritisation, data management and dissemination: additional work to be absorbed by the Agency
- IT tool development cost (data submission, processing, output): contribution of 15% for common components (0.25 FTE per year)
- Horizontal support (governance & enablers / administrative overhead): contribution of 15% (0.25 FTE per year)

Total: 2 FTEs per year

Task 2

The reporting of chemicals monitoring data under POPs regulation will require no or only very minimal additional resources, as POPs monitoring data in waters are to be reported under the water legislation and resources for that were proposed, POPs monitoring data in air are already being reported to EEA as part of the air quality legislation and there are only very limited additional data sets in the environment, mainly in soil which is usually collected by JRC. In addition, hosting of any additional data sets in the environment is also covered in the resource for common data platform.

Summary of additional resource needs for the POPs regulation:

Agency	**Summary of tasks**		
ECHA		Financial resource needs:	2024: **EUR 0** 2025: **EUR 35 000** 2026: **EUR 50 000** 2027: **EUR 50 000** 2028: **EUR 50 000**
		Human resource needs:	2024: **0 TAs**, **0 CAs** 2025: **1 TAs, 0 CAs** 2026: **2 TAs, 0 CAs** 2027: **2 TAs, 0 CAs** 2028: **2 TAs, 0 CAs**
EEA		Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 TAs, 0 CAs** 2025: **0 TAs, 0 CAs** 2026: **0 TAs, 0 CAs** 2027: **0 TAs, 0 CAs** 2028: **0 TAs, 0 CAs**

Future budget line: DG Environment

Candidate for fees: No

16. MEDICAL DEVICES REGULATION

Responsible body:

Currently: Commission with the support of the SCHEER Committee

(Re-)attribution planned to: ECHA

Legal basis for (re-)attribution: Omnibus regulation for reattribution of tasks

Type of task: existing

Brief task overview: (1) Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of phthalates in medical devices; (2) Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of CMR and endocrine-disrupting substances in medical devices. (3) Ad hoc requests for opinion on safety of a chemical in medical devices (not part of the proposal but possible based on general clause in ECHA founding regulation).

Detailed process description:

Current process:

Article 5 paragraph 2 of the Regulation 2017/745 on medical devices stipulates: "A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose." Accordingly, Section 10.4 of Annex I, which deals with substances in medical devices, states that "Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device." Particular substances of concern are those which (a) are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, or (b) have endocrine-disrupting properties (ED).

The Regulation further states that:

"Devices, or those parts thereof or those materials used therein that:

- are invasive and come into direct contact with the human body,
- (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

shall only contain any such substance above the concentration of 0.1% weight by weight where justified pursuant to Section 10.4.2. The justification shall be based on several elements, including the latest relevant scientific committee guidelines, if applicable and available."

Specifically for phtalates, according to Section 10.4.3, the Commission shall provide a mandate to the relevant scientific committee to prepare such guidelines for phthalates which are subject to these provisions. These guidelines are explicitly requested by the Regulation to be available at the latest on the date of application of the Regulation, and are to be updated whenever appropriate on the basis of the latest scientific evidence, or at least every five years. In its latest guidelines of 2019, the SCHEER recommended that "Pending on new scientific evidence, it is recommended to evaluate the use and usefulness of these Guidelines after an application period of three years."

The Regulation also includes the option for the Commission to mandate the relevant committee to prepare guidelines on other CMR and endocrine-disrupting substances, where appropriate.

Upon request by DG SANTE, the guidelines and opinions are produced by the relevant committee (SCHEER). The process includes public consultation. Opinions are delivered to the Commission who publishes them. The list of recent SCHEER opinions is https://health.ec.europa.eu/scientific-committees/scientific-committee-health-environmental-and-emerging-risks-scheer/scheer-opinions_en

The first guideline on how to perform the benefit-risk assessment of the presence of phthalates in medical devices was prepared by SCHEER committee on request of the Commission in 2019. The

guideline is available here and an example of benefit/risk assessment opinion on a substance (DEHP) is available here.

There was no request for the preparation of the guidelines on how to perform the benefit-risk assessment of the presence of CMR and endocrine-disrupting substances in medical device and no such guidelines exists.

Changes in the process: Yes

The Commission would request ECHA to prepare or review the guidelines on how to perform the benefit-risk assessment of the presence of CMRs, endocrine disruptors and phthalates. The guideline would be developed or reviewed by ECHA secretariat and when appropriate or when requested by the Commission, ECHA will consult the Committee for Risk Assessment and the Committee for Socio-Economic Analysis.

The process would follow a standardised procedure, including most likely the following steps:

- The Commission issues the request for an opinion
- Substance identification and prioritisation
- Dossier preparation (by ECHA staff) with risk assessment, including
    - Hazard/risk assessment
    - Exposure assessment
    - Assessment of alternatives
- Call for evidence/public consultation
- Potentially RAC opinion development
- Potentially SEAC opinion development

Proximity to ECHA mandate: The development of the guidelines on how to perform the risk-benefit analysis for the use of substances fits well with the mandate of ECHA, which develops various guidelines for industry for the implementation of REACH (e.g. guidelines on risk assessment of chemicals, guidelines on assessment of alternatives of chemicals, guideline on socio-economic assessment).

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and CMRs under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk, exposure and socio-economic assessment - Committee opinion development - IT capabilities for stakeholder consultation and dissemination (including regulatory intentions)
Re-use of data	High	Reuse of data collected under other chemical legislation, especially also on substances in products such as medical devices via the SCIP database.
Workload balancing	Medium	In a 5-year cycle, the workload of Agency experts and Committee experts can be balanced (although resource estimates are already annualised).
IT tools:	High	Not an IT-intensive process, but reuse of IT capabilities for case

automation and economies of scale		management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under other chemical legislation.
Robustness of assessment and acceptance	High	Centralising scientific work from dispersed Commission services and committees to one central EU Agency and its experts. Involvement of ECHA's scientific committees adds more scientific robustness to the process.
Independence	High	Moving scientific work from dispersed Commission services and committees to Agency experts and well-established committees in the European Chemicals Agency with a stricter separation between science and policy. ECHA and its committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Projected impact on ECHA:

- ECHA Committees/bodies: **low impact**. The task generates low impact on the setup / organisation / staffing of Committees/bodies. The involvement of committees is on ad hoc basis, maximum one opinion every 5 years
- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **medium impact**. The task relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Workload and resource implications:

Current workload and resource use

The SCHEER Committee has worked on six chemical-related medical device opinions in the period 2014-2022 (i.e. average of 1 opinion every 2 years):

Medical Devices	
Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties	June 2019
Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk	Feb 2016
Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users	Apr 2015
Opinion on the safety of surgical meshes used in urogynaecological surgery	Dec 2015
Opinion on the safety of the use of bisphenol A in medical devices	Feb 2015
Opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants	Sept 2014

The DG SANTE Secretariat covers both SCCS and SCHEER tasks and consists of 4 FTE from the Commission staff + 2 FTE from an outsourced contract (EUR 250 000 annually) for technical and administrative support (literature search, editing and proofreading of opinions, website mastering, assistance for the Health-EU newsletter, dissemination activities), equally split over both committees. The SCHEER committee itself consists of 17 external experts. The advice on chemicals in medical devices can be roughly estimated to constitute ca. 10 % of the work of the SCHEER committee (4 out of 29 opinions during 2015-2022), which corresponds to ca. 0.3 FTE (10% of 3 FTEs from SCHEER secretariat).

The operational costs for two committees (that includes special indemnities, accommodation, daily allowances, travel costs, reimbursement for rapporteurship, etc) operated by the Commission were EUR 2 883 030 for 6 years (2016-2021), which makes it approximately EUR 240 000 per year per committee. It must be noted that the operational costs in 2019 were EUR 340 000, which then went down because of the pandemic measures. The workload of SCHEER dedicated to support of medical devices regulation amounts to 10% of its time, which corresponds to operational costs of EUR 24 000 (or at higher level of 2019 to EUR 34 000).

The DG SANTE medical device unit spends, according to its own accounts, 0.1 FTE annually on following up on such scientific opinions requested from SCHEER.

The current resources spent by the Commission can be summarized as follows:

DG SANTE (policy unit)	0.1 FTE per year
DG SANTE (Committees unit, including external support)	0.3 FTE (10% of the SCHEER secretariat) Operational costs ca. EUR 24 000/year (at peak EUR 34 000/year)
Total	***Ca.* 0.4 FTEs annually**

It should be noted that such Commission resources do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.).

Current budget line: Budget line of DG SANTE (EU4Health programme)

Future workload and resource needs:

The review of the guidelines on how to performing risk-benefit analysis of use of phthalates in medical devices is due in 2024. It will be still reviewed by the SCHEER committee, the work has started in April 2023. The next review will be due in 2029.

The Commission does not envisage in the near future asking for the guidelines on how to perform risk-benefit analysis of use of CMRs and ED in medical devices.

ECHA resource needs would be as follows:

- Development of a guideline for performing risk-benefit assessment of the presence of phthalates in certain medical devices every 5 years, including, where requested or appropriate, scientific committee opinion forming: 0.2 FTE (~unit cost of 1 REACH restriction = 1 (light dossier) – 1.5 (complex dossier) FTE)
- Development of a guideline for performing risk-benefit assessment on the use of CMR and endocrine-disrupting substances or other ad hoc mandate on chemicals in medical devices every 5 years: 0.2 FTE (~unit cost of 1 REACH restriction = 1 – 1.5 FTE)
- Scientific support services: substance identification and prioritisation, data management and dissemination: contribution of 0.1 FTE based on the size of the task
- IT tool development cost (data submission, processing, output): contribution of 15% for common components (0.1 FTE)
- Horizontal support (governance & enablers / administrative overhead): contribution of 15% (0.1 FTE)

Total: 0.7 FTEs

Considering that the envisaged frequency of the work is very low, the involvement of the Committees is only where necessary, the first work will likely materialise only in 2029, the work can be absorbed by the agency without any additional resources.

Summary of additional resource needs for the medical devices regulation:

Agency	**Summary of tasks**		
ECHA	- Guideline on phthalates - Guideline on CMRs or EDs	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 FTE** 2025: **0 FTE** 2026: **0 FTE** 2027: **0 FTE** 2028: **0 FTE**

Future budget line: DG SANTE

Candidate for fees: No

17. EEA FOUNDING REGULATION (1210/90)

Responsible body:

Currently: EEA

(Re-)attribution planned to: EEA, expanding the existing tasks

Legal basis for reattribution: omnibus regulation on reattribution of task

Type of task: New

Brief task overview:

1. Developing methodologies for assessment related to chemicals in the fields falling within its mission
2. Cooperating with other agencies as regards exchange of data, defining formats and controlled vocabularies and development of methodologies related to chemicals.

Detailed process description:

Current process:

Task 1

EEA has some very specific tasks with some relevance to the development of methodologies mentioned in the current founding regulation. These are:

(iv) to help ensure that environmental data at European level are comparable and, if necessary, to encourage by appropriate means improved harmonization of methods of measurement;

(viii) to stimulate the development of methods of assessing the cost of damage to the environment and the costs of environmental preventive, protection and restoration policies;

(xii) to support the Commission in the process of exchange of information on the development of Environmental Assessment methodologies and best practice;

EEA however lacks the mandate and obligation to develop methodologies and for the assessment related to chemicals. This disadvantages the EEA as compared to other agencies.

Task 2

The EEA founding regulation contains some provisions related cooperation. The Article 15 states:

1. The Agency shall actively seek the cooperation of other Community bodies and programmes, and notably the Joint Research Centre, the Statistical Office and the Community's environmental research and development programmes. In particular:

- cooperation with the Joint Research Centre shall include the tasks set out in the Annex under A,
- coordination with the Statistical Office of the European Communities (Eurostat) and the statistical programme of the European Communities will follow the guidelines outlined in the Annex under B.

2. The Agency shall also cooperate actively with other bodies such as the European Space Agency, the Organization for Economic Cooperation and Development, the Council of Europe and the International Energy Agency as well as the United Nations and its specialized agencies, particularly the United Nations Environment Programme (UNEP), the World Meteorological Organization and the International Atomic Energy Authority.

2a. The Agency may cooperate in areas of common interest with those institutions in countries which are not members of the European Communities which can provide data, information and expertise, methodologies of data collection, analysis and assessment which are of mutual interest and which are necessary for the successful completion of the Agency's work.

3. The cooperation referred to in paragraphs 1, 2 and 2a must in particular take account of the need to avoid any duplication of effort.

The Annex A to the regulation lists some areas for cooperation with JRC:

A. Cooperation with the Joint Research Centre

- Harmonization of environmental measurement methods (1).
- Intercalibration of instruments (1).
- Standardization of data formats.
- Development of new environmental measurement methods and instruments.
- Other tasks as agreed between the Executive Director of the Agency and the Director-General of the Joint Research Centre.

The existing provisions do not give an explicit mandate nor obligation to EEA to cooperate with ECHA, EMA and EFSA in those areas. In order to achieve the one substance, one assessment ambition, it is necessary to strengthen the provisions on cooperation.

Future process:

Task 1:

EEA will have a mandate to develop methodologies for the assessments related to chemicals it performs and it will develop such methodologies based on its needs.

Task 2:

EEA actively cooperates with ECHA, EFSA and EMA as regards:

- exchange of data on chemicals and defining formats and controlled vocabularies for such data
- development of methodologies related to chemicals,
- operation of early warning system for chemicals
- operation of framework of indicators of chemical policies

The cooperation is foreseen both ways, i.e. when EEA itself makes some development in those specified areas within its domain as well as when EFSA, ECHA and EMA make some development in those areas within their domains. The goal is to ensure coherence, consistency and interoperability in the specified areas.

Proximity to Agency mandate: Both tasks fit well with the mandate of EEA as both tasks target the areas of the EEA mandate.

Projected synergies and added value of reattribution: Improving coherence, consistency and interoperability among the Agencies work is the key added value.

Projected impact on EEA:

- EEA Committees/bodies: **no impact**. The task does not involve the committee/network.
- EEA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- EEA key experts: **low impact**. The task relies on expert competencies, but the task is limited and spread over time in its nature.

Workload and resource implications:

Future workload and resource needs:

The work on the new tasks is limited and spread over time in it is nature. On a need basis, it requires that EEA will develop methodologies for the assessment it performs as regards chemicals. The development and setting the methodology is a standard practice for whoever performs the assessments, so this task can be seen as a formalisation of existing EEA work. There is no need for additional resources for this task.

EEA will also need to cooperate with ECHA, EFSA and EMA in the areas on data, formats, methodologies, early warning system and indicator framework. The need for additional resources for cooperation on these are already covered under the legislative proposal on data (operation of common

data platform, operation of early warning system and operation of indicator framework) and there is no need for additional resources on this general formal mandate for agency to cooperate.

Summary of additional resource needs for EEA founding regulation:

Agency	Summary of tasks		
EEA	- Development of methodologies for assessments related to chemicals within its missions - Cooperation with ECHA, EFSA, EMA on issues related to chemical	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 FTE** 2025: **0 FTE** 2026: **0 FTE** 2027: **0 FTE** 2028: **0 FTE**

Future budget line: DG Environment

Candidate for fees: No

18. GENERAL FOOD LAW (178/2002)

Responsible body:

Currently: EFSA

(Re-)attribution planned to: EFSA, expanding and modifying the existing tasks

Legal basis for reattribution: omnibus regulation on reattribution of task

Type of task: New

Brief task overview:

1. Developing methodologies for assessment of chemicals in the fields falling within its mission
2. Cooperating with other agencies as regards exchange of data, defining formats and controlled vocabularies, development of methodologies related to chemicals
3. Preventing and solving divergent opinions on chemicals with ECHA and EMA

Detailed process description:

Current process:

Task 1

EFSA has a very clear tasks in Article 23 to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission. The mandate is sufficient and no change is required.

Task 2

The EFSA founding regulation contains some provisions related to cooperation. The Article 22 that defines the mission of EFSA states:

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.
   It shall act in close cooperation with the competent bodies in the Member States that carry out similar tasks to those of the Authority and, where appropriate, with the relevant Union

agencies.

The existing provisions are rather general. In order to achieve the one substance, one assessment ambition, it is necessary to strengthen the provisions on cooperation.

Task 3

EFSA founding regulation specifies provisions for preventing and solving divergent scientific opinions with other agencies. Article 30 states:

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.
2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.
3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.
4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

The provisions need to be aligned with those for other agencies. In addition, there is a need to strengthen the requirement to solve the divergent view by agencies among themselves, before the matter is referred to the Commission to be solved.

<u>Future process:</u>

Task 1:

The existing mandate for development of methodologies is sufficient and no change is required.

Task 2:

EFSA actively cooperates with ECHA, EEA and EMA as regards:

- exchange of data on chemicals and defining formats and controlled vocabularies for such data
- development of methodologies related to chemicals,
- operation of early warning system for chemicals
- operation of framework of indicators of chemical policies

The cooperation is foreseen both ways, *i.e.* when EFSA itself makes some development in those specified areas within its domain as well as when EEA, ECHA or EMA make some development in those areas within their domains. The goal is to ensure coherence, consistency and interoperability in the specified areas.

Task 3:

EFSA and body concerned shall first attempt to solve the divergent opinion on scientific or technical issues by themselves. They shall revert the decision to the Commission only if they were not able to solve the issue. In addition, if the divergence come from different hazard identification or characterisation, then the Commission shall request ECHA to prepare a proposal for harmonised classification under the CLP regulation.

Proximity to Agency mandate: The tasks fit well with the mandate of EFSA as both tasks target the areas of the EFSA mandate, and they are just improvement of existing tasks.

Projected synergies and added value of reattribution: Improving coherence, consistency and interoperability among the Agencies work is the key added value.

Projected impact on EFSA:

- EFSA Committees/bodies: **low impact**. The task might require some ad hoc involvement of committee/panels or their consultation.
- EFSA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- EFSA key experts: **low impact**. The task relies on expert competencies, but the task is limited and spread over time in its nature.

Workload and resource implications:

Future workload and resource needs:

EFSA will need to cooperate with ECHA, EEA and EMA in the areas on data, formats, methodologies, early warning system and indicator framework. The need for additional resources for cooperation on these are already covered under the legislative proposal on data (operation of common data platform) or they are already within the mandate of EFSA (early warning system). Consequently, there is no need for additional resources on this general formal mandate for Authority to cooperate.

EFSA will need to try to solve any divergence in technical or scientific issue with the other agency. EFSA already has such obligation in the existing regulation. The new task will require that the agencies make more effort to solve the issue among themselves, instead of just forwarding the problem to the Commission. Although it might require slightly higher amount of work by the Authority as compared to today, such situations are rare and therefore this can be absorbed by the Authority without any additional resources.

Summary of additional resource needs for General Food Law regulation:

Agency	Summary of tasks		
EFSA	- Cooperation with ECHA, EFSA, EMA on issues related to chemical - Preventing and solving divergent opinions or assessments	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 FTE** 2025: **0 FTE** 2026: **0 FTE** 2027: **0 FTE** 2028: **0 FTE**

Future budget line: None

Candidate for fees: No

19. EU COMMON DATA PLATFORM ON CHEMICALS

Responsible body:

Currently: N/A, no current process

(Re-)attribution planned to: ECHA, EFSA, EMA, EEA, EU-OSHA, JRCLegal basis for reattribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data

platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: new (new infrastructure but building on existing data and services)

Brief task overview: Setting up and operation of the common data platform on chemicals.

Detailed process description:

The principal aim of this new IT infrastructure operating as part of the Green Deal Data Space is to support effective and coherent chemical safety assessments. It will provide integrated, user-differentiated and highly functional access to chemicals-related datasets owned or managed by EU agencies and IPCHEM (see section 18 below) and provide space for dedicated services supporting EU chemicals policy and legislative implementation. Those dedicated services include the provision of information on the obligations under EU acts on chemicals (see section 23), a repository of reference values (see section 22), information on regulatory processes on chemicals (see section 21), information platform for chemical monitoring (see section 20) and the database on environmental sustainability related information on chemicals (see section 24). An integral aspect of the platform is its governance, ensuring continuous evolution and relevance through the inclusion of further functionalities, datasets and services (e.g. on academic studies) and ensuring support to the thriving ecosystem of services outside the platform.

Current process:

A comprehensive assessment of the status of the chemicals data landscape was made in a feasibility study on a common open data platform[58]. There is a large amount of chemicals data in databases, much of it compiled following legal provisions and used in the regulatory processes but also disseminated by EU agencies and the Commission for transparency and public use. Comprehensive IT development has been taking place in the agencies, optimising tools applied to internal data within the sectors, at least in specific circumstances also using common building blocks (e.g. IUCLID for information on chemical hazards). IPCHEM (see section 20) has been developed for use across sectors but is limited to chemical occurrence data.

Effective common access to different types of chemicals data across those solutions has however not been made available and is therefore also not systematically applied in EU chemicals assessments, also as any ad hoc integration is hampered by different conditions of use, differences in data formats and applied controlled vocabularies, not least for chemical substance identification.

There is inefficiency and duplication as individual projects repeat the same efforts merging and curating certain data across sectors for specific needs such as the validation of predictive tools. There is also a loss of coherence or there is even divergence between assessments of the same or similar substances or groups of substances due to differences in the datasets used.

Changes envisioned as part of setting up the common data platform

The feasibility study on a common open data platform on chemical safety data has already identified the steps needed to establish the platform and based on the input by various stakeholders identified a set of use cases that could be prioritised for the initial implementation of the platform, with the functionalities and datasets to be integrated. The work in the study has been validated by the experts responsible for the datasets considered for initial integration in the platform: a dedicated interservice team led by ECHA, identified as the appropriate host for the platform.

