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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

{COM(2023) 779 final}

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Glossary

Term or acronym	Meaning or definition
ACT	Activities Coordination Tool
CLP	Classification, labelling and packaging
DGM	Data generation mechanism
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EREN	Emergency Response Experimentation Network
EQS	Environmental quality standard
FAIR	Findable, Accessible, Interoperable and Reusable
FTE	Full-time equivalent
HBLV	Health-based limit value
INCI	International nomenclature of cosmetic ingredients
IPCHEM	Information platform on chemical monitoring
JRC	Joint research centre
LUCAS	Land Use/Cover Area frame statistical Survey
MRL	Maximum residue limit

OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
OHT	OECD harmonised template
PACT	Public Activities Coordination Tool
PARC	Partnership for the Assessment of Risk from Chemicals
POP	Persistent organic pollutant

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. They form part of virtually every product we use for our well-being, the products we use to protect our health and security, and the innovative solutions to meet new challenges. 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 chemicals 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 can cause cancers, affect the immune, respiratory, endocrine, reproductive and cardiovascular systems and increase our vulnerability to disease. Exposure to these harmful chemicals is therefore a threat to human health. In addition, chemical pollution of the environment is one of the key drivers putting the earth at risk[2], affecting and amplifying planetary crises such as climate change, degradation of ecosystems and loss of biodiversity. Examples of these effects are the negative effects chemicals have on pollinators, insects, aquatic ecosystems, and on the bird population.

The European Union has developed a comprehensive regulatory framework for chemicals. The aim is to provide 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. A fitness check of the most relevant chemicals legislation (excluding REACH) ('fitness check')[3] assessed over 40 pieces of legislation. It concluded that overall, the EU chemicals regulatory framework delivers results as intended and is fit-for-purpose. However, it found a number of significant weaknesses that prevent the framework from achieving its full potential. If not rapidly addressed, the framework will struggle to cope effectively with the risks posed by existing and new chemicals.

The EU chemicals regulatory framework has the overall objective to provide high-level protection of human health and the environment from exposure to chemicals. The risk management processes introduced by each piece of legislation draw heavily from **scientific and technical assessments** of chemicals' properties, their uses, exposure and risks and of the socio-economic consequences of the risk management measures planned.

To conserve natural resources and protect ecosystems and people, within the limits of our planet, assessing the environmental impacts generated by chemicals along their entire life cycle is needed. Evaluation of several impact categories, such as climate change and resource use, requires access to robust and high-quality information and can guide the design, development and production of chemicals that provide a desirable function or

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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.

3 Fitness Check of the most relevant chemicals legislation (excluding REACH).

service while being **safe and sustainable**. Moreover, **availability of sustainability information** could trigger the demand for chemicals with lower environmental impacts, and therefore have direct benefit for health and the environment.

To prevent harm caused by harmful chemicals, it is also essential to be able to identify as early as possible any emerging chemical risks and to anticipate unforeseen consequences related to the use of chemicals and their release into the environment. This requires having information on early warning signals.

Building on the findings of the fitness check, the Commission committed in the European Green Deal[4] to present a chemicals strategy for sustainability[5] ('the strategy'). As part of this work, it committed to start using the '**one substance – one assessment'** approach to **improve the efficiency, effectiveness, coherence and transparency of issuing safety assessments** of chemicals across different pieces of EU legislation.

The one substance, one assessment approach focuses on the main factors influencing the efficiency, effectiveness, coherence and transparency of safety assessments. It covers:

- *Initiation of chemicals safety assessments*. This means synchronising and coordinating the initiation or triggering of assessments to the extent possible and assessing groups of substances instead of assessing each substance individually to the extent possible.
- *Allocation of tasks*. This involves allocating clear responsibilities for performing assessments in such a way that best use is made of available expertise and resources and a good cooperation among all parties involved.
- *Information*. Ensuring that information is easily findable, accessible, interoperable, secure, of high quality and shared and reused to ensure that assessors have access to all available data without technical or administrative burden.
- *Methodologies*. The methods used for the assessments are coherent and to the extent possible harmonised.
- *Transparency*. Ensuring a high level of transparency in performing assessments as well as in the underlying scientific data and information on chemicals.