[58] Feasibility study on a common open platform on chemical safety data - Publications Office of the EU (europa.eu)

The team turned it into a practical 3-year development and operations roadmap, and quantified resources in the Project Initiation Document. It can be summarised around three main headlines:

- design and construction of a **data container**: the technical platform solution and the data definitions and ingestion mechanisms that enable it to receive data. While ECHA is responsible for the IT infrastructure of the data container, cooperation (and – depending on the data type – lead) by the other agencies in setting the data definitions and supporting the general governance of the platform on aspects such as the determination of basic functionalities (ingestion, use and outputs, dedicated services featuring in the platform) and further evolution is essential.
- The **data content** activities: data transformation, curation and confidentiality assessment. Upload of every integrated dataset will, while based on commonly agreed rules and vocabularies, and supported as appropriate with ingestion tools, remain the responsibility of the data source owners (i.e. agencies), unless explicitly agreed otherwise. For data source owners, this work will overlap with work on standard data formats and controlled vocabularies of own datasets. Preparation of **dedicated services** available in the platform will include both work on technical platform functionality as well as on data content. Currently, identified services (covered separately in the sections below) include: platform on chemicals monitoring (transfer of current IPCHEM), repository of reference values, information on obligations under EU acts on chemicals (expansion of current EUCLEF), information on regulatory processes (expansion of current PACT), repository of standard data formats and controlled vocabularies and database on environmental sustainability related data.

The comprehensive roadmap of the Project Initiation Document includes a detailed list of 32 deliverables on content (in addition to 8 deliverables related to project management), planned across the three years of development. Herein some highlight on the extent of planned minimum viable product (MVP):

- Improving the quality of assessments and facilitating a one substance-one assessment approach is the principal supported **use case**; other use cases include the improvement of quality of safety information and data, grouping and prioritisation of chemicals, enhancing knowledge building through sharing of research outcomes (solution under development), provision of methods and standards.

- The container/content approach to the development of the **technical platform** will be automated to the extent possible, using existing 'building blocks' i.e. relevant services provided by the cloud platform. It will follow the "intentional architecture, emergent designs" principle, leading to a container with availability of all necessary networking and development services in the public cloud, with the necessary management tools, identity rules, enforceable policies and security controls, and a modular and extensible character for further evolution of e.g. analytical functionalities.

- Each dataset planned for integration will be prepared for ingestion into the platform by:
    - Basic curation / profiling / metadata according to platform requirements
    - Mapping and conversion to agreed formats, use of controlled vocabularies
    - Incorporation of agreed substance identifiers, controlled vocabularies and tagging
    - Allocation of confidentiality levels / user groups (in MVP, confidential data should be filtered before being disseminated through the platform)
    - Quality control after conversion
    - Mechanisms for (periodic) ingestion by the platform; updates, versioning

- The following datasets will be included in the MVP integration:
    - **ECHA REACH:** REACH registrations including Chemical Safety Reports (CSR). This dataset already features IUCLID formatted data covering substance information,

physico-chemical properties, (eco)toxicological data, environmental fate and use information for more than 24 000 unique substances.

- **ECHA Classification, Labelling and Packaging (CLP):** Classification and labelling (C&L) inventory. Based on industry C&L notifications for more than 200 000 substances and EU harmonised classifications for ca. 4 600 substances. The C&L inventory is based on a IUCLID C&L format and structured metadata.
- **ECHA Biocidal Products Regulation (BPR):** biocidal active substance approval process data features more than 900 active substance-product type combinations. The authorised biocidal products dataset contains over 6 000 approved products. The process information is in a structured format but assessment reports, opinions etc. are included as attachments. The conversion of SPCs (summary of product characteristics) IUCLID format is underway.
- **ECHA Prior Informed Consent (PIC)**: Substances subject to PIC the Regulation (ca 260 listed substances or substance groups).
- **ECHA Persistent Organic Pollutants (POP)**: 1) list of POPs, featuring 30 substances or substance groups; 2) list of substances proposed to be included in the POP list of the Stockholm Convention.
- **EFSA OpenFoodTox:** summary of all EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs.
- **EFSA Chemical Monitoring Data:** Chemical monitoring data for pesticides and veterinary medicinal product residues and contaminants data. The individual measurements of chemicals in food/feed and other materials sampled as part of official controls and enforcement activities in SSD2 format. Sampling by member states is legally mandated under Regulation (EU) 2017/625 and associated implementing acts. Additionally, measurements of chemicals in food and feed received from industry or other sources in response to call for data. This data is available in IPCHEM.
- **EFSA OpenEFSA: A**ll information related to EFSA's scientific work. Tracking of the risk assessment process from receipt of dossier to adoption of the opinion. Information available includes status of assessments, dossiers and studies, meeting agendas and minutes, information on experts (DOIs), public consultations).
- **EFSA EU_PPP Agency IUCLID:** IUCLID dossiers submitted by applicants (industry) under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. Four submission types are supported, EU PPP Active substance, EU PPP Microorganism, EU PPP Maximum Residues Levels, EU PPP Basic substance.
- **EEA Air Quality:** The EEA gathers air quality data from a wide range of sources including current status of Europe's air quality through five different air pollutants (European Air Quality Index), latest measurements from Europe's air quality monitoring network and Statistics for air pollutants calculated from officially-verified country data for years until 'X-2'.
- **EEA Waterbase Water Quality:** The dataset contains time series of concentrations of nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters. This database also contains the records reported under the Water Framework Directive Watch List for chemicals in surface waters.
- **EEA Waterbase emissions:** The dataset contains time series of emissions of nutrients and hazardous substances to water, reported by EEA member countries and cooperating countries. It also contains data on yearly riverine input loads to transitional, coastal and marine waters.

- **EEA Industrial emissions:** The data set contains data reported by Member States in the scope of the E-PRTR Regulation and Industrial Emissions Directive. The data is reported annually and includes releases to air/water/land and pollutant transfers of 91 pollutants and waste transfers of hazardous and non-hazardous waste (facilities in the scope of E-PRTR); environmental permit information, application of best available techniques (BAT) conclusions, inspections and other information on IED installations; air emissions, operating hours and energy input from large combustion plants; and nominal capacity from waste incinerators. This data is contained within the same database. The information is displayed in the European Industrial Emissions Portal and the full database is published on the EEA data service in access format, with some extracts published as Excel spreadsheets.
- **EEA National Emission reductions Commitments (NEC) Directive emission inventory data:** Data on emissions of air pollutants (ammonia (NH3), non-methane volatile organic compounds (NMVOC), nitrogen oxides (NOx), particulate matter 2.5 (PM2.5) and sulphur dioxide (SO2)) reported annually by Member States to the European Commission (with copies to EEA) under Directive 2016/2284 of the European Parliament and of the Council on the reduction of national emissions of certain atmospheric pollutants.
- **EMA human medicinal products data** (environmental risk assessment and non-clinical safety data)
- **EMA veterinary medicinal products** (environmental risk assessment and maximum residue limit (MRL) values and MRL assessment data)

- **IPCHEM (JRC)**: the existing platform for chemical occurrence data in its function and with data will be integrated into the common data platform in two steps (see also section 18). Its data is structured into four modules, according to the chemical monitoring data categorisation: Environmental monitoring, Human Bio-Monitoring, Food and Feed, and Products and Indoor Air.

- Further datasets to be integrated are identified also as **dedicated services** as they include the need for preparation and curation:
  - **Regulatory processes information:** 9 different ECHA processes and related regulatory process data are currently included ECHA's Public Activities Coordination Tool (PACT), providing an overview of substance-specific activities. The scope of the tool under the platform (see section 19) will include contributions by all the agencies.
  - **EU Chemicals Legislation Finder (EUCLEF):** An overview of the European Union's legislation on chemicals. This existing service by ECHA will in future be included under the platform (see section 23). It currently contains 51 pieces of legislation and is integrated in ECHA's substance database. For each piece of legislation included in EUCLEF, a summary is provided containing the scope, obligations, exemptions, regulatory activities and lists of impacted substances, together with links to the full legal texts in all EU languages. The data management of EUCLEF data is outsourced by ECHA to a service provider.
  - **Repository of reference values:** reference values covered by the datasets described above will be made available from the moment the datasets are ingested in the platform. The outcome of the related **Health-based limit value repository (HBLVR)** study will inform when and in which format the additional datasets could be incorporated in the platform.
  - **Formats and controlled vocabularies:** agreed rules will be effectively shared on the platform itself for integration purposes but also for use beyond the platform. This dataset will include the work of (common) substance identification that can be then used across any substance-specific chemical datasets.

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- Introducing principal data-related dimension of the current **European Observatory for Nanomaterials (EUON)** in the common data platform has been agreed through identification of the observatory as one of further dedicated services on the platform, allowing it also to expand to other chemicals/materials selected to benefit from such additional compilation.
- As part of the new study notification mechanism, a database of study notifications will be established and accessible through the common data platform.

Proximity to the mandate of the EU agencies: While ECHA's core mandate is focused on the safety assessment of chemicals, it also includes the dissemination of information on chemicals and, as expressed in its vision, being 'the centre of knowledge on the sustainable management of chemicals'. A better sharing of data between EU authorities can contribute to the success of ECHA's core mandate. There is a similar proximity in the mandates of the other agencies involved in the development and operation of the platform through collaboration on the interoperability of their respective data to be integrated in the platform. The use of shared data can contribute to the success of their core mandates when tasked with assessments involving chemicals.

Projected synergies and added value of (re)attribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA and other agencies already support similar work on data dissemination under REACH and other legislation. Several key capacities can be reused/reinforced: - IT capabilities for data integration and public and confidential data dissemination - IT capabilities for data submission and publication of regulatory intentions - solutions of the chemicals legislation finder and chemical occurrence data IPCHEM
Re-use of data	High	Reuse of data collected under other chemical legislation to populate the new platform aimed to facilitate re-use by ECHA and other agencies (as well as other users).
Workload balancing	Low	With IT development work clearly defined in a 3-year project plan and after that a running phase with much less resources, there is a clear resource plan and little or no room for workload balancing (and resource estimates are already annualised).
IT tools: automation and economies of scale	High	Reuse of IT capabilities for regulatory intentions management and data dissemination building blocks. ECHA is also required to build an EU repository of reference values and manage the chemicals legislation finder, building on existing tools.
Support services: economies of scale	High	Reuse of scientific support services (e.g. substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value

Scientific consistency	High	Opportunity to improve data sharing between EU authorities to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under several chemical legislations.
Robustness of assessment and acceptance	High	Centralising all data on chemicals in one central EU platform will broaden the knowledge base and improve the robustness of the scientific advice provided to the Commission; re-use of (same) data will facilitate acceptance of conclusions.
Independence	Low	/
Transparency	High	Centralising all data on chemicals in one central EU platform will help to improve: - Overall process transparency for EU chemicals legislation - Predictability for industry stakeholders thanks to the publication of regulatory intentions - Dissemination of scientific data and outcomes

Main risks and opportunities:

- Risks: Complex IT project with many stakeholders. Needs robust governance, clear roles and responsibilities, resources and funding. Legal text needs to include legal basis for ECHA to build and host and govern the platform and for other EU authorities a legal obligation to provide data.
- Opportunities: The proposal for a regulation establishing a common data platform and a monitoring and outlook framework for chemicals should take away barriers to sharing (confidential) data and support its re-use. Opportunities include also further benefits arising from coordinated development of IT services between agencies and a frame that will facilitate the evolution of existing and the development of new digital services and application of artificial intelligence based on chemicals data (e.g. predictive tools, safe and sustainable by design).

Projected impact on agencies:

- Committees/bodies of the agencies: **no impact**. The task does not require the involvement of committees /bodies
- Data model(s) and IT infrastructure: **high impact**. The task requires investment in entirely new data structures and IT systems/capabilities, principally on ECHA's side but also on the side of data source owners preparing datasets for integration into the common data platform
- Key experts: **high impact**. The task relies heavily on expert competencies; while an important segment of preparing the IT solutions can be outsourced, work on internal data linkages and rules supporting integration will rely on internal experts, which are limited within the agencies and also critical to ensure continuity of ongoing regulatory tasks

Projected workload and resource implications:

There are extensive resources already employed in current IT/data infrastructures of the agencies, and in the planning of the (re)attribution of tasks an IT overhead is considered to ensure the tasks are adequately supported. It is expected that some reattribution will take place to optimally exploit synergies with the work on the common data platform. That platform is however a new infrastructure that in spite of longer-term benefits such as an increased effectiveness of tasks and efficiencies of

individual IT solutions (formats, vocabularies, reusable building blocks, addressing at least part of dissemination expectation etc.) requires investment to be developed, to prepare the datasets in adequate formats and to cover necessary overhead for operations. For dedicated services described separately in specific sections below, only a summary of the resource estimation is given as a repetition, in order to avoid potential double counting.

Estimates for agencies are made on the basis of the datasets identified to be included in the MVP (see above) and the current state of the dataset and under the assumption that ECHA develops and hosts the common data platform.

The estimation of workload/resources required is targeting different aspects of the platform's lifecycle:

Work description	**Who**	**Resource needs estimate**
Development of the platform (including infrastructure costs until go-live)		
Project management Infrastructure setup Governance setup and operation Coordination of and consultation on common data formats, rules and controlled vocabularies, functionalities and platform evolution (future planning)	ECHA, EFSA, EEA, EMA, EU-OSHA, COM incl. JRC	Development by 2027; development duration 3 years for years 2025, 2026, 2027, annual estimates of staff expenditure, with possible outsourcing and IT costs, one-off: ECHA: Staff 8.5 FTE (includes supervision of subcontracting); EUR 1 500 000 EFSA: Staff 1.5 FTEs; EUR 320 000 EEA: Staff 1.5 FTE EMA: Staff 1.5 FTEs EU-OSHA: Staff 0 FTEs JRC: see IPCHEM below; existing staff, EUR 60 000 per year, included in existing IPCHEM support Note: estimate includes any infrastructure -specific work related to the dedicated services of the common data platform.
Preparation for integration of selected datasets (1st time)		
Basic curation / profiling / metadata Mapping and conversion to agreed formats, use of agreed substance identifiers, controlled vocabularies and tagging, quality control Confidentiality levels/user groups/filtering Mechanisms for (periodic) ingestion by the platform; updates, versioning For dedicated services: preparation of datasets and functionalities	ECHA, EFSA, EEA, EMA, EU-OSHA COM incl. JRC	Development by 2027; development duration 3 years for years 2025, 2026, 2027, annual estimates of staff expenditure, with possible outsourcing and II costs, one-off: ECHA: Staff 1.5 FTE (includes supervision of subcontracting); EUR 170 000 EFSA: Staff 3.5 FTEs; EUR 350 000 EEA: Staff 1.5 FTE; EUR 200 000 EMA: Staff 1.5 FTE; EUR 100 000 EU-OSHA: Staff 0 FTE JRC: see IPCHEM below; existing staff, EUR 120 000 per year, included in existing IPCHEM support

		Note: estimate includes any dataset-ingestion specific work related to the dedicated services (preparation of all MVP identified services attributed to ECHA).
Operation of the platform after 3-year development phase, including infrastructure costs after the go-live	ECHA, EFSA, EEA, EMA, EU-OSHA COM incl. JRC	Recurrent costs, annual estimates of staff expenditure and costs: ECHA: Staff 4 FTE; EUR 600 000 EFSA: Staff 2 FTE; EUR 500 000 EEA: Staff 1 FTE; EUR 200 000 EMA: Staff 2 FTE; EUR 0 EU-OSHA: Staff 0 FTE Note: IPCHEM would be fully integrated, the majority of its data managed by EEA, and part by ECHA. Also includes evolution for at least 1 low and 1 medium complexity project (see below).

In total, the development of the platform and the integration of the datasets identified in the MVP is estimated to require 21 FTEs and ca. EUR 2 823 000 annually in the first 3 years, and recurrent operational requirements at the level of 9 FTEs and EUR 1 300 000 annually afterwards.

Summary of additional resource needs for the common data platform on chemicals:

Agency	**Summary of tasks**		
ECHA		Financial resource needs:	2025: **EUR 0** 2026: **EUR 2 226 000** 2027: **EUR 2 793 000** 2028: **EUR 600 000**
		Human resource needs:	2025: **4 TA, 6 CAs** 2026: **4 TA, 6 CAs** 2027: **4 TA, 6 CAs** 2028: **4 TA, 0 CAs**
EEA		Financial resource needs:	2025: **EUR 0** 2026: **EUR 266 000** 2027: **EUR 334 000** 2028: **EUR 200 000**
		Human resource needs:	2025: **1 TA, 2 CAs** 2026: **1 TA, 2 CAs** 2027: **1 TA, 2 CAs** 2028: **1 TA, 0 CAs**
EFSA		Financial resource needs:	2025: **EUR 670 000** 2026: **EUR 670 000** 2027: **EUR 670 000** 2028: **EUR 500 000**
		Human resource needs:	2025: **0 TA, 5 CAs** 2026: **0 TA, 5 CAs** 2027: **0 TA, 5 CAs** 2028: **0 TA, 2 CAs**
EMA		Financial resource needs:	2025: **EUR 100 000** 2026: **EUR 100 000** 2027: **EUR 100 000** 2028: **EUR 0**
		Human resource needs:	2025: **0 TA, 3 CAs** 2026: **0 TA, 3 CAs** 2027: **0 TA, 3 CAs** 2028: **0 TA, 2 CAs**

EU - OSHA		Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2025: **0 FTE** 2026: **0 FTE** 2027: **0 FTE** 2028: **0 FTE**
JRC		Financial resource needs:	2025: **EUR 180 000** 2026: **EUR 180 000** 2027: **EUR 180 000** 2028: **EUR 0**

Future budget line: DG Environment, DG SANTE

Candidate for fees: No

20. INFORMATION PLATFORM FOR CHEMICAL MONITORING (IPCHEM)

Responsible body:

Currently: Commission (JRC), EFSA and EEA

(Re-)attribution planned to: ECHA (operation and maintenance of IPCHEM, hosting occupational monitoring data), EEA (for collecting and hosting human biomonitoring data (HBM), hosting environmental occurrence data and indoor air quality data), EMA (providing relevant data), EU-OSHA (providing relevant data)

Legal basis for (re-)attribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: Existing

Brief task overview:

1. Overall operation and maintenance of the Information Platform for Chemical Monitoring (IPCHEM) and provision of data to be shared via IPCHEM.
2. Collection and hosting of human biomonitoring data
3. Hosting of environmental occurrence data
4. Hosting of indoor air monitoring data
5. Hosting of occupational monitoring data
6. Providing relevant data

Detailed process description:

Current process:

IPCHEM provides centralised, readily available and automated access to chemical monitoring data held by the European Commission, European agencies, Member State Bodies, Research Centres and Academic Institutions. It provides chemical monitoring data and information of defined quality in terms of spatial, temporal, methodological and metrological traceability as well as a reporting tool for chemical monitoring data (see https://ipchem.jrc.ec.europa.eu).

IPCHEM is a functioning platform hosted and operated by JRC on request of DG ENV. EEA, EFSA and JRC are involved in the operation of the platform as module coordinators and as data providers. Work on IPCHEM is included in the work programme of the agencies.

IPCHEM is currently structured into four thematic modules:

- Module for environmental occurrence data;
- Module for food and feed occurrence data;
- Module for human biomonitoring data;
- Module for product and indoor air data. It should be noted that for this module only the indoor air part is developed and populated with data; templates for metadata and data are developed.

As described in the IPCHEM governance paper, the IPCHEM governance framework involves many actors with multiple roles, who are involved in many ways at different levels, requiring strong interactions and collaboration.

These actors are: Policy Lead, Scientific and Technical Lead, Module coordinators, Data providers and Partners/collaborators.

JRC currently has the scientific and technical lead of IPCHEM, with the main responsibilities of:

- Developing and maintaining the IPCHEM platform infrastructure, functionality and security;
- Coordinating technical development and facilitating harmonisation (standardisation) of metadata and data reporting;
- Data integration and liaison with data providers;
- Contribution to exploitation of IPCHEM for policy priorities;
- Promoting IPCHEM by facilitating its use through technical guidance;
- Supporting and guiding module coordinators;
- Strategy formulation and priority setting.

The four modules are coordinated by different actors, based on the best match of the thematic area with ongoing activities. Current coordinators are EFSA for food and feed, EEA for environment and human biomonitoring and JRC for indoor air and products. The responsibilities of the module coordinators focus on:

- Identifying important data sets and data providers;
- Supporting the evolution of metadata and data templates in the thematic area;
- Contributing to the utilisation of IPCHEM for addressing policy questions;
- Liaison with data providers;
- Promoting IPCHEM as policy/regulatory support tool.

The table below describes the four categories of data included in IPCHEM, the associated data sources and updating frequency, actors involved in the data integration process outside the IPCHEM team, to which extent data formats are already harmonised and possible future entities to take care of these data flows:

	Source of data	**Regular updates**	**Current players in data handling**	**Standard formats**	**Frequency of related requests to integrate such data into IPCHEM**	**Future expected requests**	**Possible future handling (EU-CDPC data provider)**
1	MS	Yes	through agency (EEA, EFSA)	Highly standardised for food and feed Standardised to some extent for environ. Data	6 datasets with annual updates contributing most to the number of records in IPCHEM	Increasing number, getting more structured	EU agencies

2	MS	Yes	Direct interaction with national agency	Well managed data sets but all in different formats	7 datasets with regular updates, contributing substantially to the number of records in IPCHEM + indoor air data and occupational monitoring data* from MS in the pipeline	moving more towards category 1 with these data	EU agencies
3	EU funded research projects	No	Individual projects or Cluster level data WG	Less standardised, all different; but reaching more harmonisation in Clusters recently	10 EU projects already included + 4 new large EU projects or Clusters in the pipeline	Remaining at similar level, e.g. an average 2-3 research clusters supported in parallel	**
4	National or regional research projects	No or very low frequency	Direct interaction with research organisation	Less standardised, all different	~6 datasets (encouraged in the beginning to populate IPCHEM, now not promoted any more)	Decreasing trend, less relevant for the future	**

Changes in the process:

ECHA shall operate and maintain IPCHEM as part of the common data platform on chemicals. In addition, ECHA will be required to host and maintain occurrence data related to workplace monitoring.

EEA will be responsible for collecting and hosting the human biomonitoring data and for hosting environmental monitoring data and indoor air data currently collected or hosted by JRC as part of IPCHEM.

IPCHEM will be integrated in the common data platform with its functionalities and data representing part of Minimum Viable Product.

The required tasks are divided according to the container-content concept. The container considers the IPCHEM platform with its data management structure and user interface, while the content refers to the monitoring data contained in the four IPCHEM modules, based on data already included and on anticipated future data needs.

Regarding the content, the four categories of data included in IPCHEM, the associated data sources and updating frequency, actors involved in the data integration process outside the IPCHEM team, to which extent data formats are already harmonised and possible future entities to take care of these data flows are shown in the table above.

Regarding the container, the term refers to the IPCHEM platform with its architecture, data management structures and user interface.

In the process of integration into the common data platform on chemicals, the data management structure is considered separately from the user interface.

1. **User interface**: The current user interface of IPCHEM was built over many years, is difficult to maintain and also not entirely fit for purpose to address all relevant envisaged uses and search types of IPCHEM.
   It is therefore proposed to re-build the user interface in the context of the integration into the common data platform. The prototype user interface developed by the JRC IPCHEM team in June 2022 should be considered as a starting point and to help estimate the resources needed. The new user interface implementation is expected to be driven by the IPCHEM and the common data platform's use cases involving monitoring (occurrence) data.
2. **Data management structure:** IPCHEM has a generalised structure, that aims to accommodate the monitoring data regarding different media and coming from several data providers. The

current harmonisation process encompasses all the transformation steps required from the source data structure to the IPCHEM harmonized one. Two different record layouts are enforced, one for the individual measurement type of datasets and the other for the statistical type of datasets; in both cases, only a common subset of the data is harmonised, and quality checked, while the remaining information provided are encapsulated as-is into a generic field called source data, using the JavaScript Object Notation (JSON) format as a convenient yet flexible vehicle.
IPCHEM has two sub-systems: IPCHEM Portal is the subsystem providing access to the harmonised and integrated data, while IPCHEM Share is the subsystem providing the file-sharing feature, compliant with the requirements defined by JRC Local Informatics Security Officer for the secure hosting of sensitive non classified data (e.g. two-factor authentication, encryption at rest, token secured application programming interface (API), etc.).
It is advised to preserve this current structure of the system, in the transfer to the common data platform. The IPCHEM team is preparing detailed documentation and can support the hand-over.

A 2-step approach is proposed as the most efficient way of integrating IPCHEM into the common data platform:

1st phase (months 1-12): making monitoring data from IPCHEM findable via the common data platform, and preparatory work for functionality handover (co-work JRC/ECHA)

Aims:

- IPCHEM extended team contributes to the work on data, in particular the selection of substance identifiers and the selection of the supported format for inclusion of monitoring (occurrence) data.
- IPCHEM data contribution to the common data platform is analysed (data governance and policy) in accordance with the legislative proposal on data
- IPCHEM extended team carries out a study to make metadata and data available in IPCHEM more FAIR, including harmonisation of module specific metadata and data fields with the common data platform requirements (point above), including in the preparation for the anticipated future data providers to the platform for individual datasets
- Linking IPCHEM to the common data platform via metadata and substance identifiers; substance search will bring back links to IPCHEM datasets with the metadata description in agreed format[22]
- Analysis (container/functionality handover), identification of use cases, implementation planning

Tasks

1. IPCHEM/EU-CDPC linking:
    a. Analysis and design for the integration of:
        i. Substance identity
        ii. Harmonised metadata (common to all modules)
    b. Implementation
        i. Preparation of SID translation tables, metadata for IPCHEM datasets
        ii. accessibility of harmonised metadata, as designed in [a.ii.](automated approach)
    c. Testing
    d. Maintenance/Servicing
2. Handover preparation IPCHEM/common data platform
    a. Analysis and design:
        i. Evaluation of the IPCHEM data governance within the common data platform (to/with platform data providers, existing IPCHEM datasets and future updates, possible use of DIGIT's hosting facilities)
        ii. FAIR evolution of the IPCHEM platform for better data harmonization and reuse:

1. Definition of harmonised formats including module specific metadata and data fields for monitoring (occurrence) data, part of joint WA3 initiative
2. Solution design for managing harmonised module specific metadata and data fields

iii. Strategy definition for IPCHEM functionalities handover to the common data platform, including the secure sharing facilities (aka IPCHEM Share), the dataset integration software procedures, and identifying the user interface capabilities that are required by the platform's use cases involving monitoring (occurrence) data (possible use of DIGIT's hosting facilities)

b. Governance aspects, data management

Resource needs 1st phase

- Platform development (60K)
  - 1 developer full time for 8 months for complementing in IPCHEM the information and formatting required for the linking with the common data platform, in addition to what is already available in the public repository (https://ipchem.jrc.ec.europa.eu/public), or in the IPCHEM share subsystem (https://ipchem.jrc.ec.europa.eu/share via secure API); this encompasses possible enhancements (e.g. JSON-LD / RDF metadata format, DCAT-AP service, etc.) to make the system more FAIR;
- Handover preparation (120K)
  - 1 analyst, expert in chemicals monitoring in charge of supporting substance identification and metadata and data harmonisation (in close collaboration with module coordinators) for 12 months
  - 1 regulatory expert to prepare the adoption of more harmonised formats and perform impact assessment (on the common data platform, data providers and modules coordinators) for 12 months

2nd phase (months 12-36): IPCHEM full integration into the common data platform

Aims:

- Single interface to IPCHEM data through common data platform
- IPCHEM functionalities are gradually handed over to the platform
- A new governance is put in place incorporating harmonisation and regulatory updates
- Data flow is established between the data providers (agencies) and the platform

Tasks

1. Supporting the common data platform occurrence data governance implementation and IPCHEM functionalities transfer to the platform
   a. Data Management
      i. Defining a new data governance
      ii. Defining a new data policy
      iii. Planning IPCHEM data management handover
   b. Implementation
      i. Supporting the implementation of IPCHEM functionalities in the platform, including the rebuilding of the user interface with up-to-date technologies, to best address the platform's uses cases involving the monitoring (occurrence) data;
      ii. Implementing IPCHEM data management handover
   c. Testing
   d. Maintenance/Servicing

i. Provisioning of support to data providers for transitioning to platform data submission

2. Implementing more rich and FAIR metadata and data formats
   a. Supporting ECHA in the design
3. Implementing business analytics features, starting from the platform's use cases involving the monitoring data
   a. Supporting ECHA in the design

Resource needs 2nd phase

- Platform development (100K)
  - 1 developer full time for 18 months for fully integrating IPCHEM metadata and data into the common data platform
- Dataset preparation (220K)
  - 1 data analyst, expert in chemicals monitoring, in charge of enhancing the IPCHEM metadata and data formats (i.e. to make metadata and data more rich and FAIR), for 24 months
  - 1 regulatory expert to prepare full transfer of the data management process (data policy, governance, data flows, etc.), for 18 months

Proximity to agencies' mandate:

- While ECHA's core mandate is focused on the safety assessment of chemicals, ECHA's mandate includes the dissemination of information on chemicals. A better sharing of data between EU authorities can contribute to the success of ECHA's core mandate. As ECHA is tasked to operate the common data platform on chemicals, the operation of IPCHEM and its integration into that platform fit well with ECHA existing tasks.
- EEA already acts as a module coordinator for human biomonitoring and thus hosting of human biomonitoring data would fit with the existing mandate of EEA. Hosting human biomonitoring data, environmental monitoring data and indoor air quality data fits well into EEA work on human health and the environment, as the data provides a good basis for the assessment of environmental impacts on human health.
- ECHA is currently performing scientific assessments underpinning the setting of occupational exposure limit values so hosting occupational monitoring data fits well with its mandate.

Projected synergies and added value of (re-)attribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already supports similar work on data dissemination under REACH and other legislation. ECHA is also tasked to develop and operate the common data platform on chemicals. Several key capacities can be reused/reinforced: - IT capabilities for data integration and public and confidential data dissemination - IT capabilities for data submission and publication of regulatory intentions - Development and operation of the common data platform on chemicals EEA already hosts environmental occurrence data and has a deep expertise in collecting and hosting the data.

Re-use of data	N/A	N/A
Workload balancing	Low	With the IT development work clearly defined in a 3-year project plan and after that a running phase with much less resources, there is a clear resource plan and little or no room for workload balancing (and resource estimates are already annualised).
IT tools: automation and economies of scale	High	Reuse of IT, reporting and hosting capabilities.
Support services: economies of scale	High	Reuse of scientific support services and of administrative services.

Projected impact on agencies

- Committees/bodies: **low impact**. The task does not require involvement of agencies' committees /bodies. EEA might use their networks for collecting human biomonitoring data
- Data model and IT infrastructure: **high impact**. The task requires investment in data structures and IT systems/capabilities
- Key experts: **high impact**. The task heavily relies on expert competencies, but these are present in the agencies.

Workload and resource implications:

Current workload and resource use:

JRC has a total of 4.5 FTE (2.5 JRC staff, 2 external consultants intramuros) assigned to the IPCHEM operation. There are also resources allocated to the contribution to IPCHEM in the work programmes of EFSA and EEA.

The current resources spent by the Commission can be summarized as follows:

DG JRC	4.5 FTE per year (2.5 JRC staff and 2 external consultants intramuros)
Yearly IT maintenance costs from JRC corporate hosting facility	EUR 11 700 per year
Total	**4.5 FTEs annually**

Current budget line: DG JRC institutional work programme

Future workload and resource use:

The integration of IPCHEM into the common data platform, the continuous provision of data by the agencies to the IPCHEM and coordination/cooperation among the agencies is included in the resource estimates under the common data platform on chemicals. The integration will be done jointly by JRC and ECHA. ECHA will take over the operation of IPCHEM from JRC and will take over hosting of occupational monitoring data. For this ECHA will need 2 FTEs. In addition, EEA will take over from JRC collection and hosting of human biomonitoring data and hosting of IPCHEM environmental occurrence data and indoor air monitoring data. For this, EEA will need 1 FTE per year. EFSA already provides data to IPCHEM and contributes to its operation and will not require any additional

resources to continue in this activity. EMA and EU-OSHA currently do not systematically collect or receive data relevant for IPCHEM and therefore will not require any additional resources.

Summary of resource needs for maintaining IPCHEM and its parts after its integration into the common data platform on chemicals:

Agency	Summary of tasks		
ECHA	Operation and development of IPCHEM Collecting and hosting occupational monitoring data	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 180 000** 2028: **EUR 180 000**
		Human resource needs:	2025: **0 TA, 0 CAs** 2026: **1 TA, 1 CAs** 2027: **1 TA, 1 CAs** 2028: **1 TA, 1 CAs**
EEA	Collecting and hosting human biomonitoring data, developing a data model and creating a reporting structure to host human biomonitoring data. Hosting indoor air data Collecting and hosting environmental occurrence data	Financial resource needs:	2025: **EUR 0** 2026: **EUR 200 000** 2027: **EUR 200 000** 2028: **EUR 50 000**
		Human resource needs:	2025: **1 TA, 0 CAs** 2026: **1 TA, 0 CAs** 2027: **1 TA, 0 CAs** 2028: **1 TA, 0 CAs**
EFSA EMA EU-OSHA	Provision of occurrence data Cooperation and coordination on IPCHEM	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**

Future budget line: DG Environment

Candidate for fees: No

21. INFORMATION ON REGULATORY PROCESSES ON CHEMICALS

Responsible body:

Currently: ECHA (existing (P)ACT), EFSA (existing OpenEFSA)

(Re-)attribution planned to: ECHA, EFSA EEA and, EU-OSHA

Legal basis for (re-)attribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: Existing but expanded to cover all chemical sectors

Brief task overview: (1) Operating (public) activities coordination tool; (2) notifying relevant information to the (public) activities coordination tool

Detailed process description:

Current process:

The Activities Coordination Tool and its public counterpart, (P)ACT, are two existing information systems developed and operated by ECHA which provide an up-to-date overview of all planned and ongoing initiatives on chemicals by authorities under REACH and CLP. The information is provided in user-friendly tables and is regularly updated. The information is provided by authorities and includes information on authorities' actions (intention/on-going/finalisation) relevant for an assessment process.

ACT helps authorities to coordinate their work by providing information on planned, ongoing or completed substance-specific activities. PACT (public ACT) ensures transparency of regulatory safety assessment work. It gives the public an 'early warning' of the substances that are on an authority's radar for exploring the need for regulatory risk management and provides a more holistic picture of what is going on under different regulatory processes. The processes and legislation already covered by (P)ACT are indicated in the table below.

Through a recent project, ECHA reviewed the tool to improve its efficiency and functionality and to allow extension to further processes under its remit.

EFSA, as part of their existing activities, also provide some level of digital transparency on their planned, ongoing and concluded assessments, as part of their general OpenEFSA portal. The portal provides access to information related to EFSA's scientific work, tracking of the risk assessment process from receipt of a dossier to adoption of the opinion. Information available includes: status of assessments, dossiers and studies, meeting agendas and minutes, information on experts (DOIs) and public consultations. The OpenEFSA portal is similar to PACT. The OpenEFSA portal does not have a confidential 'ACT' part. The processes and legislation already covered by OpenEFSA are indicated in the table below.

Metadata and formats behind both IT tools are not easily comparable, but a lot of work has already been put in the organisation of this information and in building processes to keep updating the systems.

<u>Changes in the process:</u>

To promote the coordination of safety assessment activities across EU legislation, the 'one substance, one assessment' approach considers progressively expanding the existing (P)ACT from including REACH and CLP regulations to including all relevant chemicals legislation with safety assessment processes and initiatives.

ECHA will operate an extended (P)ACT service, starting with a similar functionality of the existing tool but addressing processes across all the sectors where chemical assessments are performed. ECHA will provide relevant information into (P)ACT for all the processes from legislation for which ECHA is or will be an assessment body. EFSA will provide to ECHA for integration into (P)ACT the relevant information for all the processes from legislation for which EFSA is an assessment body and that are already covered in the OpenEFSA portal. In other words, EFSA is toensure that OpenEFSA information feeds into the (P)ACT and is further complemented for confidential part on intentions, where relevant. Finally, EEA and EU-OSHA will provide to ECHA for integration into PACT any relevant information for the process from legislation for which EU-OSHA is an assessment body. The processes and legislation to be included in the extended (P)ACT are identified in the table below. The extended (P)ACT will be available as a specific service under the common data platform (dedicated service on 'information on regulatory processes on chemicals'), with the identification of individual processes as well as associated datasets (starting with substance identification) covered by the controlled vocabularies. The service will maintain the differentiated authorities/public access, with up-to-date public information on declared registries of intent, status of assessment in progress and outcomes (including documentation) once concluded. Authorities will have access to further

categories and datasets for informing on preliminary intent supporting exchange and coordination as appropriate, and where relevant access to working material during the process. The governance will be done through the governance of the common data platform on chemicals.

To control complexity, a solution as regards the update of the information in the platform, maintenance of relevant lists, metadata and supporting datasets will need to be prepared by the agencies involved as principal actors in particular processes, even for cases where further actors may be involved or even ultimately responsible for the process outcome (e.g. national authorities).

Overview of legislation and processes included or to be included in (P)ACT (referred to as 'information on regulatory processes on chemicals' as the dedicated service in the common data platform on chemicals):

Legislation	**Processes already covered or to be included in ACT** **(ACT covers also intentions)**	**Processes already covered or to be included in PACT** **(PACT covers the ongoing processes)**
Legislation already covered in (P)ACT		
Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency	- Screening - Dossier evaluation - Substance evaluation - ED, PBT identification - RMOA - SVHC identification - Annex XIV - Application for authorisation - Restriction	- - Dossier evaluation - Substance evaluation - ED, PBT identification - RMOA - SVHC identification - - - Restriction
Regulation (EC) 1272/2008 on classification, labelling and packaging of chemicals of substances and mixtures	- CLH	- CLH
Regulation (EU) 2019/1021 on persistent organic pollutants	-	- Proposal for listing - Limit values (UTC, low POP content)
Legislation for which discussions for inclusion in (P)ACT are ongoing		
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products	Discussions are ongoing: - Evaluation of active substance - Opinion of BPC on active substance approval	
Legislation identified to be included in (P)ACT and for which ECHA is or will be an assessment body		
Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work	- Setting EU OELs; - Setting national OELs	
Directive 98/24/EC on the protection of workers from the risks related to chemical agents at work	- Setting EU OELs - Setting national OELs	

Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos	- Setting new EU OELs
Stockholm Convention on persistent organic pollutants	- Intention to nominate a substance as POP
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	- Review of exemptions
Directive 2000/53/EC on end-of life vehicles	- Review of exemptions
Proposal for a Regulation concerning batteries and waste batteries	- Restriction process
Directive 2008/105/EC on environmental quality standards in the field of water policy	- EQS derivation EU and national - addition/removal of substance to watch list
Directive 2006/118/EC on the protection of groundwater against pollution and deterioration	- Limit value derivation EU and national? - Addition/removal of substance to watch list
Directive (EU) 2020/2184 on the quality of water intended for human consumption	- Safety assessment of contact materials
Regulation (EC) No 1223/2009 on cosmetic products	- Safety assessment;
Directive 2009/48/EC on the safety of toys	- Safety assessment;
Legislation identified to be included in (P)ACT and for which EFSA is an assessment body and information is included in OpenEFSA	
Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety	- To be included (relevant processes to be identified)
Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food - Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food - Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food - Commission Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods - Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs - Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food - Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food	- Safety assessment

Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs Commission Directive 93/11/EEC concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers	
Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings **Regulation (EC) No 1333/2008 on food additives** **Regulation (EC) No 1332/2008 on food enzymes** **Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods** - Commission Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings	- Safety assessment
Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients	- Safety assessment
Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food - Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs - Commission Implementing Regulation (EU) No 884/2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins - Commission Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs - Commission Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs - Commission Regulation (EU) 2017/644 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs - Commission Regulation (EC) No 1882/2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs	- Safety assessment
Directive 2002/32/EC on undesirable substances in animal feed	- Safety assessment

Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market	- Safety assessment as part of the substance (re-)approval process
Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin	- Safety assessment as part of the reviewing, amending, setting, deleting of MRLs
Regulation (EC) No 1831/2003 on additives for use in animal nutrition - Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives	- Safety assessment

Proximity to the mandate of agencies: for ECHA **very high**, as it developed and operated the tool, and is designated as the manager of the common data platform in the future. For EFSA **very high**, as EFSA already operates the OpenEFSA portal.

Projected synergies and added value of reattribution:

Synergies come from the fact that one system or dedicated service can serve multiple agencies. The added value of the system is that all agencies and stakeholders will be able to find out at one place about the ongoing or planned regulatory processes on substances. The development of the dedicated service on information on regulatory processes on chemicals (I.e. extended PACT) will be done as part of the development of the common data platform on chemicals, exploiting the same governance process and building blocks required.

Main risks and opportunities:

The development of an all-encompassing controlled vocabulary and rules for all the different contributors will be extensive. It is however not considered a risk as all processes are individually well controlled by the agencies responsible for the implementation of the individual pieces of legislation. Risks are mitigated by the designated role of the agencies. The dedicated service on information on regulatory processes on chemicals provides a major opportunity to facilitate the coordination between the assessments and reuse of assessments performed elsewhere, to avoid duplication of work and to save time when informed decisions on further management actions can be taken.

Projected impact on agencies

- Committees/bodies: **no impact**. The task does not require the involvement of committees /bodies (with the exemption of their secretariat that will be the main provider of respective information from the committees to the dedicated service on information on regulatory processes, as is the case now for PACT)
- Agencies' data model and IT infrastructure: **high impact**. The same considerations apply as for the development of the common data platform in its entirety. The data models of 4 agencies for this type of information will have to be aligned.
- Agencies' key experts: **no impact**. The task does not require a specific expertise. The task is effectively just a reporting/documenting of the processes.

Projected workload and resource implications:

<u>Future workload and resource needs:</u>

Work description	Who	Resource needs estimate
Developing the dedicated service on information on regulatory processes on chemicals as part of the common data platform		
Designing and developing the dedicated service's data structure, functionalities and IT service. Notably most of the building blocks of existing ECHA (P)ACT can be reused. Experiences from similar portals like OpenEFSA from other agencies need to be included. Proper consideration must be given to the service's functioning through differentiated access (agencies/public) and the ability to efficiently (albeit within constraints) serve during transitional periods while legal provisions on sharing between agencies are still being adopted.	ECHA	See common data platform estimates: preparation of the dedicated service on information on regulatory processes on chemicals is already included in the estimate as part of MVP basic IT infrastructure. The dedicated service is expected to be included already in the first demo at T0+12 months, likely with limited coverage of processes included (ECHA, EFSA). Full functionality is expected in the goLive version in 2028.
Cooperation with and providing input to ECHA for the development of the dedicated service on information on regulatory processes on chemicals (as part of the common data platform governance)	EFSA, EEA, EU-OSHA, COM	Contribution expected by EFSA, EEA, EU-OSHA and COM to help identify structure and functionalities, also on the basis of own experiences and expected needs. Ideally covered by the agencies' core staff but can include external IT expertise in particular when one was covering existing solutions. Resources should be absorbed by the agencies as part of the resources assigned to the development of the common data platform.
Based on common agreements, preparation of internal dataflows, packaging of regulatory processes information and supporting ingestion into the common data platform	ECHA, EFSA, EEA, EU-OSHA COM	ECHA will have to integrate the remaining data flows for legislation not yet included in the current PACT. This is covered by the resources allocated as part of the proposals which reattributes certain processes to ECHA and which should be included in PACT. EFSA already have the data flows developed. They might need to be amended and retargeted to feed into the dedicated service on information on regulatory processes on chemicals. EEA, EU-OSHA will need to develop data flows and integrate them into the dedicated service. Resource needs are covered in the estimation for the operation of the common data platform
Provision of regulatory information		
Keeping the dedicated service on information on regulatory processes on chemicals up-to-date by recurrent ingestion of new information and revision of existing one. The processes may include other actors than the agencies (e.g. competent authorities), however agencies would be responsible for packaging the	ECHA, EFSA, EEA, EU-OSHA	While it is anticipated that the internal dataflows will reflect agreements on common metadata on processes, resulting in little overhead in order to 'package' for the platform, some additional resources will be required. The extent depends on the number of processes initiated (and should therefore be covered within proportionate IT overhead in case additional tasks are attributed to an agency), and to a degree the level of detail regarding information on intermediate steps and data to be associated.

information and linking with ECHA's platform, in a consistent manner.		A general estimate of basic information is considered in the estimate for common data platform operations – no further resources are included here.
Providing 'legacy regulatory information' (i.e. information already available before entry into force of the regulation establishing the common data platform)	ECHA, EFSA, EMA	It is considered that information already provided in some structure on respective IT platforms will be able to be introduced into the dedicated service on information on regulatory processes on chemicals. This would be achieved in a progressive way (with prioritization) but should be achieved with resources covered by the common data platform operation.