To enable the design, production and use of chemicals that are safe and sustainable by design, and throughout their life cycle, the strategy announced that the Commission would develop criteria for chemicals that are 'safe and sustainable by design'. To that end, a comprehensive assessment of both safety and sustainability throughout the whole life cycle of chemicals is required[6].

To strengthen the science-policy interface, the strategy announced that the Commission would develop an early warning and action system for chemicals to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research. It also announced that the Commission would develop a framework of indicators to monitor the

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4 The European Green Deal. COM (2019) 640 final.

5 The Chemicals Strategy for Sustainability. COM (2020) 667 final.

6 Commission Recommendation (EU) 2022/2510 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H2510).

drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation.

The EU action plan *Towards Zero Pollution for Air, Water and Soil*[7] ('the EU action plan') contributed to the strategy's objectives by committing to developing an integrated **zero pollution monitoring and outlook framework.** It also consolidated the roles of the European Environment Agency (EEA) and the Commission's Joint Research Centre in close collaboration with the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), the European Maritime Safety Agency and other relevant agencies as the EU's knowledge centres of excellence for the zero-pollution monitoring and outlook framework.

In addition, the EU action plan and the proposal for a regulation on establishing a framework for setting ecodesign requirements for sustainable products[8] emphasise the commitment to ensure that chemicals and materials are as safe and sustainable as possible by design and during their life cycle, so that material cycles are non-toxic.

To fulfil the commitment to start using the one substance, one assessment approach and in order to collate relevant information on the safety and sustainability of chemicals and on early warning signals for chemicals risks, the strategy identified the following actions:

- develop a **common open data platform on chemicals**[9] to facilitate the sharing, access and re-use of information on chemicals coming from all sources.
- Promote the re-use and harmonisation of human and environmental **health-based limit values** among EU risk assessors and managers through a centralised and curated EU repository.
- 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 and national authorities to **commission testing and monitoring** of substances as part of the regulatory framework when further information is considered necessary.
- Remove legislative obstacles for the **re-use of data** and better streamline the flow of chemicals data between EU and national authorities.
- 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.
- Develop a framework of indicators to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation.

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7 The EU Action Plan 'Towards Zero Pollution for Air, Water, and Soil. COM/2021/400 final.

8 Proposal for a regulation of the European Union and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC. COM(2022) 142 final.

9 As part of the European Green Deal data space announced under the EU data strategy. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European Strategy for Data. COM (2020) 66 final.

The European Parliament resolution[10] of 10 July 2020 welcomed the strategy and the **application of the one substance, one assessment principle** in order to better use the resources of the Union's agencies and scientific bodies, avoid duplication of efforts, including testing, 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, while taking into account the special situation of SMEs. The European Parliament initiated a project to assess the feasibility of consolidating the chemicals data collected by the institutions, bodies and agencies of the European Union.

The European Parliament's resolution also called on the Commission to **establish a fully connected and interoperable EU chemical safety database** so as to facilitate the seamless sharing of data between authorities and provide public access to researchers, regulators, industry and the citizens at large. Moreover, the resolution stressed the need to **develop 'safe and sustainable by design' criteria** to help prevent and control pollution, improve the tracing of hazardous chemicals in products, and promote their substitution by safer and more sustainable alternatives.

The Council conclusions[11] of 15 March 2021 also welcomed the strategy and the aim of the one substance, one assessment approach to simplify and improve the transparency of the regulatory framework for hazard and risk assessment of chemicals while emphasising that this approach should not create delays in regulatory actions nor increase administrative burden. The conclusions highlighted the relevance of a comprehensive information base on chemicals and on chemicals' overall environmental footprint, including their impact on the climate, biodiversity and marine environment. The conclusions also welcomed the establishment of an EU chemical early warning and action system and called for the development, in collaboration with the Member States, of a comprehensive chemicals monitoring framework as part of a wider zero pollution monitoring and outlook framework, with publicly accessible results, to oversee the driving forces and impacts of chemical pollution on human health and the environment, to complement monitoring of the presence of chemicals in ecosystems, and to measure the effectiveness of chemicals legislation.