Overview of resource needs per agency for the operation of the dedicated service on information on regulatory processes on chemicals:

Agency	**Summary of tasks**		
ECHA	Designing and developing the dedicated service' data structure, functionalities and IT service. Operating the dedicated service as part of the common data platform on chemicals Based on common agreements, preparation of internal dataflows, packaging of regulatory processes information and supporting ingestion into the common data platform Keeping the dedicated service up-to-date by recurrent ingestion of new information and revision of existing one. Providing 'legacy regulatory information'	Financial resource needs:	Included as part of the common data platform on chemicals + to be absorbed as part of the individual regulatory processes
		Human resource needs:	Included as part of the common data platform on chemicals + to be absorbed as part of the individual regulatory processes
EEA EU-OSHA	Cooperation with and providing input to ECHA for the development of the dedicated service Based on common agreements, preparation of internal dataflows, packaging of regulatory processes information and supporting ingestion into the common data platform Keeping the dedicated service up-to-date by recurrent ingestion of new information and revision of existing one. Providing 'legacy regulatory information'	Financial resource needs:	EEA and EU-OSHA are currently not involved in any processes relevant for the database, therefore no resources are required for them.
		Human resource needs:	Included as part of the common data platform on chemicals + to be absorbed as part of the individual regulatory processes
EFSA	Cooperation with and providing input to ECHA for the development of the dedicated service Based on common agreements, preparation of internal dataflows, packaging of regulatory processes information and supporting ingestion into the common data platform Keeping the dedicated service up-to-date by recurrent ingestion of new information and revision of existing one. Providing 'legacy regulatory information'	Financial resource needs:	Included as part of the common data platform on chemicals + to be absorbed as part of the individual regulatory processes
		Human resource needs:	Included as part of the common data platform on chemicals + to be absorbed as part of the individual regulatory processes

Future budget line: As part of the agencies' budgets

Candidate for fees: No

22. REPOSITORY OF REFERENCE VALUES

Responsible body:

Currently: ECHA (some reference values as part of EUCLEF), EFSA (some reference values as part of open food tox database), Commission – DG SANTE (some reference values as part of the pesticides database)

(Re-)attribution planned to: ECHA, EFSA, EMA, EU-OSHA [and Commission – DG SANTE]

Legal basis for (re-)attribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: Existing but extending the scope and centralizing the reference values in one repository

Brief task overview: Setting up and operating a centralized repository of reference values derived or collected as part of the implementation of Union chemicals legislation or on the request of the Commission also those provided by the Member States or international organization.

Detailed process description:

Current process:

EFSA has developed and is maintaining the OpenFoodTox database[1]. It is a structured database (Exel sheet) summarising the outcomes of all hazard identification and characterisation for human health (plant protection products, food improvement agents, and contaminants), animal health (feed additives, pesticides and contaminants) and the environment (feed additives and pesticides) performed by EFSA. OpenFoodTox provides information on substance identity and characterisation, links to EFSA's related output, relevant background EU legislation, and a summary of the critical toxicological endpoints and reference values for the substance. The data model of OpenFoodTox has been designed using an OECD Harmonised Template (OHT) as a basis to collect and structure the data in a harmonised manner. The database is being populated by an external contractor who extracts the relevant information from the EFSA opinions. The database contains scientific values from EFSA's opinions. Currently, relevant information from all opinions delivered by EFSA is already included in the database and EFSA continues updating the database.

The EU pesticides database[2] is the official source for pesticide Maximum Residue Levels (MRLs) in food products. It is maintained by the Commission – DG SANTE - and it contains both the current and historical information on MRLs of pesticides with the residue definition and a coded list of commodities to which the MRLs apply. The database contains regulatory reference values from the relevant legislation. The Commission – DG SANTE - continues updating it.

ECHA has developed and operates the EU Chemicals Legislation Finder (EUCLEF)[3]. It is an online service to access an overview of 56 pieces of EU chemicals legislation. The purpose of EUCLEF is to offer users the possibility to navigate through the EU chemicals legislative framework and find relevant information on how substances are regulated across the EU. EUCLEF was developed to help companies who need to track their obligations across different EU laws. EUCLEF lists some regulatory reference values derived and applicable under these legislative pieces. There might be an overlap between information in EUCLEF and in the EU pesticides database.

Changes in the process:

ECHA establishes and operates the centralized EU repository of reference values as part of a database with information on the provisions and legal obligations applicable to chemicals under the Union acts by adapting the existing EUCLEF system (see section 23). Both the repository of reference values and a dedicated service on information on the obligations under EU acts on chemicals (i.e. an expanded EUCLEF system) are established as part of the common data platform and the governance structure of the platform is also used to govern the development and operation of the repository of reference values.

ECHA makes available in the repository all regulatory reference values adopted under EU chemicals legislation (this is broader than today and contains more metadata information).

ECHA extracts and feeds into the repository all 'legacy scientific reference values' from ECHA's opinions (i.e all reference values already derived by ECHA before the entry into force of the regulation establishing the common data platform and which are not formally adopted under EU legislation). For 'new reference values' ECHA starts providing reference values on a continuous basis to the repository as new opinions are adopted by ECHA.

EFSA provides the collection of 'legacy scientific reference values' (i.e. those which are not formally adopted under EU legislation but derived by EFSA) from the Open Food Tox to ECHA to be integrated in the repository. For 'new scientific reference values' (i.e. those that are not formally adopted under EU legislation but derived by EFSA) EFSA continues providing relevant information on a continuous basis to the repository (or to ECHA) as new opinions are adopted by EFSA.

The Commission – DG SANTE - continues to operate and populate the EU pesticide database with new regulatory reference values. The Commission – DG SANTE - establishes a dynamic link for provision of the information from the EU pesticide database to ECHA to be made available also via the repository.

EMA provides on a continuous basis to ECHA all new (i.e. adopted after entry into force of the regulation establishing the common data platform) predicted no effect concentrations (PNECs) derived as part of the environmental risk assessment under Directive 2001/83/EC, Regulation (EC) No 726/2004 and Regulation (EU) 2019/6

EEA and EU-OSHA provide on a continuous basis to ECHA all new scientific reference values they might derive in the future, as currently they do not do so.

The governance of the common data platform is used for governing the development and operation of the repository.

Proximity to agencies' mandate:

The tasks fit well with the mandate of each agency. EFSA, ECHA and EMA provide scientific reference values from the assessments they perform. ECHA is already operating EUCLEF and is tasked to operate the common data platform, so for ECHA it is an extension of its current work.

Projected synergies and added value of (re-)attribution:

Operating only one repository of reference values compared to several separate ones will save resources. The existing IT solution and contractual arrangement available in ECHA can be reused.

Main risks and opportunities: There might be an overlap between reference values in the repository and in the EU pesticide database.

Projected impact on agencies

- ECHA/EMA/EFSA committees/bodies: **low impact**. The rapporteurs of opinions might be asked to extract the reference values and metadata for integration into the repository as part of the finalisation of the opinion.
- ECHA data model and IT infrastructure: **medium impact**. The task requires adaptation of the EUCLEF IT solution.
- EMA/EFSA data model and IT infrastructure: **low impact**. EMA and EFSA would use the data model set by the repository. They would be reusing the IT solution provided by ECHA. ECHA/EMA/EFSA key experts: **low impact**. Experts are needed to extract relevant information from the opinion into the repository.

Projected workload and resource implications:

Work description	**Who**	**Resource needs estimate**
Setting up the repository on the basis of EUCLEF		
Designing and developing the repository as expansion of EUCLEF and as part of the common data platform Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform) during development	ECHA	Development by 2028; development duration 3 years (years 2025, 2026, 2027) One-off costs for contracting the development (to supplement IT costs of EUCLEF): - 2025: EUR 0 - 2026: EUR 550 000 - 2027: EUR 550 000 The IT development can be subcontracted but it will need to be overseen/supervised by ECHA staff. The development is to be coordinated with other agencies. Estimated coordination for the development phase (2025-2027): 1 FTE per year
Contribution to the development phase	EMA, EFSA, EEA, EU-OSHA COM	negligible; should be absorbed by the agencies
Operating the repository as part of EUCLEF		
Operation/hosting, maintenance and update of the repository as part of EUCLEF and as part of the common data platform	ECHA	Recurrent costs as of 2028: EUR 200 000 and 1 FTE per year. This is to cover the improvements and maintenance of the repository as part of the EUCLEF and the common data platform, contact with data providers, covering specific needs of the repository
Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform governance)	ECHA, EFSA, EMA EEA, EU-OSHA COM	Recurrent resource ideally covered by the agencies' core staff. Negligible; should be absorbed by the agencies
Provision of data		
Providing 'new scientific reference data'	ECHA, EFSA, EMA, EEA,	Putting the data into the repository with adequate metadata information will require some additional resources from the agencies or from the rapporteurs of opinions. The amount will depend on how many opinions with limit values the agency sets per year. The work will be spread over time and could be absorbed

	EU-OSHA	by the resources spent on the development of the opinion, for example by ensuring that the opinion format has specific fields dedicated to the limit values information.
Providing 'legacy scientific reference values'	ECHA, EFSA,	EFSA has already compiled all 'old scientific reference values' in the open food tox repository; no additional resources needed for this; ECHA needs to progressively extract the old scientific reference values from their opinions. This would be a one-off exercise that could be outsourced. The following resources for contracting will be needed: ECHA: - 2026 (200 opinions): EUR 100 000 - 2027 (200 opinions): EUR 100 000 - 2028: Euro 0 The management of the contract is to be done as part of the common data platform resources
Providing 'formally adopted regulatory reference values'	ECHA	ECHA has already a contractual agreement for the provision of reference values under the operation of EUCLEF. This should be expanded to cover all formally adopted regulatory reference values and to collate also necessary metadata. The current EUCLEF financing related to data provision assumes the maintenance of 51 pieces of legislation, at a cost of EUR 8 400/year for each legislation, or EUR 430 000/yearin total. To top-up EUCLEF to cover the Eur-Lex legislations with human health or environmental limit values in the scope of the repository, ca 25 pieces of legislation would be added to the current scope, amounting to an additional data provision cost of EUR 200 000 /year. This is already covered in the estimation of the resource needs for operating and hosting the repository above.
Receiving and processing national reference values	ECHA	A proposal for revision of water legislation requires MSs to report national EQS to ECHA. The **resources for this part of the work were already proposed** under the proposal for revision of water legislation (and are thus not covered under the proposal for a regulation establishing the common data platform). The only other national limit values of interest are the national occupational exposure limits (OELs). There is no legal obligation to report those to EU institutions. The same system/set up developed for water EQS could be used for the OELs and Member States would be asked to report voluntarily. **No additional resources needed**.

Summary of additional resource needs for the establishment and operation of a repository of reference values:

Agency	Summary of tasks		
ECHA	Designing and developing the repository as expansion of EUCLEF and as part of the common data platform	Financial resource needs:	2025: **EUR 650 000** 2026: **EUR 650 000** 2027: **EUR 200 000** 2028: **EUR 200 000**

	Operation/hosting, maintenance and update of the repository as part of the EUCLEF and of the common data platform Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform) during development Providing 'new scientific reference data' Providing 'old scientific reference values' Providing 'formally adopted regulatory reference values' Receiving and processing national reference values	Human resource needs:	2025: **1 TA**, **0 CAs** 2026: **1 TA**, **0 CAs** 2027: **1 TA**, **0 CAs** 2028: **1 TA**, **0 CAs**
EFSA	Contribution to the development phase Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform) during development Providing 'new scientific reference data' Providing 'old scientific reference values'	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	Covered by EU common data platform on chemicals resource 2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**
EMA	Contribution to the development phase Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform on chemicals) during development Providing 'new scientific reference data' (i.e. PNECs)	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	Covered by EU common data platform on chemicals resource 2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**
EEA EU-OSHA	Contribution to the development phase Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform) during development Providing 'new scientific reference data'	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	No relevant data managed by the agencies; 2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**
DG SANTE	Contribution to the development phase Coordination of and consultation with other agencies contributing to the repository (as part of the common data platform on chemicals) during development	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**

Future budget line: DG Environment

Candidate for fees: No

23. INFORMATION ON THE OBLIGATIONS UNDER UNION ACTS ON CHEMICALS

Responsible body:

Currently: Commission, delegated to ECHA

(Re-)attribution planned to: ECHA

Legal basis for (re-)attribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: existing

Brief task overview: Operation of a database with information on the provisions and legal obligations applicable to chemicals under the Union acts providing a single point of entry to information on various pieces of EU legislation applicable to a given chemical substance.

Detailed process description

Current process

EU Chemicals Legislation Finder (EUCLEF) is a database, compiled by ECHA from multiple sources, presently covering 51 pieces of EU legislation and organized in a way that enables searching and listing all regulations and regulatory lists in which a substance (directly, or inheriting the regulatory context of a parent substance) appears. To ensure continuous relevance, the database is regularly (several times per year) updated. Advanced searches, links to applicable documents and exporting of aggregated results are enabled. Industry, in particular SMEs, is the principal user addressed, as the efficient access to information on obligations reduces costs and increases compliance.

EUCLEF is hosted by ECHA as part of its dissemination pages. EUCLEF has been developed and is maintained by an external contractor managed by ECHA. The information in the database is regularly updated also by the contractor who regularly searches for updates in legislative provisions, such as Eur-Lex, and keeps the EUCLEF database up to date.

Changes envisioned as part of setting up common data platform

Database with information on the provisions and legal obligations applicable to chemicals under the Union acts will be established as an integral dedicated service within the common data platform. The database will be built from the existing EUCLEF. Its principle task should not change from the existing service, but the scope of EUCLEF will be slightly extended to cover all legislation within the scope of common data platform. In addition, EUCLEF will be reshaped to fit with the standard data format and controlled vocabulary and graphical interface to the common data platform. Further, EUCLEF will be expanded to integrate in it also the repository of reference values, as it partly overlaps in scope but also in sources and approaches required to keep the information updated.

Proximity to ECHA mandate: ECHA has the appropriate data and expertise to perform this task. ECHA already operates the system in its current form and it fits well with the new mandate to operate the common data platform on chemicals.

Projected synergies and added value of (re)attribution:

Type	Synergies	
Reuse of	High	ECHA's existing processes and methodologies can be fully reused for the new task. Eventually the service will benefit from its

capabilities		position within the common data platform, exploiting capabilities developed within it.
Re-use of data	High	Reuse of data in the EU data space (Eur-Lex) and data collected under other chemicals legislation
Workload balancing	Low	Existing process based on external contract. Integration requirements will be passed through revised specification.
IT tools: automation and economies of scale	High	Reuse of existing solution, together with IT capabilities developed in the platform. Joint revision with the new repository of reference values.
Support services: economies of scale	High	Reuse of support services within the platform (e.g. substance identification, data management and dissemination). Reuse of administrative services.

Type	Added value	
Compliance, robust implementation leading to safe handling	High	Facilitating a comprehensive understanding of legal frames applying to a specific substance for its full lifecycle supports adequate and efficient activities, implementation of legislation and development of policies.
Transparency	High	Compiling information that is public by default, but by merging and by using advanced tools to visualize the information provides a unique insight that is often missed by data alone.

Main risks and opportunities:

The current EUCLEF solution provided by an external consultant is robust and the risks of interrupting the continuous provision of information and the efforts required to integrate in the platform are low, provided that funding is maintained at a similar level as today. There is an opportunity to allow for a more efficient update of the database by automating the reading of entries from Eur-LEx. For that, a collaboration with the Commission's publication office is required to ensure adequate structuring of the information in Eur-Lex. Another opportunity is to integrate the repository of reference values into the system, using joint efforts and practices.

Projected impact on ECHA:

- ECHA committees/bodies: **no impact**. The task does not require the involvement of ECHA committees /bodies.
- ECHA data model and IT infrastructure: **medium impact**. Becoming a sustainable part of the common data platform, it will require some changes in the data model. However, being an existing service to be included in the platform, significant efforts in addition to continuous funding at the existing operational level should not be required. Given the investments in IT and data under the EUCLEF task since 2019, its continued implementation would not require significant further efforts in this area.
- ECHA key experts: **low impact**. The task relies on expert competencies, but as externally-

supported service in the operational phase this requires lower ECHA oversight, and the additional support to development the required for integration into the common data platform is expected to be covered by the ECHA experts dedicated to the platform development.

Projected workload and resource implications:

Current workload and resource use:

ECHA already developed and currently maintains the EU Legislation Finder (EUCLEF). It does so under a Contribution Agreement with DG GROW for which it receives a varying sum of money depending on the year (EUR 1 000 000 – EUR 1 400 000 annually), but no posts. ECHA runs the service through the employment of 4 interim staff members (ca. EUR 270 000/year) and outsourcing to contractors: communication activities and external helpdesk ca. EUR 60 000/year, IT costs ca. EUR 200 000/year, data costs ca. EUR 430 000/year. Via the Contribution Agreement this activity does not currently contribute to the cost of running the ECHA (administrative overhead or IT development).

Future workload and resource needs:

No additional resources are required for this work. The existing resources for EUCLEF will be used to continue operating, further developing and slightly expanding the system. The dedicated service on information on the obligations under EU acts on chemicals will have to be integrated into the platform, but the resource needs for adaptation are already covered under the common data platform. The major extension of EUCLEF – incorporation of the repository of reference values – are accounted for separately (see section 22). Although no additional resources are required under the proposal for the regulation establishing a common data platform on chemicals and establishing a monitoring and outlook framework for chemicals, the legislative proposal for a regulation on ECHA that is in preparation should address the fact that the operation of the EUCLEF became a structural task for ECHA and that the financing should become part of the annual contribution to ECHA.

Work description	**Who**	**Additional resource needs estimate**
Operation of dedicated service on information on obligations under EU acts on chemicals– maintaining the system, periodically updating the database with data	ECHA	None, but the existing resources and financing for EUCLEF must be maintained.
Development phase - incorporation of the dedicated service into the common data platform: reviewing, aligning database structure and format; association with controlled vocabularies (as they are being developed)	ECHA	Resources required for the integration are already considered by the estimates on EUCLEF operation (above – some level of continuous adaptation to technical progress is part of operation) and under common data platform ECHA common data platform data ingestion estimation.
Development phase – incorporation of repository of reference values into dedicated service on information on obligations under EU acts on chemicals	ECHA	Resources estimated under the repository of health-based limit values.

Summary of additional resource needs for the dedicated service on information on obligations under EU acts on chemicals:

Agency	**Summary of tasks**		
ECHA	Operation of dedicated service on information on obligations under EU acts on chemicals – maintaining the	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**

	system, periodically updating the database	Human resource needs:	2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**

Future budget line: n/a

Candidate for fees: No

24. DATABASE ON ENVIRONMENTAL SUSTAINABILITY RELATED INFORMATION

Responsible body:

Currently: N/A, no current process

(Re-)attribution planned to: ECHA, EEA, EFSA, EMA and EU-OSHA

Legal basis for reattribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: new (new infrastructure but building on existing datasets)

Brief task overview: Setting up and operation of a database on environmental sustainability related data and providing relevant data to the database.

Detailed process description:

Current process:

There is an increasing amount of data related to environmental sustainability of chemicals, often generated in research and innovation projects. It is also expected that the implementation of the European Green Deal and its various initiatives, including the implementation of the Safety and Sustainability by Design framework for chemicals and materials, as well as regulatory initiatives such as the Ecodesign Regulation for sustainable products and the Sustainability Corporate Reporting Directive will further increase the availability of certain environmental sustainability data for chemicals.

There is no ongoing process to systematically collect all relevant information on the environmental performance of chemicals throughout their lifecycle. While there are initiatives compiling (some) data used for sustainability assessments, in particular data needed for the life cycle assessment of products, there are no standard data formats or controlled vocabularies for information related to environmental sustainability, which hinders coherence between assessments of the impacts of the same chemical on the environment.

Changes in the process:

ECHA is to set up and operate a database on environmental sustainability related data, which is established as part of the common pata Platform. For that purpose, ECHA extracts and feeds into the database information from all relevant datasets already integrated in the common data platform but also further relevant external datasets identified by the Commission.

EEA, EFSA, EMA and EU-OSHA provide to ECHA relevant data related to environmental sustainability of chemicals they host or hold in addition to the chemicals data already available in the common data platform.

Progressively, more data will be integrated in the database, as more data will become available in response to the European Green Deal and the various initiatives requiring the assessment of

sustainability of materials, products and services. Further datasets presently under preparation by the Partnership for the Assessment of Risks from Chemicals (PARC) and generated through the implementation of the safe and sustainable by design framework should be utilised and integrated as appropriate.

The Commission identifies existing datasets on environmental sustainability related information for inclusion in the common data platform and designs relevant related database functionalities.

The governance of the common data platform is used for governing the development and operation of the database.

Proximity to agencies' mandate:

The task fits well with the mandate of each agency. ECHA has a long standing expertise on collection of information on substances. It is a key part of ECHA's mandate. Other agencies (EFSA, EEA, EMA and EU-OSHA) also collects or make available information on chemicals related to their mandate. EEA will in the future operate the Industrial Emissions Portal that might collect some data related to environmental sustainability of chemicals on industrial sites, including on 91 pollutants.

Projected synergies and added value of (re-)attribution:

Operating only one database to systematically collect and relate all relevant information on the environmental performance of chemicals throughout their lifecycle and facilitate operation of tools and efficient assessment of environmental sustainability by different actors leads to synergies.

Main risks and opportunities:

There is a lot of activity in the field of sustainability assessments leading to multiple and not always coordinated activities and risks of 'lock-in' of specific solutions. A lot is still to be defined and agreed in this field; even some of the concepts are still under development and testing. Precise advance planning of solutions is therefore not possible at present. The opportunity of having a central 'beacon' in the form of a dedicated database around which the activities can coalesce, coordinate and individually contribute is a major opportunity.

Projected impact on agencies

- ECHA committees/bodies: **no impact**. There is no involvement of the committees
- ECHA data model and IT infrastructure: **high impact**. The task requires the development of an IT solution.
- EMA/EFSA/EEA/EU-OSHA data model and IT infrastructure: **no or low impact**. agencies would provide the data they host or hold.

Workload and resource implications:

<u>Current workload and resource use:</u>

This is a new task and there is no existing work or resources.

<u>Future workload and resource needs:</u>

The additional resources are needed only for ECHA for the development of the database. It is envisaged that the majority of data to be integrated to the database will come from outside the EU agencies, such as research consortia or companies' reporting. The EU agencies currently do not actively collect or receive the relevant data, and if they have any of such data, the amount of information held is currently very limited. Therefore, the resources for provision of such data could be absorbed by the agencies.

Work description	Who	Resource needs estimate

Setting up the database on environmental sustainability related data		
Infrastructure setup Consultation on database functionalities Identification of relevant datasets already integrated in the common data platform	ECHA	Development during 6 years (2025, 2026, 2027,2028,2029, 2030); ECHA: Staff 1 FTE per year
Providing relevant input on environmental sustainability related information	EEA, EFSA, EMA EU-OSHA	Negligible: to be absorbed by the agencies' existing work.
Operating the database on environmental sustainability related data		
Integrating additional datasets	ECHA	Recurrent costs as of 2030: ECHA: Staff 1 FTE per year
Providing relevant environmental sustainability related information	EEA, EFSA, EMA, EU-OSHA	Negligible; should be absorbed by the agencies

Summary of resource needs for the database on environmental sustainability related data:

Agency	Summary of tasks		
ECHA	Database on environmental sustainability related data – developing, maintaining the system, periodically updating the database	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2025: **1 TA, 0 CAs** 2026: **1 TA, 0 CAs** 2027: **1 TA, 0 CAs** 2028: **1 TA, 0 CAs**

Future budget line: DG ENV

Candidate for fees: No

25. MECHANISM FOR INITIATING TESTING AND MONITORING

Responsible body:

Currently: EFSA, no current process exists beyond the food sector

(Re-)attribution planned to: EFSA (as it is currently) and ECHA (for the new process for the chemical sector beyond chemicals covered by the General Food Law)

Legal basis for reattribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

Type of task: new

Brief task overview: Commissioning scientific studies supporting the implementation and evaluation of legislation within the mandate of ECHA

Detailed process description:

Current process:

Pursuant to the Transparency Regulation[59], the Commission, in exceptional circumstances of serious controversies or conflicting results, may request EFSA to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

At the same time, pursuant to Article 32 of the General Food Law[60], EFSA, using the best independent scientific resources available, shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion and EFSA shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

EFSA implements this latter obligation through regular commissioning of scientific studies managed by the Science Studies and Project Identification and Development Office (SPIDO). The goals of these projects are:

- Enhance EFSA's capacity to identify studies/projects benefitting regulatory processes/science
- Fill knowledge gaps to ensure preparedness for:
    - Possible divergences on sensitive matters ('verification' studies)
    - Future risk assessment requirements dues to evolving scientific knowledge and legislation
- Enhance capacity building and build partnerships

If there is a request from the Commission for a verification study, the resources are used for commissioning such study. No request has been received from the Commission so far.

The EFSA roadmap for the studies for 2022 includes specific projects on artificial intelligence, new approach methodologies, environmental risk assessment, combined exposure to multiple chemicals. For the years 2023 and 2024 the roadmap includes studies on evidence-based risk communication in the EU food safety system, OMICS and bioinformatic approaches in risk assessment, new risk assessment methodologies and harmonised animal welfare data and advancing aggregate exposure to chemicals in EU.

<u>New process:</u>

EFSA will continue the operation of their mechanism to commission scientific studies, which is focused on food sector.

ECHA will get a mandate to commission scientific studies for the performance of its mission, i.e. in support of the implementation or evaluation of chemicals legislation within the mandate of ECHA. The Commission will be empowered to request ECHA to commission such studies as well.

ECHA and EFSA will have to closely cooperate when commissioning scientific studies to avoid duplication, maximise synergies and ensure coherence of safety assessments across legislation in line with the one substance, one assessment objectives.

Proximity to agencies' mandate: The task fits well with the mandate of ECHA because it is focused on the commissioning of studies which are in the mandate of ECHA.

Projected synergies and added value of (re-)attribution:

[59] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231 6.9.2019, p.1)

[60] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

The added value of this task is that ECHA will be able to commission necessary studies and thus improve the implementation and evaluation of the legislation within its mandate and complement the existing mechanism for the chemicals in food sector. Synergies will be achieved by requiring cooperation between EFSA and ECHA. In addition, ECHA will be able to create synergies with the work it is doing in support of PARC.

Main risks and opportunities:

The main opportunity comes from joined work of ECHA and EFSA on commissioning studies, serving the plethora of chemicals legislation and thus improving the coherence and harmonisation of assessment methods across legislation.

Projected impact on agencies :

- ECHA committees/bodies: **low impact**. The task does not require the involvement of ECHA committees/bodies but ECHA may require input from the committees for the identification of study needs
- ECHA data model and IT infrastructure: **no impact**. This task does not have an impact on the IT infrastructure beyond storing the project outcomes
- ECHA key experts: **medium impact**. The task will rely on expert competencies, which are limited within ECHA and the agency may need to recruit additional personnel.

Projected workload and resource implications:

Current resources allocated to similar work:

Resources allocated to EFSA for 'food-related data generation mechanism'	
Human resources for additional ad hoc studies	4 FTEs per year
Toxicological studies (H2020-FP9)	2 FTEs per year
Additional operational budget for additional ad hoc studies (Prediction: 16 studies a year)	2020: EUR 6 million 2021: EUR 10.5 million 2022: EUR 15.0 million 2023: EUR 15.0 million 2024: EUR 15.0 million

When the PARC project was initiated, 2 FTEs were allocated to ECHA to allow its engagement in the project and support its implementation.

Future workload and resource needs:

EFSA will continue operating its data generation mechanism. The additional work required for EFSA will be to cooperate with ECHA on commissioning studies and on joint decision-making on which studies to commission and how to perform them. These costs should be however absorbed by the existing resources.

It is envisaged that there will be synergies between the studies run by EFSA and by ECHA, for example from pooling study subjects of the projects into one commissioning. It is therefore expected that ECHA should get a lower amount of human and operational resources than EFSA. No additional resources would be needed to follow the research projects, as such resources were already allocated to ECHA for the PARC project.

Summary of additional resource needs for a data generation mechanism:

Agency	**Summary of tasks**		
ECHA	Commissioning scientific studies on its own initiative or on the request of the Commission	Financial resource needs:	2025: **EUR 0** 2026: **EUR 1 000 000** 2027: **EUR 3 000 000** 2028: **EUR 5 000 000**

	Cooperating with EFSA on commissioning studies and on joint decision-making on which studies and how to follow-up	Human resource needs:	2025: **1 TA**, **0 CAs** 2026: **1 TA**, **1 CAs** 2027: **1 TA**, **1 CAs** 2028: **1 TA**, **1 CAs**
EFSA	Cooperating with EFSA on commissioning studies and on joint decision-making on which studies and how to follow-up	Financial resource needs:	Covered by the existing data generation mechanism
		Human resource needs:	Covered by the existing data generation mechanism

Future budget line: DG Environment

Candidate for fees: No

26. MECHANISM FOR NOTIFICATION OF STUDIES

Responsible body:

Currently: EFSA

(Re-)attribution planned to: EFSA (for notifications under the General Food Law[61]), ECHA (for notifications of studies beyond the food sector)

Legal basis for reattribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: new

Brief task overview: Operation of an on-line system for receiving and storing notification of information on studies commissioned or carried out cby industry and contractual research laboratories

Detailed process description:

Current process:

To ensure that the EU risk assessor has knowledge of all studies performed by an applicant, Regulation (EU) 2019/1381 (Transparency Regulation) contains a requirement to notify studies that are commissioned or carried out in the context of the preparation of an application for approval process in the food chain, at pre-submission phase. Information about the notified studies is made public once a corresponding valid application has been submitted and information on it is made public in accordance with the applicable rules on transparency. The Transparency Regulation also provides for consequences and certain procedural requirements in the case of non-compliance.

The studies are notified by the industry commissioning them as well as by the laboratories performing them. They are notified to EFSA and EFSA operates an online system (database) for receiving and storing the notifications. The system has existed for since 27 March 2021 and 15 652 notifications were received up until March 2023.

[61] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31 1.2.2002, p.1)

EFSA verifies the compliance with the notification requirements once the application or notification is received in relation to which Union law contains provisions for EFSA to provide a scientific output.. This work is done automatically but requires also some manual checks.

Future process:

The obligation to notify studies would be extended from the food legislation to all chemicals legislation except the medicinal and veterinary products. EFSA would continue to operate its existing notifications database for notifications made under the General Food Law, while ECHA would set up its own database for notifications of studies carried out in the context of other EU chemical legislation.

Verification of compliance with the notification requirement would be done by the actor or agency responsible for the legislation in question (e.g. under Biocidal Products Regulation, ECHA would verify the compliance with the notification of studies when application for authorisation for biocidal product or biocidal active substance would be received. Also, under REACH, ECHA would verify the compliance with the notification of studies as part of the compliance check of the registration dossiers).

Proximity to agencies' mandate:

The task is very close to the EFSA and ECHA mandate. EFSA already operates a database of notifications for the food sector. ECHA is or will be responsible for the assessment work under the remaining legislation (i.e. legislation beyond food sector), therefore, the operation of the notification database for the remaining legislation fits well with ECHA's mandate.

Projected synergies and added value of (re-)attribution:

ECHA can build on EFSA's existing expertise and experience and can thus ensure harmonised identification of study notifications. Existing processes under the biocidal product regulation (such as application evaluation) and under REACH (such as dossier compliance check) can be used to include checking the compliance with the notification requirements.

Projected impact on agencies:

- committees/bodies: EFSA - **no impact**. The task does not require involvement of EFSA committees /bodies. ECHA – **low impact**. The task would require checking compliance with the notification provisions by the rapporteur member of the biocidal product committee.
- Data model and IT infrastructure: EFSA - **low impact**. The existing repository of studies continues to be operated. The system will have to be linked with or incorporated into the common data platform. ECHA – **high impact**. ECHA will need to set up a new IT infrastructure. In addition, REACH registration will have to be adapted to facilitate the reporting of the notification number for a submitted study.
- Key experts: ECHA and EFSA - **low impact**. The task will rely on expert competencies, which exist in the agencies.

Projected workload and resource implications:

Current workload and resource use:

The following resources were allocated to EFSA for the implementation of the notification of studies mechanism as part of the transparency regulation:

Resources allocated to EFSA for 'food-related notification of studies'	
Register of commissioned studies	2 FTEs per year
Register of commissioned studies (development and operation)	2020: EUR 160 000 2021: EUR 280 000

	2022: EUR 400 0002023: EUR 400 000 2024: EUR 400 000

Current budget line: DG SANTE

Future workload and resource needs:

ECHA will need to set up a database of study notifications and an IT interface for receiving the notifications. The system needs to be operational within 2 years from the entry into force of the legislation (expected mid 2027). ECHA and EFSA will have to cooperate to ensure a common approach for the identification of information notified to both systems. ECHA will have to build an automatic solution that requires lead registrants or applicant to include the notification number into the registration or biocidal product dossiers, respectively, or indicate the reason why a study was not notified. It will also require adapting the dossier format to capture the notification number or justification, and connect the submission system to the database of study notifications. This would be a one-off-cost of adapting the REACH IT and the biocidal products system. For setting up the system it is estimated that additional 3 FTEs per year will be needed and an operational budget of EUR 1 600 000 to commission the external support in the development of the system.

Once the system is set up ECHA will have to operate it, maintain it and make the necessary adaptations. ECHA will have to provide helpdesk to reply requests of duty holders. ECHA will also facilitate checking the compliance with the notification provisions.

For the Biocidal Products Regulation, the notification of studies would be checked for active substance approval as part of new applications, Art 95 dossiers and renewals. It can be estimated that there would be a need to check 50 dossiers a year (containing ca. 100 notifications). The notification of studies would be also checked for biocidal product authorisation. In 2022, 160 applications were received (containing ca. 45 notifications). The checks would be performed by the Member States competent authorities, while ECHA would make available to them the summary of notifications. It is expected that verification of notifications would not take more than 4 hours per dossier. This could be absorbed by the overall resources dedicated by the Member States for the evaluation of the applications, as it is marginal compared to the overall resource need for the evaluation of an application.

For REACH, ECHA receives from lead registrants on average yearly about 3 600 updates of the registrations and about 300 new registrations. Updates can be submitted for a variety of reasons and may or may not contain studies. When submitted in response to an evaluation decision and when submitted due to an increase in information requirements following an increased tonnage band, they most likely contain new studies. Companies may also include new studies for other reasons, e.g. to follow regulatory changes or to strengthen adaptations. The number of annually submitted new studies from increase in tonnage band and in response to evaluation decisions is 1 400. The new registrations are estimated to contain on average 12 studies, i.e. 3 600 studies for 300 new registrations per year. In summary, ECHA receives on average 3 900 registrations per year (updates + new registrations) containing some 5 000 experimental studies that would need to be notified per year. This would result in ca. 7 500 notifications, as it is assumed that ca. 50% of studies would have to be notified also by commercial laboratories.

Compliance with the notification-of-studies requirement would be checked as part of the registration compliance check. ECHA checks approximately 300 registrations per year for compliance. Checking the compliance with the study-notification requirement would not take more than 4 hours per dossier. This would amount to 1 200 hour per year, i.e. ca 0.6 FTE. However, it is likely that registrations selected for a compliance check would not consist of only new registrations or updated registrations for which the requirement of notification of studies applies, and thus the number of checks for

complying with study-notifications requirements would be lower. In addition, when one is performing a full compliance check of a registration, the additional time for checking compliance with the study-notification requirement is negligible.

For any other legislation, ECHA might need to assist Member State authorities in their enforcement action and for those legislative pieces, where a dossier containing studies is submitted by duty holders to ECHA, ECHA can verify the compliance when evaluating such dossier (e.g. under RoHS directive, there might be some 3 dossiers per year requesting derogation which potentially might contain study results).

It is estimated that 3 FTEs per year and an operational budget of EUR 200 000 per year will be needed for ECHA to operate the system, deal with requests from duty holders and to assist in compliance check.

ECHA will have to cooperate with EFSA also on the integration of EFSA's notifications database into the common data platform. This part of work is covered by the resources planned for the common data platform.

Summary of additional resource needs for the mechanism for notification of studies:

Agency	**Summary of tasks**		
ECHA	Setup and operation of notifications database and ensuring common approach for the identification of information notified to EFSA and ECHA system Adaptation of the REACH registration system to include study notifications numbers Adaptation of the biocidal products regulation system to include study notifications numbers Helpdesk Verification of compliance with the study notification requirements as part of the REACH compliance check and biocides authorization Support to Member State authorities in enforcement	Financial resource needs:	2025: **EUR 0** 2026: **EUR 1 200 000** 2027: **EUR 400 000** 2028: **EUR 200 000**
		Human resource needs:	2025: **1 TA, 2 CA** 2026: **1 TA, 2 CA** 2027: **1 TA, 2 CA** 2028: **1 TA, 2 CA**
EFSA	Continue running its existing notifications database Coordination with ECHA to ensure common approach for the identification of information notified to EFSA and ECHA systems	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**

Future budget line: DG Environment

Candidate for fees: No

27. EU Chemical Early Warning and Action System and Indicator Framework for Chemicals

Responsible body:

Currently: EEA, ECHA

(Re-)attribution planned to: EEA, ECHA in collaboration with EFSA, EMA and EU-OSHA (expanding the task)

Legal basis for reattribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: existing (Task 2) and new (Task 1)

Brief task overview:

1. Establishment and operation of an EU early warning and action system for emerging chemical risks through developing and compiling early warning signals and drawing up summary report to inform regulatory follow up actions
2. Establishment and operation of the indicator framework for chemicals

Detailed process description:

Current process:

Task 1 is a new task and there is no ongoing process or activity for this task.

As regards Task 2 (framework of indicators), the EEA and ECHA are jointly developing a framework of indicators for chemicals policy to monitor the drivers and impacts of exposure of environment and humans to chemicals and to provide a fact base to measure the effectiveness of chemicals legislation in protecting human health and the environment. The framework of indicators is being developed as part of the framework of indicators for zero pollution. The indicators for chemical policies are expected to monitor:

- the drivers of human and environmental exposure to chemicals, namely the production and use of chemicals, regulation of these activities;
- the impacts of chemicals, in terms of emissions and occurrence in environmental matrices and in humans compared against effect levels, and—where possible—their impacts on human health and the environment;
- progress with the industrial transition to safe and sustainable chemicals.

The framework will consist of a set of indicators that is annually updated and presented in the form of a dashboard. EEA and ECHA plan to publish the baseline information for the first set of indicators in 2024. The EEA and ECHA are the technical co-leads of the Commission inter-service working group on chemicals indicators (WG8 of the Chemicals Strategy). During 2021, the working group developed the first concept paper and agreed on the full set of candidate indicators. In 2022 the indicators were further developed, in cooperation with the services involved. For each candidate indicator, EEA and ECHA prepared a prototype and validated data availability, potential data representation and interpretation. In 2023 EEA and ECHA will prepare the dashboard, conclude the development of the indicators and case studies, as well as develop the synthesis report. EEA and ECHA have established a data flow to quantify the selected indicators, and will continue to coordinate work for the preparation of indicators that are expected to be available after 2024.

Changes in the process / New process:

Task 1 – early warning and action system

This is a new task. The early warning and action system will complement the implementation of the EU legislation on chemicals by adopting a proactive and systematic approach to the identification of emerging chemical risks. The system will consist of an annual compilation of a report summarising the collection of early warning signals, identifying potential emerging risks from chemicals and presenting the report and its finding to the expert working group on one substance, one assessment

for discussion and decision on the need for potential follow-up policy or regulatory action. The system would be developed progressively. Initially, it will rely on existing early warning systems and signals, such as the EFSA's emerging risks exchange network (EREN), the national warning systems (*e.g.* SamTox, SIGNAAL), targeted literature searches performed by EEA, as well as on relevant existing data and information made available by EFSA, ECHA, EEA, EMA and EU-OSHA. Progressively, more signals would be developed by the cooperating agencies (i.e. EEA, ECHA, EFSA, EMA, EU-OSHA) and the tools for early warning signals developed by the Partnership for the Assessment of Risks from Chemicals (PARC) would be utilised and integrated as appropriate.

The types of signals that could feed into the EU early warning and action system for emerging chemical risks include:

- substances on the market currently produced and used in small quantities but with high growth potential,
- new substances at research and development stage not yet on the market,
- new scientific knowledge leading to a more critical assessment of the risk (e.g., discovery of subtle effects or sensitive species),
- New substances on the market, such as recently developed substitutes for regulated substances,
- substances for which emerging evidence raises concerns due to:
    - improvements in the sensitivity of analytical methods,
    - chemical mixtures/combination effects of chemicals,
    - new toxicological evidence,
    - newly identified exposure routes,
    - increasing levels and scale of exposure or trends in the profile of the exposure,
    - development of the legislation,
    - new susceptible at-risk population or at-risk groups.
- industry data (e.g., development of alternatives, production volumes)
- biological signals (e.g., biodiversity loss)

Task 2

This is an existing task. The framework of indicators will be maintained and further developed by EEA in collaboration with ECHA, EFSA, EMA, EU-OSHA and the Commission. The dashboard of indicators shall be integrated into the common data platform on chemicals and the relevant information shall be made available as part of the report on early warnings.

Proximity to Agencies' mandate:

The task of having a lead for the early warning system for chemicals fits well with the core mandate of EEA, as EEA already operates a number of early warning systems for other areas (e.g. waste). The task of co-developing the indicator framework fits well with the mandates of EEA and ECHA, as ECHA is an agency that as part of the operation of common data platform manages access to all chemicals related data held by other agencies and EEA already operates number of indicators as part of its work on the assessment of the state of environment. The task of providing information/data for the early warning system and indicator framework within their competence fits well with the mandates of EEA, ECHA, EFSA, EMA and EU-OSHA as they collate and hold the relevant information as part of their mandates.

Projected synergies and added value of (re-)attribution:

Attribution of the lead to EEA will provide for synergies with existing early warning systems and with the EEA's work on indicators, including its work on the zero-pollution indicator framework. EEA has already been tasked to develop a framework of indicators in collaboration with ECHA. For EEA, the lead on an early warning system can be considered as a natural expansion of its work on indicators, as several indicators can serve also as early warning signals. In addition, EEA (and also

ECHA) are involved in the Partnership for the Assessment of Risks from Chemicals (PARC) through which they can steer the development of the tools for early warning signals.

Projected impact on agencies:

- EEA/ECHA/EMA/EFSA/EU-OSHA committees/bodies: **low impact**. EEA might use some of their networks for the provision of early warning signals. No other additional impact on committees is expected for EMA, EFSA, ECHA or EU-OSHA
- EEA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems.
- EEA/ECHA/EMA/EFSA/EU-OSHA key experts: **low impact**. Expertise existing in the agencies can be used for these tasks.

Workload and resource implications:

Current workload and resource use:

Task 1 is a new task and there is no existing work or resources.

Task 2 is an existing task. Resources for this work were allocated to both EEA and ECHA, as part of the resource allocation under the 8th Environment Action Programme. ECHA uses 2 FTEs (1 TA and 1 CA) for the development of the chemical indicators (out of 2 FTEs allocated under the 8th EAP). These resources are used by ECHA for the management and consolidation of databases, provision of chemicals data in order to complete the respective emerging risk reports and contribution to chemical policy indicators and other inputs to EEA's work. EEA uses 1 FTE for the work on indicators (out of 15 allocated under the 8th EAP). These resources are used by EEA for the integrated analysis of pollution impacts on environment and health and on reporting on cross-cutting areas of the zero-pollution ambition of the green deal, in close cooperation with ECHA and EFSA.

Future workload and resource needs:

Task 1 – Early warning and action system for emerging chemicals risks

Work description	**Who**	**Resource needs estimate**
Setting up the EU early warning and action system		
Identifying and selecting existing working procedures, setting up the necessary contacts with other agencies and Member States experts, developing the early warning signals available in EEA. Compiling report on system set-up, signal generators and data sources, working procedures and consulting the expert group on one substance, one assessment for feedback	EEA	Development by 2026; development duration 2 years (2025, 2026); Resource needs: - Staff 1 FTE per year - Operational budget EUR 300 000 in 2026 Setting up of the system and compiling report shall be based on information gathered from identified signal generators, including ECHA, EFSA, EU-OSHA and EMA.
Providing relevant input for the setting up the early warning and action system	ECHA, EFSA, EMA , EU-OSHA	Negligible: to be absorbed by the agencies' existing work.
Operating the EU early warning and action system		

Conduct a horizon scanning and foresight exercise, including organising an annual workshop, to identify early warning signals, including: • performing a literature search, • reviewing the EEA data flows on chemicals in the environment • compiling the early warning signals from collaborating EU agencies, including from data provided by ECHA, EFSA and EMA and EU-OSHA • compiling the early warning signals from relevant initiatives, such as the EEA Eionet network and Horizon Europe partnership PARC • operating relevant early warning tools developed under PARC. Producing and publishing an annual report on early warning signals and presenting it to Commission, relevant EU agencies and Member States for decision on potential regulatory follow up actions.	EEA	Recurrent costs as of 2027: - Staff 1 FTE per year - EUR 150 000 per year for annual studies for literature review, horizon scanning, foresight and support in systemic examination of potential chemical risks and covering annual workshop costs Operating the system and compiling report shall be based on information gathered from identified signal generators, including ECHA, EFSA and EMA.
Providing relevant data and information on early warning risks	ECHA, EFSA, EU-OSHA EMA,	Negligible; should be absorbed by the agencies; EFSA already operates food related early warning system; ECHA develops indicators and the resources allocated for that should cover also this activity; EMA and EU-OSHA should contribute with the existing information they identify.

Task 2 – Framework of indicators

There is no need for additional resources for Task 2, but the current resources need to be maintained to ensure operation of the indicator framework.

Work description	**Who**	**Resource needs estimate**
Maintaining and further developing the framework of indicators for chemicals	EEA, ECHA	Resources already allocated (EEA: 1 FTEs, ECHA: 2 FTEs) No additional resources needed, but they should be maintained

Summary of additional resource needs for early warning and action system and indicator framework for chemicals:

Agency	**Summary of tasks**		
EEA	Literature review, horizon scanning, foresight and support in systemic examination of potential chemical risks and covering annual workshop costs Review of existing working procedures for early warning signals for chemicals, including signal generators. Review of EEA data flows on chemicals in the environment to identify early warning signals available in EEA.	Financial resource needs:	2025: **EUR 0** 2026: **EUR 300 000** 2027: **EUR 150 000** 2028: **EUR 150 000**
		Human resource needs:	2025: **1 TA**, **0 CAs** 2026: **1 TA**, **0 CAs** 2027: **1 TA**, **0 CAs** 2028: **1 TA**, **0 CAs**

	Compiling the early warning signals from collaborating EU agencies. Compiling the early warning signals from relevant initiatives, such as the EEA Eionet network and Horizon Europe partnership PARC, including with the early warning tools developed under PARC, as appropriate. Producing and publishing an annual report on early warning signals and presenting it to expert group on one substance, one assessment.		
ECHA EMA EFSA EU-OSHA	Providing relevant data and information on early warning risks within their competence.	Financial resource needs:	None, it should be absorbed by the agency
		Human resource needs:	None, it should be absorbed by the agency

Budget line: DG Environment

Candidate for fees: No

28. OBSERVATORY FOR SPECIFIC CHEMICALS WITH POTENTIAL CONTRIBUTION TO EMERGING CHEMICAL RISKS

Responsible body:

Currently: Commission, delegated to ECHA

(Re-)attribution planned to: ECHA

Legal basis for reattribution: Proposal for a regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Type of task: existing

Brief task overview: Operate the observatory for specific chemicals with potential contribution to emerging chemical risks

Detailed process description:

Current process:

ECHA operates EU Observatory for nanomaterials (EUON) that includes the following activities:

- Dissemination and communication (webpages, newsletters, opinions) about different aspects of nanomaterials;
- Commissioning number of 'paper' studies every year on various aspects of nanomaterials to fill knowledge gaps based on the proposals received from stakeholders via an open call for proposals;
- Running the NanoData nanotechnology knowledge base which periodically takes stock of market development on nanomaterials (e.g. statistics of growth in sectors, patents, ….);
- Providing service as a portal to 'nano' community where links to external resources (e.g., eNanoMapper serving as a common resource where EU-funded projects on nanomaterials and nanotechnologies can place their results and where some tools are made available);
- Operating a database that compiles data on nanomaterials from some sources, such as REACH

registration, EU nano inventories (FR, BE) - and present it together with a slightly advanced search functionality linked to nanoforms.

The EUON is funded by the European Commission and is hosted and maintained by ECHA.

Changes in the process:

Continue performing 'the EUON' activities, maintaining the principal objective of providing transparency on selected class of materials, but modifying its remit and exploiting new infrastructure:

- Expanding the scope to other chemicals and materials, such as complex advanced materials or (other) materials identified through the early warning system, selected based on the assessment by the Commission of expected need and benefit of their inclusion in the observatory;
- Using as appropriate the new data generation mechanism to commission also studies related to nanomaterials (initially) and, later, also other selected groups of chemicals and materials;
- Operating a database that compiles data on nanomaterials and making it accessible via the common data platform to maximize integration with information from other datasets in the platform and its utility as additional source of information, including as appropriate in work on the framework of indicators;
- ECHA to dedicate part of its dissemination effort on chemicals to nanomaterials (initially) and other materials(later).

Proximity to agency mandate: the EUON task was assigned to ECHA because it was assessed to have the appropriate data and expertise to perform this task, this is confirmed by the fact that this task has been successfully performed by ECHA for over more than 5 years.

Main risks and opportunities: There are clear synergies and overlaps between EUON's compilation of European nanomaterial inventories ("Search for nanomaterials" section) and the future EU common data platform on chemicals. There are also clear synergies and overlaps between commissioning studies on nanomaterials and the new data generation mechanism. There might be also some overlaps and synergies between the NanoData nanotechnology knowledge base and the work on the famework of indicators and on the early warning system. The exploitation of these overlaps is an opportunity of the reattribution of tasks proposal.

Projected impact on ECHA:

- ECHA committees/bodies: **no impact**. The task does not require the involvement of ECHA committees /bodies.
- ECHA data model and IT infrastructure: **low impact**. Given the investments in IT and data under this task since 2017, its continued implementation would not require significant further efforts in this area. The existing databases can be integrated into the common data platform.
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks.

Projected workload and resource implications:

Current workload and resources used:

The work is financed via the Contribution Agreement between ECHA and DG GROW and sometimes additional funding from DG RTD. The contribution consists of approximately EUR 700 000 per year (calculated as an average of contributions over the last 10 years: 2016 - EUR 900 000, 2017 – EUR 600 000, 2018 – EUR 600 000, 2019 – EUR 600 000, 2020 – EUR 828 000, 2021 – EUR 600 000, 2022 – EUR 809 000, 2023 – EUR 614 000, 2024 – EUR 619 000, 2025 – EUR 624 000). From the contributions received, ECHA employs 3 CAs (ca. EUR 270 000) and uses ca. EUR 430 000 as an operational budget for commissioning or the calls.

The current resources spent by the Commission can be summarized as follows:

DG GROW – ECHA contribution agreement	**3 FTEs** (3 CAs)
Operational budget	**EUR 430 000 per year**

Current budget line: DG GROW (SMP-COSME)

Future workload and resource needs:

Keeping it as a coherent set of services compiling and disseminating reliable information on selected groups of materials, the Commission intends to integrate the work of the EUON into other work streams assigned to the agency, namely operating the nanomaterials database as part of the common data platform, commissioning certain studies through the new data generation mechanism, integrating some signals from the NanoData nanotechnology knowledge base into the work onthe framework of indicators and an early warning and action system, and specific dissemination into general communication on chemicals. The scope of EUON will be also extended to other chemicals and materials, such as complex advanced materials or (other) materials identified through the early warning system, selected based on the assessment by the Commission of expected need and benefit of their inclusion in the observatory

No additional resources are required for this work, but the existing resources for EUON must be maintained. The existing resources for EUON will be used to continue operating, further developing and slightly expanding the system. The dedicated service on information on the obligations under EU acts on chemicals will have to be integrated into the platform, but the resource needs for adaptation are already covered under the common data platform. Although no additional resources are required under the proposal for the regulation establishing a common data platform on chemicals and establishing a monitoring and outlook framework for chemicals, the legislative proposal for a regulation on ECHA that is in preparation should address the fact that the operation of the EUON became a structural task for ECHA and that the financing should become part of the annual contribution to ECHA.

Summary of additional resource needs for the observatory for specific chemicals with potential contribution to emerging chemical risks:

Agency	**Summary of tasks**		
ECHA	Commissioning of studies on nanomaterials and other materials potentially presenting new emerging chemical risks (e.g., complex advanced materials via the data generation mechanism Operating 'nanomaterials' database Dissemination and communication on nano- and (e.g., complex advanced) materials Running the NanoData nanotechnology knowledge database. Providing service to 'nano' community	Financial resource needs:	2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2025: **0 FTEs** 2026: **0 FTEs** 2027: **0 FTEs** 2028: **0 FTEs**

Budget line: n/a

Candidate for fees: No

29. COOPERATION OF ECHA WITH OTHER EU AGENCIES

Responsible body:

Currently: ECHA

(Re-)attribution planned to: ECHA, expanding the existing tasks

Legal basis for reattribution: ECHA founding regulation

Type of task: New, expanding the existing task

Brief task overview:

1. Developing methodologies for assessment of chemicals in the fields falling within its mission;
2. Cooperating with other agencies as regards exchange of data, defining formats and controlled vocabularies and development of methodologies related to chemicals;
3. Preventing and solving divergent opinions on chemicals with EFSA and EMA.

Detailed process description:

Current process:

Task 1

ECHA has some very specific tasks with some relevance to the development of methodologies mentioned in the current founding provisions under REACH. The Article 77 of REACH on the tasks of the Agency lists the following tasks:

- providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;
- providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States under Title XIII;
- providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1);
- preparing explanatory information on this Regulation for other stakeholders;
- keeping a Manual of Decisions and Opinions based on conclusions from the Member State Committee regarding interpretation and implementation of this Regulation;

ECHA however lacks the mandate and obligation to develop methodologies for the assessment related to chemicals. This disadvantages the ECHA as compared to other agencies and does not allow ECHA to actively participate or contribute to the development of assessment methods.

Task 2

The ECHA founding provisions under REACH contain provisions related to cooperation. The Article 110 of REACH on the relations with relevant community bodies states:

- The Agency shall cooperate with other Community bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.

- The Executive Director, having consulted the Committee on Risk Assessment and the European Food Safety Authority, shall establish rules of procedure concerning substances for which an opinion has been sought in a food safety context. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission. This Title shall not otherwise affect the competences vested in the European Food Safety Authority.
- This Title shall not affect the competences vested in the European Medicines Agency.
- The Executive Director, having consulted the Committee on Risk Assessment, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work, shall establish rules of procedure concerning worker protection issues. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.
  This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work and the European Agency for Health and Safety at Work.

The existing provisions are rather general. In order to achieve the one substance, one assessment ambition, it is necessary to strengthen the provisions on cooperation and make them coherent with the provisions of other EU Agencies.

Task 3

ECHA founding regulation specifies provisions for preventing and solving divergent scientific opinions with other agencies. Article 95 on conflicts of opinion with other bodies states:

- The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of community law, including Community Agencies, carrying out a similar task in relation to issues of common concern.
- Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.
- Where there is a fundamental conflict over scientific or technical points and the body concerned is a Community Agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

The provisions need to be aligned with those for other agencies. In addition, there is a need to strengthen the requirement to solve the divergent view by agencies among themselves, before the matter is referred to the Commission to be solved.

<u>Future process:</u>

Task 1:

ECHA should have a mandate to develop methodologies for the assessments related to chemicals it performs based on its needs. It should have also a mandate similar to EFSA to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission.

Task 2:

ECHA actively cooperates with EFSA, EEA and EMA as regards:

- exchange of data on chemicals and defining formats and controlled vocabularies for

such data
- development of methodologies related to chemicals.

The cooperation is foreseen both ways, *i.e.* when ECHA itself makes some development in those specified areas within its domain as well as when EFSA, EEA and EMA make some development in those areas within their domains. The goal is to ensure coherence, consistency and interoperability in the specified areas.

Task 3:

ECHA and body concerned shall first attempt to solve the divergent opinion on scientific or technical issues by themselves. They shall revert the decision to the Commission only if they were not able to solve the issue. In addition, if the divergence come from divergence in hazard assessment, the Commission should request ECHA to prepare a proposal for harmonised classification under the CLP regulation.

Proximity to Agency mandate: The tasks fit well with the mandate of ECHA as all three tasks target the areas of the ECHA mandate, and they are just improvement, specification or expansion of existing tasks.

Projected synergies and added value of reattribution: Improving coherence, consistency and interoperability among the Agencies work is the key added value.

Projected impact on ECHA:

- ECHA Committees/bodies: **low impact**. The task might require some ad hoc involvement of committee/panels or their consultation.
- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **low impact**. The task relies on expert competencies, but the task is limited and spread over time in its nature.

Workload and resource implications:

<u>Future workload and resource needs:</u>

The work on the new tasks is limited and spread over time in it is nature. On a need basis, it requires that ECHA will develop methodologies for the assessment it performs as regards chemicals. The development and setting the methodology is a standard practice for whoever performs the assessments, so this task can be seen as a formalisation of existing ECHA work. There is no need for additional resources for this task.

ECHA will need to cooperate with EFSA, EEA and EMA in the areas on data, formats and methodologies. The need for additional resources for cooperation on these are already covered under the legislative proposal on data (operation of common data platform) or they are already within the mandate of ECHA. Consequently, there is no need for additional resources on this general formal mandate for ECHA to cooperate.

ECHA will need to try to solve any divergence in technical or scientific issue with the other agency. ECHA already has such obligation in the existing regulation. The new task will require that the agencies make more effort to solve the issue among themselves, instead of just forwarding the problem to the Commission. Although it might require slightly higher amount of work by the agency as compared to today, such situations are rare and therefore this can be absorbed by the agency without any additional resources.

Summary of additional resource needs for cooperation of ECHA with other EU Agencies:

Agency	Summary of tasks		
ECHA	- Development of methodologies for assessments related to chemicals within its missions - Cooperation with EFSA, EEA and EMA on issues related to chemicals - Preventing and solving divergent opinions or assessments	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 FTE** 2025: **0 FTE** 2026: **0 FTE** 2027: **0 FTE** 2028: **0 FTE**

Future budget line: DG GROW

Candidate for fees: No

30. SCIENTIFIC OPINIONS ON OCCUPATIONAL EXPOSURE LIMITS

Responsible body:

Currently: Commission, delegated to ECHA

(Re-)attribution planned to: ECHA

Legal basis for reattribution: ECHA founding regulation

Type of task: existing

Brief task overview: Assessments underpinning setting the EU occupational exposure levels

Detailed process description:

Current process:

Occupational exposure limit (OEL) values are adopted under two legal frameworks (Chemical Agents Directive (CAD) and Carcinogens and Mutagens Directive (CMD)) that form an integral part of the EU's mechanism for protecting the health of workers. In addition, there is a specific directive on asbestos that includes an OEL for this substance. Occupational exposure limits adopted by the EU need to be integrated into the national legislative framework.

ECHA and its Committee for Risk Assessment (RAC) have been supporting the European Commission's Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL) by providing scientific opinions on OELs since 2019. This work was previously carried out by DG EMPL's Scientific Committee on Occupational Exposure Limits (SCOEL).

Following the request from DG EMPL, ECHA prepares a scientific report for its Committee for Risk Assessment (RAC) based on the available scientific data and any relevant information collected through a 90-day call for evidence. The scientific report is subject to a 60-day open consultation. RAC then develops its opinion based on a review of ECHA's scientific report and the information provided during the consultation. ECHA's scientific report becomes an integral part of RAC's opinion and forms an annex to the opinion. The adopted final RAC opinion is then forwarded to DG EMPL.

DG EMPL will discuss RAC's report in the tripartite Working Party on Chemicals. This working party prepares a draft opinion on the proposed occupational exposure limit, which is

then presented to the tripartite Advisory Committee on Safety and Health for adoption. In the end, the Commission adopts a legislative proposal. For binding OELs, this happens through the ordinary legislative procedure for adoption by the Council and the European Parliament. For indicative OELs, it happens through a Commission directive.

Change in the process: No

Proximity to ECHA mandate: The task is currently already performed by ECHA via an Service Level Agreement (SLA) and is a good fit with its core mandate.

Main risks and opportunities: Resources in ECHA staffing are a limiting factor to do more OELs proposals. Capacity of the RAC secretariat is also a limiting factor.

Projected impact on ECHA:

- ECHA Committees/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to the (additional) workload
- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Workload and resource implications:

Current workload and resources used:

The number of RAC opinion on OELs varies between 0 and 3 opinions per year, with average of 1.5 opinion per year.

	Number of RAC opinions on OELs per year						
RAC opinion on	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Occupational exposure limits (OELs)	0	2	3	0	2	2	

ECHA provides scientific advice for the setting of Occupational Exposure Limits under a Service Level Agreement (SLA) with DG EMPL. To assess 5 substances annually, ECHA receives 4 CA posts and in total EUR 975 000 that includes resources for those 4 CA posts.

The current resources spent by the Commission can be summarized as follows:

DG EMPL – ECHA Service Level Agreement	**4 FTEs** (4 CAs)
Operational budget	**EUR 575 000/year**

Through the SLA this activity does not currently contribute to the staff cost of running the Agency, although it contributes to Infrastructure and Operational costs (administrative overhead or IT development).

Current budget line: Budget line of DG EMPL

Future workload and resource needs:

The Commission intends to stop the arrangement via a SLA and formally assign this task to ECHA by enshrining it in its mandate. The normal resource needs for REACH restriction dossier, which includes also socio-economic assessment and SEAC opinion is 1 (light dossier) - 1.5 (complex dossier) FTEs. As the OEL derivation does not require socio-economic assessment nor SEAC opinion and is principle lighter than restriction dossier, the average resource needs for one OEL is 0.8 FTEs. The Commission wishes to get at least 5 OELs per

year, which requires at least 4 FTEs per year. Overhead of 15% is required to contribution for common component of IT tool development (data submission, processing, output), which is additional 0.6 FTE, and overhead of 15 % is required to contribution for horizontal support (governance, enablers, administrative overhead), which is additional 0.6 FTE. In total, it makes 5.2 FTEs

Summary of resource needs for scientific opinions on OELs:

Agency	Summary of tasks		
ECHA	Preparation of 5 dossiers/year with proposal for OEL Public consultation RAC opinion on the 5 dossiers per year and input from the public consultation	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 200 000** 2027: **EUR 200 000** 2028: **EUR 200 000**
		Human resource needs:	2024: **0 TA**, **0 CA** 2025: **3 TA**, **2 CA** 2026: **3 TA**, **2 CA** 2027: **3 TA**, **2 CA** 2028: **3 TA**, **2 CA**

Future budget line: DG Employment

Candidate for funding: No

31. REACH REGULATION (1907/2006)

Responsible body:

Currently: ECHA

(Re-)attribution planned to: ECHA (changes in tasks)

Legal basis for reattribution: Revision of REACH regulation

Type of task: New or modified existing tasks

Brief task overview:

1. Registration
2. Authorisation
3. Restriction
4. Evaluation
5. Enforcement

Detailed process description:

Change in the process: Yes

Task 1 Registration

Additional information requirements are foreseen to enable the identification and regulation of substances, in particular:

- endocrine disruptors and persistent substances, for which new hazard classes have been recently created in the CLP Regulation;
- polymers will be added to the scope of REACH (notification obligation for all polymers, registration only for those polymers which are more likely to be hazardous);

- chemical safety assessment will be made stricter through a so-called "mixture allocation factor" to take into account multiple exposure to different chemical substances (so called "cocktail effect"). It will initially only apply to high tonnage substances and with some opt-out possibilities under certain conditions only and if specific risk assessments taking into account multiple exposure are not already provided in the registration dossier;
- a chemical safety assessment will be required for substances in the 1-10 tonnage band.

Task 2 Authorisation

REACH authorisation, with its system of applicant by applicant decisions on allowing or not the use of the concerned substances, will be replaced by a simpler, less granular system. Details are still under discussion and include considerations of establishing a system calling for early information on use, exposure and alternatives, notably from downstream uses, to inform the decision on the best regulatory approach per substance.

Additionally, the concept of essential uses will be implemented to take into account the needs of society (essential uses) or push to faster phase-out of substances for non-essential uses.

Task 3 Restriction

Where risks are obvious, simpler restriction procedures in the so-called "Generic Risk management Approach" (GRA) will be extended from CMRs to new hazard classes and from consumer to professional uses.

Likewise the authorisation process, the essential use concept will be implemented to derogate essential uses from the restrictions by taking into account the needs of society (essential uses) or to push for faster phase-out of substances for non-essential uses.

Task 4 Evaluation

Several provisions related to dossier and substance evaluation and its decision-making will be modified to enhance efficiency of the processes and re-focus attention of testing proposal examinations from volume-considerations to animal testing and complex studies. Annually adopted Community Rolling Action Plan will be replaced with lightweight registry of substance evaluations that would be justified based on hazard or risk considerations. ECHA will also be able to perform substance evaluation alongside MS competent authorities.

Task 5 Enforcement

A number of actions is foreseen, which include revoking registration in case of persistent incompliance or expiry of the technical dossier, Commission audits of Member States' enforcement systems, improving customs controls, enabling OLAF to investigate breaches of REACH, improving access to justice and dealing with online sales from third countries to consumers.

Proximity to ECHA mandate: The tasks are core tasks already performed by ECHA and therefore there is a good fit with its core mandate.

Projected impact on ECHA:

- ECHA Committees/bodies: **low impact**. The changes in the tasks on restriction and authorisation may slightly reduce the workloead of the committees
- ECHA data model and IT infrastructure: **medium impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems

- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Workload and resource implications:

Current workload and resources used:

Current budget line: Budget line of DG GROW

Future workload and resource needs:

Task 1 Registration

Changes in Uses and exposure will require:

- Unquantified costs to ECHA to update guidance and IT tools (one-off direct administrative costs);
- EUR 160 000 costs to ECHA for additional manual Technical Completeness Check (recurrent direct administrative costs).

Changes on registration requirements for polymers:

The impact assessment estimates that the registration of polymers will entail additional EUR 141 million for ECHA (one-off direct administrative costs). ECHA has provided a more detailed breakdown of costs and FTEs, according to their own estimates:

- Capacity building and guidance development (industry and authority): 5-10 FTE annually from 2024 until 2033, EUR 0.9-1.5 million
- Notification, incl. support to industry: 10-15 FTE in 2027, 10-20 FTE in 2028, 2029 and 2030, and 10-15 FTE in 2031, marginal onwards, EUR 3 million
- Developing grouping criteria: 5-10 FTE annually from 2029 to 2032, EUR 1.5-2 million
- Registration, incl. support to industry: between 10 and 60 FTE annually from 2031 onwards, EUR 4-5 million

		2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038
Activity	unit															
Capacity	FTE	5-10	5-10	5-10	5-10	5-10	5-10	5-10	5-10	5-10	5-10					
Notification	FTE				10-15	10-20	10-20	10-20	10-15	small	small	small				
Grouping	FTE						5-10	5-10	5-10	5-10						
Registration	FTE								10-15	15-20	30-45	35-65	35-60	35-65	35-60	25-35
Total (app)	FTE	5-10	5-10	5-10	15-25	15-30	20-40	20-40	30-50	25-40	35-55	35-65	35-60	35-65	35-60	25-35

Capacity	Euro		€ 0.9-1.5 million													
Notification	Euro					€ 3 million										
Grouping	Euro						€ 1.5 - 2 million									
Registration	Euro								€ 4 - 5 million							

Task 2 Authorisation

No change in resource needs expected as a result of the revision

Task 3 Restriction

No change in resource needs expected as a result of the revision

Task 4 Evaluation

Required evaluation resources are to an important degree proportional to the registration situation (number of registrations, changes to information requirements) and the ambition level applied (compliance check strategy *e.g.* number of compliance checks).

While an assessment of currently ongoing Joint Evaluation Action Plan is only expected at its finalisation in 2027, until which time the current ECHA resources for evaluation are required at current level, it is generally considered that afterwards the proportion of resources working on present and incoming registrations would be freed. On the other side, additional resources to assess and address efficiencies in new polymer registrations will be required after 2031 (see above).

While no quantified resource estimate could be made for the application of revocation processes and efficiency measures, it is considered that new needs are offset by the efficiency gains during evaluations and in their follow-up. Similar would apply for the expected increase in testing proposals but ability for a lighter process. The exception is required additional resource for ECHA's contribution to substance evaluations.

Agency	**Summary of tasks**	**Resource needs**	
ECHA	Dossier and substance Evaluation: • ECHA's contribution to substance evaluations is expected at the level of contribution of a larger Member State (e.g. 3 substances/year, estimated to require 4.5 FTE[3])	Note: these are additional resource needs for the ongoing processes	2027 onwards: 4.5 FTE

The evaluation processes are closely tied with the Member State Committee, whose main task is to assess the evaluation decisions. The changes will not require new capacity or change the nature of the work. The number of evaluation decisions to be taken is not expected to importantly change (within +-20%); any increase in testing proposal examination decisions that might come would be associated with likely more simple content from lower tier animal testing.

Task 5 Enforcement

External Audit Capacity:

- Costs for ECHA Secretariat for Audit Capacity concerning REACH only, in the range of 0.1 to 0.13 FTE, i.e. from 21.5 working days to 29, which would amount to annual costs for ECHA Secretariat between around EUR 11 481 to 15 486 (recurring annual costs).

- Costs for ECHA Secretariat for External Audit Capacity covering REACH and CLP, in the range of 0.1 to 0.15 FTE, i.e. from 21.5 working days to 32, which would amount to annual costs for ECHA Secretariat between around EUR 11 481 to 17 088 (recurring annual costs), or EUR 225 000 to 335 000 over 30 years. These are related to administrative support to discussions in Forum that may take place in relation to Commission audits of MSs control systems.
- Forum: some costs will be incurred as it can be expected that in some Forum meetings (maybe once per year) an agenda point may be included to discuss either the Commission programme for audits or the outcome of audits/controls carried out by the Commission.

Customs:

- Costs for ECHA Secretariat to make the interconnection, under the responsibility of the Commission, of ECHA electronic systems with national single window environments for customs through the EU Single Window Environment for customs, for the automated controls of registrations, authorisations (and restrictions). The budget is estimated at about EUR 100 000.
- The workload in ECHA to handle this development, its maintenance, and potentially the updates of company accounts by importers and only representatives (around 14 000), the inquiries from companies, as well as the support to the work of the ECHA Forum triggered by these new measures is estimated together at around 1,6 FTEs

The resource needs for the implementation of the revised obligations under REACH should be absorbed by the existing resources for REACH and CLP.

Summary of resource needs for REACH revision:

Agency	**Summary of tasks**		
ECHA	Implementing • Registration, • Authorisation • Restriction • Evaluation • Enforcement	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 TA**, **0 CA** 2025: **0 TA**, **0 CA** 2026: **0 TA**, **0 CA** 2027: **0 TA**, **0 CA** 2028: **0 TA**, **0 CA**

Future budget line: DG GROW

Candidate for funding: No

32. COSMETIC PRODUCTS REGULATION

Responsible body:

Currently: Commission with the support of the SCCS committee

(Re-)attribution planned to: ECHA

Legal basis for reattribution: revision of the Cosmetic Products Regulation (1223/2009)

Type of task: existing

Brief task overview:

(1) Safety assessment of chemicals used as ingredients in cosmetic products underlying the authorisation of colorants, preservatives and UV-filters

(2) Opinion to the Commission underlying the prohibition or restriction of substances where concerns are raised due to potential risk to human health

(3) Safety assessment of chemicals, classified as CMR, used as ingredients in cosmetic products, when an application for exemption was introduced,

(4) Opinion to the Commission on the safety of nanomaterials

(5) Preparation of Notes of Guidance for the testing of cosmetic ingredients including nanomaterials, non-animal testing methodology, and their safety evaluation

Detailed process description:

Current process:

The Cosmetic Products Regulation requires that the responsible persons and, under certain circumstances, the distributors of cosmetic products notify electronically their products before placed on the European market through the Cosmetic Products Notification Portal (CPNP). The information to be submitted is specified in Article 13 as follows:

- the category of cosmetic product and its name or names, enabling its specific identification;
- the name and address of the responsible person where the product information file is made readily accessible;
- the country of origin in the case of import;
- the Member State in which the cosmetic product is to be placed on the market;
- the contact details of a physical person to contact in the case of necessity
- the presence of substances in the form of nanomaterials, and their identification including the chemical name (IUPAC) and other descriptors and the reasonably foreseeable exposure conditions;
- the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;
- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The CPNP is accessible to competent authorities, European poison centres, cosmetic products responsible persons and distributors of cosmetic products.

The Cosmetic Products Regulation requires that a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use. In order to demonstrate that, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I. The Commission shall adopt appropriate guidelines to facilitate, in particular SMEs, to produce the cosmetic product safety report.

Taking into consideration the impact of the chemical ingredients on human health, the Cosmetic Products Regulation lays down limitations and requirements for the use of substances in cosmetic products. The rules are listed in Articles 14-17 and the following annexes:

- Annex II - List of substances prohibited in cosmetic products
- Annex III - List of substances restricted in cosmetic products
- Annex IV - List of colourants allowed in cosmetic products
- Annex V - List of preservatives allowed in cosmetic products
- Annex VI - List of UV filters allowed in cosmetic products

Certain groups of substances, i.e. colorants, preservatives and UV-filters must be authorised by the Commission, i.e. placed on the respective annex (IV, V or VI), prior to their use in cosmetic products. Certain subtances are prohibited (Annex II) and cannot be used in cosmetic products and certain substances are restricted (Annex III) and they can be used only when fulfilling the conditions of the restriction.

The safety assessment of the cosmetic ingredients (substances) in the EU is performed by the Scientific Committee on Consumer Safety (SCCS). It is based on safety dossiers submitted by applicants (individual company/associations or by competent authorities) or by the Commission. Based on its opinions, Commission may decide to amend the relevant Annexes. The safety of cosmetic products with all their ingredients is evaluated by "a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline" (Article 10(2) of the Cosmetic Products Regulation) before placing them on the EU market.

Task 1: Process for the authorisation of colorants, preservatives and UV-filters (including in nano forms) is as follows:

1. The amendment of the annexes IV, V or VI of the Cosmetic Products Regulation and associated technical and scientific work is initiated by the submission of a safety dossier by economic operators (applicant) to the Commission.
2. Commission evaluates the completeness of the dossier and prepares a mandate to the SCCS.
3. SCCS performs a risk assessment (9-12 months). The preliminary Opinion is published and open for comments (4-8 weeks) before being finalised. A final opinion is published on the SCCS' website.
4. Commission prepares a Working Document based on the final SCCS Opinion and shares it for discussion with the members of the Working Group on Cosmetic Products (participants: MS, Industry, SMEs and civil society organisations).
5. Commission prepares a Draft Regulation.
6. Draft Commission Regulation is discussed with the Standing Committee on Cosmetic Products, which comprises of MS authorities and the Commission.
7. TBT notification is launched with a commenting period of 2 months.
8. MS vote in the Standing Committee on Cosmetic Products (comitology) on the draft Commission Implementing Regulation.
9. Scrutiny period by the Council and the European Parliament of 3 months.
10. Adoption of the Regualtion by the Commission and publication in the Official Journal of the EU.

Task 2: Process for prohibition or restriction of a substance used in cosmetic products where concerns are raised due to a potential risk to human health is as follows:

1. The Commission may amend the annexes II and VI of the Cosmetic Products Regulation (CPR) if concerns for human health due to the use of a substance in cosmetics were raised by e.g. Member States, economic operators (industry, SMEs) or

civil society organisations (NGOs).

2. The Commission evaluates the information/data gathered and prepares a mandate to the SCCS.
3. SCCS performs a risk assessment (9-12 months). The preliminary Opinion is published and open for comments (4-8 weeks) before being finalised. A final opinion is published on the SCCS' website.
4. The Commission may prepare a Working Document based on the final SCCS Opinion and share it for discussion with the members of the WG on Cosmetic Products (participants: MS, Industry, SMEs and civil society organisations).
5. The Commission prepares a Draft Regulation.
6. The draft Commission Implementing Regulation is discussed with the Standing Committee on Cosmetic Products.
7. TBT notification is launched with a commenting period of 2 months.
8. MS vote in the Standing Committee on Cosmetic Products (comitology) on the draft Commission Implementing Regulation.
9. Scrutiny period by the Council and the European Parliament of 3 months.
10. Adoption of the Regualtion by the Commission and publication in the Official Journal of the EU

Task 3: The use of CMR substances (category 1A, 1B, or 2 under CLP) is prohibited in cosmetic products, apart from "exceptional" cases. This prohibition is implemented by amending Annex II-VI of the Regulation. Once a substance receives its harmonised classification as CMRs cat 1A, 1B or 2 under CLP regulation, the Commission must update the annexes of the CPR within 15 months. There is no involvement of SCCS in this process, as there is no safety assessment performed except in the case of derogation requests. Economic operators can, on a voluntary basis, prepare and submit safety dossiers to defend the use of a substance in cosmetics. In such a case the Commission can launch 'calls for data' in order to acquire as much information as possible for a full risk assessment.

If there is a request from industry for derogation, then the Commission mandates the SCCS to perform a safety assessment and following the outcome of the SCCS assessment the Commission may amend Annexes III - VI.

Task 4: Cosmetic products containing nanomaterials *other than* colourants, preservatives and UV-filters require a specific notification on the CPNP 6 months *before* they are placed on the market. If the Commission has concerns regarding the safety of a nanomaterial, it may request the SCCS to perform a risk assessment. The SCCS may also use information gathered from published literature and/or received from other stakeholders as a result of the Commission's call for data. The SCCS has 6 months to deliver its final opinion. In cases where further data/clarifications are needed, the 6-months clock starts again once the necessary data/information is provided by the applicant.

Task 5: The SCCS, with involvement of the Commission updates approximately every other year a technical guidance document concerning different aspects of testing and safety evaluation of cosmetic substances (called SCCS Notes of guidance'). The emphasis of this guidance is on cosmetic ingredients, including nanomaterials although some guidance is also indirectly given for the safety assessment of finished products. It is designed to provide guidance to public authorities and to the economic operators (safety assessors) to improve harmonised compliance with the current cosmetic EU legislation.

Administrative support for the SCCS

The SCCS is currently managed by DG SANTE within the Commission, which provides secretariat services for the committee. The Secretariat is responsible for providing scientific and administrative support necessary to facilitate the efficient functioning of the Committee, to monitor compliance with the Rules of Procedure, particularly in relation to the requirements for excellence, independence, commitment, confidentiality and transparency, to ensure communication on the Committees' activities, the appropriate stakeholder dialogue, publication of the opinions and other relevant documents. Moreover, the Secretariat provides support to the Committee and organises and applies quality control of the opinions as far as completeness, consistency, clarity, correspondence with requests and with editorial standards are concerned. Further tasks can be found in the rules of procedure.

Changes in the process:

It is envisaged that the SCCS will become part of ECHA, and therefore ECHA will take over the secretarial tasks of the committee. It is important that the flexible arrangements are put in place to allow the best integration of the SCCS in ECHA and, in particular, in view of any future reorganisation of the Agency's bodies, that would take into account the experience with SCCS work in ECHA and the need to increase the capacity of the existing committees in ECHA as a consequence of number of reattributions.

In view of the targeted revision of the CPR, apart from CMRs, additional hazard classes will be subject to risk management measures covering substances classified as endocrine disruptors, and the separate process will be established to examine the safety of substances that could affect the respiratory system and chemicals toxic to a specific target organ toxicant (STOT), which will also require the safety assessment by the SCCS. This is expected to result in a significant increase in the workload of the SCCS and the supporting work of the ECHA's secretariat.

Proximity to ECHA mandate: The risk assessment of chemicals including data management and facilitating the work of committees is a core part of the ECHA mandate. The task is therefore closely related to ECHA's core mandate and ECHA has the needed data, competences and expertise to perform the task. Synergies could be achieved if the work of the SCCS committee would be translocated into ECHA, both in terms of efficiencies, as in terms of coherence of scientific opinions.

Projected synergies and added value of reattribution:

Type	Synergies	
Reuse of capabilities	High	Process and expertise: ECHA already performs similar work on restrictions, derogations and setting of limit values under REACH and other legislation. Several key capacities can be reused/reinforced: - Hazard, risk and exposure assessment - Exposure limit value definition - Committee opinion development - Existing IT capabilities for industry dossier submission, stakeholder consultation and dissemination

Re-use of data	High	Reuse of data collected under other chemical legislation, especially REACH & CLP, with a focus on CMRs endocrine disruptors or other hazardous chemicals.
Workload balancing	Low	With an estimated workload of 11 opinions to be worked on in parallel, there is little room for workload balancing.
IT tools: automation and economies of scale	High	Industry actors can submit their derogation requests reusing existing ECHA submission tools, at the same time automating the existing process. In addition, reuse of IT capabilities for case management, public consultation, interaction with Member States, regulatory intentions management and data dissemination.
Support services: economies of scale	High	Reuse of scientific support services (e.g. committee secretariat, prioritisation and grouping of substances, substance identification, data management and dissemination). Reuse of administrative services.

Type	**Added value**	
Scientific consistency	High	Opportunity to align priority setting, timeline, process and methodology with other related legislation to improve coherence in the scientific advice provided to the Commission. Reuse of data collected under other chemical legislation. Opportunity to promote risk assessment methodologies based on non-animal data beyond cosmetic area.
Independence	High	Moving the SCCS and its tasks to the European Chemicals Agency will continue ensuring the strict separation between science and policy. ECHA and its committees work under strict conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.
Transparency	High	ECHA's involvement will bring additional transparency to the process: - Overall process transparency - Publication of regulatory intentions of EU authorities improves predictability for industry stakeholders - Public consultation/call for evidence - Stakeholder involvement/observer status - Dissemination of scientific data and outcomes

Main risks and opportunities: The high impact on the ECHA committee structure needs to be addressed and the existing expertise in the SCCS committee should be retained to the extent possible. There is a need to ensure continuity of the opinion making to ensure undisturbed

implementation of the Cosmetic Products Regulation. Working methodologies would need to be adapted.

Projected impact on ECHA:

- ECHA Committees/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to the additional workload and due to a new committee

	SCCS		
	# of opinions per year	**rapporteur**	**Type of opinion**
Opinions	11	SCCS member	
Notes of guidance	1	SCCS member	

- ECHA data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- ECHA key experts: **high impact**. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks

Projected workload and resource implications:

Current workload and resource use:

SCCS delivers on average 11 final opinions per year (see table below), while it has a maximum of 20 opinions in the pipeline at any given moment based on its current composition and structure. The SCCS is used mainly to support the Cosmetic Products Regulation but has provided scientific advice for other sectors in the past, albeit rarely.

	Number of SCCS opinions					
	2016	2017	2018	2019	2020	2021
Number of opinions	7	9	13	12	6	19

DG GROW staff has one policy officer (1 FTE) dedicated to the work of the SCCS in relation to the implementation of the CPR. The proposed reorganisation will not change the need for the FTEs from the side of DG as it is not involved in the safety assessment as such.

The secretariat of the scientific committees hosted by DG SANTE employs 4 FTE of DG SANTE and 2 additional FTEs of external interim staff (for technical and administrative support like literature search, editing and proofreading of opinions, website mastering, assistance for the Health-EU newsletter, dissemination activities). The staff of 6 FTEs is equally split over two committees (i.e., SCCS and SCHEER), which means that 3 FTEs are used to support work of SCCS. The SCCS is structured into 3 working groups that deal with several opinions at the same time (sometimes up to 20). Usually, each SCCS member is a rapporteur for 1 opinion at a time, however, quite often and in view of their expertise some members are rapporteurs for multiple opinions in parallel. External experts sometimes can also be nominated as rapporteurs.

The operational costs for SCCS and SCHEER (that includes special indemnities, accommodation, daily allowances, travel costs, reimbursement for rapporteurship, etc) operated by the Commission were EUR 2 883 030 for 6 years (2016-2021), which makes it approximately EUR 240 000 per year per committee. It must be noted that the operational costs

varies per year. For example, in 2019 the operational costs were EUR 370 000, which then went down because of pandemic measures.

The resource use can be summarized as follow:

DG SANTE secretariat	3 FTEs (2 internal + 1 external)
SCCS committee	100% of membership capacity (14 members + 4 external experts) Yearly operational budget for members of the committee was on 6 year average (2016-2021) EUR 240 000 per year
Total	**Ca. 3 FTEs**

(to convert the cost of consultants into FTEs, the cost of 1 FTE consultant is estimated at ca. EUR 66 000 annually)

Such Commission resources do not include contributions to the administrative overhead of the Commission (HR, Finance, IT tools, etc.).

Current budget line: DG SANTE + DG GROW

Future workload and resource needs:

Because of the planned introduction of new risk management measures to cover substances classified as endocrine disruptors, and the process for examining the safety of substances that could affect the respiratory system and chemicals toxic to a specific target organ toxicant (STOT), it is expected that the number of exemption requests might grow significantly and that there will be a need for more than the current average of 11 opinions per year, with more than up to 20 opinions in the pipeline at any given moment. However, in view of the maximum capacity of the SCCS based on its current composition the overall number of assessments per year may not change dramatically.

If the current ECHA estimation of resources is applied to the complexity of dossier reviewed by the SCCS, we can extrapolate the following future allocation of FTEs: 0.35 FTE for low complexity dossier (4 dossiers out of 11 which would require 1.4 FTE), 0.5 FTE for average complexity (4 dossiers out of 11 would require 2 FTE) and 0.65 FTE for complex dossier (3 dossiers out of 11 which would require 1.95 FTE). For 11 opinions per year this makes 5.4 FTEs. Overhead of 15% is required to contribution for common component of IT tool development (data submission, processing, output), and overhead of 15 % is required to contribution for horizontal support (governance, enablers, administrative overhead), which is additional 1.6 FTE. In total, it makes 7 FTEs. In addition, there is a need to cover travelling, accommodation, contingency costs related to members of the SCCS, in total some EUR 300 000/year.

Summary of resource needs for cosmetic product regulation:

Agency	**Summary of tasks**		
ECHA	Assessment for Restriction/prohibition of substances Assessments for authorisation of substances and exemption requests	Financial resource needs:	2024: **EUR0** 2025: **EUR 0** 2026: **EUR 300 000** 2027: **EUR 300 000** 2028: **EUR 300 000**

	Update of the Guidance document	Human resource needs:	2024: **0 TAs, 0 CAs** 2025: **7 TAs, 0 CAs** 2026: **7 TAs, 0 CAs** 2027: **7 TAs, 0 CAs** 2028: **7 TAs, 0 CAs**

Future budget line: DG GROW

Candidate for fees: No

33. SCIENTIFIC COMMITTEES AND THEIR SECRETARIAT (SCCS/SCHEER)

Responsible body:

Currently: Commission (DG SANTE) providing the secretariat and operating the two committees

(Re-)attribution planned to: chemical work of both Committees to ECHA and partly also to EFSA and EEA; non-chemical work to the Scientific Advisory Mechanism (SAM), under DG RTD.

Legal basis for reattribution: Revisions, omnibus regulation + Commission Decision

Type of task: existing

Brief task overview: Providing secretariat for the Scientific Committee on Consumer Safety (SCCS) and on Health, Environmental and Emerging Risks (SCHEER) and providing opinions on variety of chemical and non-chemical related subjects.

Detailed process description:

Current process:

When preparing policy or proposals related to consumer safety, health and the environment, the Commission relies on two independent Scientific Committees to provide it with sound scientific advice and draw its attention to new and emerging problems.

For this purpose, the Commission Decision C(2015)5383[1] established the following scientific committees:

- Scientific Committee on Consumer Safety (**SCCS**), and
- Scientific Committee on Health, Environmental and Emerging Risks (**SCHEER**).

Formal mandate

The **SCCS** on request of Commission services shall provide opinions on questions concerning health and safety risks, notably chemical, biological, mechanical and other physical risks, of:

1. non-food consumer products such as
   - cosmetic products and their ingredients, including nanomaterials, hair dyes, fragrance ingredients, UV filters, preservatives, colorants, etc.;
   - personal care and household products such as detergents; toys, textiles, clothing, etc.
2. services such as tattooing, artificial sun tanning, etc.

The **SCHEER** on request of Commission services shall provide opinions on questions concerning health, environmental and emerging risks.

1. In particular, the Committee shall provide opinions on questions concerning emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Union risk assessment bodies. Examples of areas of activity include potential risks associated with antimicrobial resistance, new technologies such as nanotechnologies, medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, physical hazards such as noise and electromagnetic fields, interaction of risk factors, synergic effects, cumulative effects, and methodologies for assessing new risks. It may also be invited to address risks related to public health determinants and nontransmissible diseases.
2. The SCHEER Committee shall also provide opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment.
3. Without prejudice to the competences conferred on the European Chemical Agency (ECHA) and other Union bodies undertaking risk assessment, it may also be invited to address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have adverse effects for human health and the environment, including biocides.
4. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

Work of Committees in practice

The **SCCS** concentrates mostly on the risk assessment of cosmetic ingredients. Opinions delivered by SCCS[2] from 2013 till today were exclusively on the safety of chemicals in cosmetics (nanomaterials, fragrances, hair dyes, preservatives, UV filters) or methodologies used for risk assessment of chemicals.

The **SCHEER**'s work covers rather large and diverse areas. Opinions delivered by SCHEER between 2014 and today (see table below) were related to areas of environmental risk assessment, medical devices, use of animals in laboratory testing, physical risks, public health (mainly tobacco), toys and rapid risk assessment.

Table: List of delivered opinions by SCHEER since 2014, with those not about safety assessment of chemicals highlighted in green:

Environmental risk assessment	
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – 5-6 rings polyaromatic hydrocarbons (PAH)	March 2023
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Tributyltin compounds	March 2023
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Dicofol	January 2023
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – PBDEs	January 2023

Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – dioxins, furans and dioxin-like PCBs	January 2023
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – HBCD	January 2023
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Triclosan	January 2023
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Mercury and its compounds	December 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Heptachlor including heptachlor epoxide	December 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Nickel and its compounds	December 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Glyphosate	December 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Hexachlorobutadiene	December 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Ibuprofen	December 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Fluoranthene	November 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Nonylphenol	November 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Diuron	October 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Bisphenol A	October 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Hexachlorobenzene	October 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – PFAS	August 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Cypermethrin	August 2022
Opinion on Draft Environmental Quality Standards for priority substances under the Water Framework Directive – Diclofenac	August 2022
Scientific Opinion on Groundwater quality standards for proposed additional pollutants in the annexes to the Groundwater Directive (2006/118/EC)	July 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Chlorpyrifos	June 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Carbamazepine	May 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Bifenthrin	May 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Azithromycin	May 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Clarithromycin	May 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Esfenvalerate	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Permethrin	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Deltamethrin	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Thiamethoxam	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Thiacloprid	March 2022

Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Clothianidin	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Acetamiprid	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - 17-Alpha-Ethinylestradiol (EE2), Beta-Estradiol (E2) and Estrone (E1	March 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Erythromycin	February 2022
Statement II on emerging health and environmental issues (2022)	January 2022
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Nicosulfuron	October 2021
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Silver and its compounds	October 2021
Scientific Opinion on "Draft Environmental Quality Standards for Priority Substances under the Water Framework Directive" - Imidacloprid	October 2021
Potential for anaerobic biodegradability in marine and freshwater of Linear Alkylbenzene Sulphonates (LAS)	June 2020
Scientific advice on Guidance Document n°27: Technical Guidance for Deriving Environmental Quality Standards	Sept 2017
Scientific advice on Proposed EU minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge	June 2017
Potential risks to human health and the environment from the use of calcium cyanamide as fertiliser	March 2016
New conclusions regarding future trends of cadmium accumulation in EU arable soils	Nov 2015
Opinion on Synthetic Biology I, II and III - Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology	Sept 2014; May 2015; Nov 2015
Opinion on Environmental risks and indirect health effects of mercury from dental amalgam (update 2014)	March 2014
Medical Devices	
Opinion on the safety of breast implants in relation to anaplastic large cell lymphoma	March 2021
Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties	June 2019
Scientific Advice on Evaluation of the availability of new scientific information on the safety of Poly Implant Prothèse (PIP) breast implants	Sept 2017
Scientific advice on the state of scientific knowledge regarding a possible connection between breast implants and anaplastic large cell lymphoma	Oct 2017
Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk	Feb 2016
Opinion on the safety of surgical meshes used in urogynaecological surgery	Dec 2015
Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users	Apr 2015
Opinion on the safety of the use of bisphenol A in medical devices	Feb 2015
Opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants	Sept 2014
Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants	May 2014
Non animal testing	
Opinion on the need for non-human primates in biomedical research, production and testing of products and devices (update 2017)	May 2017
Physical risks	
Opinion on the potential risks to human health of Light Emitting Diodes (LEDs)	June 2018
Opinion on Biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps	Feb 2017
Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes	Nov 2016

Final opinion on potential health effects of exposure to electromagnetic fields (EMF)	Jan 2015
Public health	
Opinion on Electronic cigarettes	April 2021
Opinion on the public health impacts and risks resulting from onshore oil and gas exploration and exploitation in the EU	Nov 2018
Final Opinion on Additives used in tobacco products (Tobacco Additives II)	Dec 2016
Rapid risk assessment	
Guidance on *ad hoc* rapid risk assessment of serious cross-border chemical health threats performed by the SCHEER	Feb 2017
Toys	
Final Opinion on Toxicological reference values for certain organic chemicals emitted from squishy toys with regard to adopting limit values under the Toy Safety Directive 2009/48/EC 'Chemicals in squishy toys'	June 2021
Final Opinion on Tolerable intake of aluminium with regards to adapting the migration limits for aluminium in toys	Sept 2017
Opinion on Estimates of the amount of toy materials ingested by children	April 2016
Opinion on Chromium VI in toys	Jan 2015
Statements	
Statement I and II on emerging health and environmental issues (2018; 2022)	Jan 2022
SCHEER Statement on emerging health and environmental issues (2018)	December 2018
SCHEER Position Paper on Emerging Issues and the Role of the SCHEER (2018)	June 2018
Memorandum on weight of evidence and uncertainties - Revision 2018	June 2018
Position Statement on emerging and newly identified health risks be drawn to the attention of the European Commission	November 2014
Nanotechnologies	
Final opinion on Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices	Jan 2015
Final opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance	June 2014

The Rules of Procedure of the Committees are fully described here:

https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/rules_procedure_2016_en.pdf.

In order to ensure the effective functioning of the Scientific Committees, these Rules of Procedure regulate the functioning of the Scientific Committees, their working groups, the role and responsibilities of members and experts, other activities related to the functioning of the Scientific Committees, as well as the role and responsibilities of their secretariat.

The members of the SCCS and SCHEER are independent experts in various fields, selected after a public Call for Experts and appointed for a five-year term (current one until the end of 2026).

Changes in the process:

The **SCCS** is embedded in the Cosmetics regulation as a risk assessment body providing opinions to ensure safety of cosmetics products. In practice, SCCS serves exclusively to the implementation of the Cosmetic Products Regulation. The impact assessment accompanying the Commission Proposal for the revision of the Cosmetic Products Regulation contains analysis of options for reattribution of SCCS's tasks to ECHA. After the reattribution of work for cosmetics regulation to ECHA, there will be no need for DG SANTE operating the SCCS.

The **SCHEER**'s work is diverse. One part of the SCHEER's work relates to chemicals, namely under the Water Framework Directive/Environmental Quality Standard Directive, Toys Directive, Medical Devices Directive, Cross-Border Health Threats Regulation and Tobacco Directive. This can be re-attributed to the EU Agencies.

Other part of work of the SCHEER covers diverse issues like electromagnetic fields, emerging issues in health and environment, medical devices (like hip or breast implants), safety of LED lights, UVC lamps and sunbeds, use of animals in laboratories, etc. This clearly does not fall under the area of chemicals and it does not really fit to any of the EU Agencies. Such work will be transferred to Scientific Advisory Mechanism – SAM, under DG RTD.

The SAM consists of the Group of Chief Scientific Advisors (in total seven), the Science Advice for Policy by European Academics (SAPEA) consortium and the SAM secretariat. The SAM functions differently than the SCHEER. The basic difference is that the SCHEER directly gets mandates from the mandating Directorates General, i.e. policy Unit dealing with legislative proposals. SAM gives scientific advice to the College and Commissioners on broader issues through a request to the Commissioner for Research, Science and Innovation. The full SAM procedure is as follows:

1. The request for advice is initiated by members of the Commission through a request to the Commissioner for Research, Science and Innovation.
2. The Commissioner for Research, Science and Innovation is responsible for formulation of the request. The SAM secretariat in cooperation with the requesting service prepares a scoping paper. The Cabinet of the Commissioner for Research, Innovation and Science consults the relevant Cabinets of the Members of the Commission on the final draft scoping paper. If agreed, the Advisors are notified by the SAM Secretariat. The final decision to adopt a scoping paper lies with the Commissioner for Research, Science and Innovation in cooperation with the Advisors.
3. Once the scoping paper with the related deadline has been adopted, the advisors appoint a lead member who asks SAM secretariat to request SAPEA to gather the evidence. SAPE collects and review the evidence and produces Evidence Review Reports (ERR). Expert workshops which are part of the evidence review process are by default organised by SAPEA.
4. In view of the evidence, the lead member/coordination group will draft the Advisors' advice, also explaining existing uncertainties as well as minority views in science, if considered relevant. The SAM Secretariat will assist the preparation, proof-reading, editing and formatting of the advice.
5. The Advisors will aim for adoption by consensus of its advice. A dissenting opinion by any member(s) of the Group of Chief Scientific Advisors will be noted. Once adopted, the Chair of the Advisors will send the advice to the Commissioner for Research, Science and Innovation who will transmit it to the other Members of the Commission, including to the President. The Director-General for Research and Innovation will inform the relevant services.

The way of working might differ, but the non-chemical topics of the SCHEER could fit well under the remit of the SAM, although targeted for a specific piece of legislation:

- Potential risks to human health of Light Emitting Diodes (LEDs)
- Biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps
- Biological effects of ultraviolet radiation relevant to health with particular reference to

sunbeds for cosmetic purposes
- Electronic cigarettes/tobacco additives
- Potential health effects of exposure to electromagnetic fields (EMF)
- Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission
- Estimates of the amount of toy materials ingested by children
- Use of animals in laboratory testing
- Synthetic biology

Proximity to Agencies' mandate:

For chemical work, see the proximity analysis under the Cosmetic Products Regulation, the Water Framework Directive/Environmental Quality Standard Directive/Ground water directive, Toys Directive, Medical Devices Directive, Cross-Border Health Threats Regulation and Tobacco Directive.

For non-chemical work, Scientific Advice Mechanism (SAM) of the DG RTD could be the best solution as they already provide scientific advice to the College. The SAM will undergo a reorganization along with the revamping of the scientific advice of the new Commission (2024-2029) with help of SG.

Projected impact on Agencies:

For chemical work, see the analysis of projected impact on Agencies under the Cosmetic Products Regulation, the Water Framework Directive/Environmental Quality Standard Directive/Ground water directive, Toys Directive, Medical Devices Directive, Cross-Border Health Threats Regulation and Tobacco Directive.

For non-chemical work, the projected impact on SAM is:

- SAM Committee/bodies: **high impact**. The task generates major impact on the setup / organisation / staffing of Committees/bodies due to the additional workload

	SAM		
	# of opinions per year	**rapporteur**	**Type of opinion**
Opinions on non-chemical topics of SCHEER	1	SAM Secretariat	

- SAM data model and IT infrastructure: **low impact**. The task can be implemented with adjustments / configuration of existing data structures and IT systems
- SAM key experts: **low impact**. The task can be accommodated with existing expertise in SAM

Workload and resource implications:

<u>Current workload and resource use:</u>

In the past, the Secretariat was part of a whole Unit in DG SANTE Brussels and had up to 20 FTEs. After the Secretariat of the Committees moved from Brussels to Luxembourg, the number of staff working for both Scientific Committees started to decline every year. Until October 2022, the Secretariat of both SCCS and SCHEER had worked with its minimum

capacity: 3 ADs officials, 1 CA and 2 external person/contractor. As of October 2022, in anticipation of the reattribution of tasks, the secretariat was reduced further, to 2 ADs officials and ½ CA. The current Secretariat estimates that minimum number would be 3 FTE per Committee (2 AD level and one secretary plus one external (contractor)). Maximum production capacity for both Committees together is production of up to 25 Opinions per year.

Key figures of the Scientific Committees' activity in term 2016-2021 are:

SCs	No. of adopted final documents	No. of meeting days*
SCCS	66	234
SCHEER	29	268
ICCG	0	5.5
Total	**95**	**507.5**

Number of opinions per Committee per year in term 2016-2021 are:

YEAR	SCCS	SCHEER
4-12/2016	7*	2
2017	9	9
2018	13	6
2019	12	3
2020	6	1
2021	19	8
TOTAL	**66**	**29**

The total budget spent for all the activities was **EUR 3 964 190,89** for term April 2016 to December 2021:

- **EUR 2 883 030,89** were spent for meeting costs - reimbursements of Chairs and Rapporteurs, special allowance, etc…
- **EUR 1 081 160,00** were spent for technical assistance (literature search, editing of opinions, website mastering and dissemination activities).

More details can be found in their Activity Report: see activity_report_sc_20132016_en.pdf (europa.eu)

Current budget line:

For both Committees, as of 2021, the funding comes from the EU budget (EU4Health). In the past it was via Consumer (DG JUST) - mainly for the SCCS - and via Health (SANTE) Programmes.

Future workload and resource needs:

For chemical work, the future workload and resource needs are estimated under the Cosmetics Product Regulation, the Water Framework Directive/Environmental Quality Standard

Directive/Ground water directive, Toys Directive, Medical Devices Directive, Cross-Border Health Threats Regulation and Tobacco Directive for their respective parts.

For non-chemical work, the experience over the last 10 years shows that the number of opinions on non-chemical issues is low and amounts to approximately 1 opinion per year. Majority of opinions on non-chemical topics are *ad-hoc*. There are few examples of opinions that are recurrent, like the once on electromagnetic fields (EMF) and on the use of animals in laboratory testing (one opinion approximately every 5 years). Currently the SAM delivers around 3-4 opinions per year. The additional 1 opinion will therefore represent a significant impact. It is estimated that addition 1 FTE for SAM secretariat will be necessary.

Summary of resource needs for non-chemical topics of SCHEER:

Agency	**Summary of tasks**		
SAM Secretariat (DG RTD)	Opinions on non-chemical topics of SCHEER	Financial resource needs:	2024: **EUR 0** 2025: **EUR 0** 2026: **EUR 0** 2027: **EUR 0** 2028: **EUR 0**
		Human resource needs:	2024: **0 TAs, 0 CAs** 2025: **1 TAs, 0 CAs** 2026: **1 TAs, 0 CAs** 2027: **1 TAs, 0 CAs** 2028: **1 TAs, 0 CAs**

Future budget line: DG RTD

Candidate for fees: No

34. ECODESIGN FOR SUSTAINABLE PRODUCTS REGULATION

Responsible body:

Currently: N/A, no current process

Reattribution planned to: TBC

Legal basis for reattribution: proposal for Ecodesign for Sustainable Products Regulation.

Type of task: new

Brief task overview: The draft regulation sets a framework provisions and the details of implementation (such as scope, IT formats, etc.) will be set at the later stage via the delegated or implementing acts. The framework provisions do not set any direct obligations on the Agencies. However, it is expected that as part of the delegated acts Agencies will be required to support several technical tasks and operate IT systems. The topic of interest from the chemical perspective is the digital product passport, where ECHA may be expected to provide information on the presence of substances of concern in products (link with the existing SCIP database, but expectations would be broader than the current scope of SCIP). ECHA may be expected to build a bridge between SCIP and the product passports, but the details of the work are not known yet.

The draft Regulation also includes a provision for the Commission to request ad-hoc advice from the Agencies when assessing the self-regulation measures; it is yet unclear whether and which Agencies' expertise would be required as part of this process and the related workload.

Proximity to Agencies mandate: ECHA's core mandate is related to the safety assessment of chemicals. The provision of information on the presence of SoC in products could be seen as an extension of the mandate from chemicals to products and from risk assessment to providing information.

Main risks and opportunities: Risk of deviating from ECHA core mandate of safety assessment of chemicals. The scope of information on chemicals in the Digital Product Passports (DPP) is expected not to be the same as in SCIP: Product passport are to report on all substances of concern, while SCIP only reports on the presence of Candidate List substances (SVHCs), which is at least a 100-fold increase in scope. Currently, with ca. 200 SVHCs in scope ECHA has received already 21 million SCIP notifications. If the scope is 100-fold bigger, the number of notifications may become excessive. If the product passport is to be a system among the companies, it remains to be seen how ECHA can contribute to such system and what role it would play.

Projected impact on ECHA

- *ECHA Committees/bodies:* ***no impact****. The task does not require involvement of ECHA Committees/bodies*
- *ECHA data model and IT infrastructure:* ***high impact****. The task requires investment in entirely new data structures and IT systems/capabilities*
- *ECHA key experts:* ***high impact****. The task heavily relies on expert competencies, which are limited within ECHA and also critical to REACH/CLP/BPR regulatory tasks*

Projected workload and resource implications

Current workload and resource use:

Not yet analysed, as the obligations are not yet clear. This will be done as part of the delegated acts once the main act is adopted.

Future workload and resource needs

Not yet analysed, as the obligations are not yet clear

35. TOBACCO PRODUCTS DIRECTIVE

Responsible body:

Currently: Commission with the support of the SCHEER Committee

Reattribution planned to: TBC

Legal basis for reattribution: revision of the Tobacco directive (2014/40/EU)

Type of task: new

Brief task overview: The tobacco directive is undergoing an evaluation and a revision of the directive is being envisaged. As part of the revision, a new scientific and technical work is being envisaged that could be potentially attributed to EU Agencies. Currently, Under Article 6(1), the Commission adopted a decision, establishing a priority list of 15 additives for which enhanced reporting obligations are in place, selected on the basis of a SCHEER scientific opinion. It is being considered whether in future in addition, a positive list of ingredients and a database would need to be established. In addition, the work may include:

- Managing the laboratory network on tobacco control;
- Checking compliance with product presentation provisions;
- Running the procedure determining characterizing flavour;
- Updating negative/positive lists of additives;
- Hosting product database and making publicly available the product information;
- Monitoring of data in product notifications;
- Assessing information on leaflets.

Proximity to Agencies' mandate: The tasks are not yet clear but those that are being considered do not naturally fit to the agencies considered in this initiative.

Main risks and opportunities: ECHA's, EFSA's and EMA's core mandate relates to the safety assessment of chemicals to protect human health and the environment. The proposed tasks are not related to that core mandate.

Projected workload and resource implications

Future workload and resource needs:

Not yet analysed, as the obligations are not yet clear.

36. REGULATION ON FLUORINATED GREENHOUSE GASES AND REGULATION ON OZONE DEPLETING SUBSTANCES

Responsible body:

Currently: Commission and EEA

Reattribution planned to: TBD

Legal basis for reattribution: revision of regulation on fluorinated greenhouse gases (517/2014) and revision of regulation on ozone depleting substances (1005/2009)

Type of task: new

Detailed task overview:

Current:

The Commission is implementing a quota and licencing system for hydrofluorocarbons as well as a similar system for ozone depleting substances (ODS) that both require registration of importers and producers of these chemicals, determination and allocation of company quota and issuing of penalties for non-compliance with the quota system. Annual company reporting data is collected and aggregated by the European Environment Agency each year. The agency

prepares a report on ODS and F-gas related activities for Member State representatives and the Commission (DG CLIMA), which includes for instance for F-gases data on imports, exports, production, destruction, and reclamation relevant to bulk F-gases and equipment containing such gases

Changes:

On 5 April 2022, the Commission presented a proposal for a regulation on fluorinated greenhouse gases (F-gases) that would repeal Regulation (EU) No 517/2014 and a proposal repealing Regulation on ozone depleting substance (EC) No 1005/2009. The proposal aims to further reduce emissions of these chemicals. The F-gas proposal would change the existing quota system, gradually reducing the supply of hydrofluorocarbons (HFC) to the EU market to approximatively 2.4 % of 2015 levels by 2048 and requiring a quota allocation price which needs to be collected. The quota revenue can partly be used for the implementation of the quota and licensing system. For ozone depleting substances the quota system will be abolished and the licencing system simplified. Both licensing systems and labelling obligations will be strengthened to improve enforcement of trade and hydrofluorocarbon (HFC) quota restrictions. Finally, the proposals would align EU legislation with the requirements of the Montreal Protocol.

The European Environmental Agency (EEA) will have to slightly adapt their reporting tool for undertakings reporting on F-gases and ozone depleting substances, due to changes in the reporting requirements.

The proposal retains the obligation on the Commission to set up and operate an electronic system for the management of the quota system for HFCs as well as the licensing of imports and exports and reporting for F-gases and for ozone depleting substances. It is not yet clear how the tasks can be implemented most effectively, but it is envisaged that an agency could take some of the tasks in case that would be deemed to be the best option at a later stage.

Proximity to Agencies' mandate: The Regulations are still under review and tasks related to setting-up and operating of the electronic system are not yet fully clear. It thus remains unclear if any of the agencies would be suitable for such tasks.

Projected workload and resource implications

Future workload and resource needs

Not yet analysed, as the tasks are not yet defined