1.2. Legal context

This initiative complements the body of EU law governing chemicals. In addition, it complements or is consistent with several specific legal provisions under specific pieces of chemicals-related legislation. It covers a very large number of Union chemicals legislations (listed in section 1.3).

The proposed provisions on setting up a common data platform on chemicals and dedicated services provided by that platform complement existing provisions on databases, repositories or platforms containing chemicals-related information issued under specific pieces of legislation. The common data platform will centralise and consolidate data on chemicals at EU level in one centrally accessible IT infrastructure. The proposed provisions also build on a project initiated by the European Parliament to assess the

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[10] The European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability. (2020/2531(RSP).

[11] The Council Conclusions on Sustainable Chemicals Strategy of the Union: Time to Deliver.

feasibility of consolidating the data on chemicals collected by EU institutions, bodies and agencies.

The proposed provisions related to the dedicated service under the common data platform on regulatory information will integrate existing practices on disseminating regulatory process information by the ECHA and EFSA, notably the Public Activities Coordination Tool[7] and OpenEFSA[8]. The provisions are consistent with the proposals made to revise Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures and the proposal for a directive 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 2013/39/EU as regards priority substances in the field of water policy, which oblige authorities to inform the ECHA on regulatory processes they intend to start or have started.

The measures to set standard data formats and controlled vocabularies by EU agencies (section 4.2.2) are consistent with and complementary to provisions under:

- Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (Articles 77 and 111);
- Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products (Articles 76 and 79);
- Commission Implementing Regulation (EU) 2021/428 adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 (Articles 1 and 2);
- Regulation (EC) 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 (Articles 39f and 39g) and
- Council Regulation (EEC) No 1210/90 on the establishment of the European Environment Agency and the European Environment Information and Observation Network (Annex A).

The proposed provisions on the use by authorities of chemicals data and information contained in the common data platform aim to align chemicals acts with EU policies on data, including the European strategy for data[12] and the Interoperable Europe Act[13].

The proposed provisions on the notification of studies commissioned or carried out by business operators are consistent with a similar notification obligation stipulated in Article 32b of Regulation (EC) 178/2002 for studies commissioned or carried out by business operators to support an application or notification in food-related areas.

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12 Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, A European strategy for data, COM/2020/66 final.

13 Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) COM(2022) 720 final.

The establishment of a data generation mechanism is consistent with Article 32 of Regulation (EC) 178/2002, which states that the EFSA shall commission scientific studies necessary for the performance of its mission.

The establishment of a database on environmental sustainability-related information is complementary to Article 19a of Directive (EU) 2022/2464[9] setting the reporting requirements needed to understand an undertaking's impacts on sustainability matters, and the information needed to understand how sustainability matters affect the undertakings' development, performance and market position and are relevant to the proposed Ecodesign for Sustainable Products Regulation[14]. The aim of the Ecodesign Regulation is, among others, to create harmonised reporting obligations for environmental sustainability information along the value chain.

This initiative relates to the proposal under preparation for a regulation on re-allocating the work on chemicals between EU agencies to ensure consistency in the assessment of chemicals and to improve efficiency. That proposed regulation makes targeted amendments to the allocation of tasks in Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Regulation (EU) 2019/1021 on persistent organic pollutants and Regulation (EU) 2017/745 on medical devices. The proposal also amends Regulation (EC) No 401/2009 establishing the EEA and Regulation (EC) No 178/2002. The aim is to ensure good cooperation between EU agencies on all aspects affecting the coherence and efficiency of assessment of chemicals (such as methodology development, exchange of data and solving divergences in scientific output).

The proposal also relates to the proposal in preparation for a founding regulation of the ECHA, which aims to strengthen the ECHA's governance and adapt it to its future role and which aims to streamline the working methods of ECHA bodies and make their financing more sustainable.

1.3. Scope of the document

This document summarises the actions taken to support the implementation of the one substance, one assessment approach, in particular in relation to the improvement of the efficiency, effectiveness, coherence and transparency of safety assessments of chemicals across EU chemicals legislation. It accompanies the horizontal legislative proposal formalising those actions. The document explains how the actions proposed contribute to achieving the one substance, one assessment objectives and the establishment of a monitoring and outlook framework for chemicals. It provides an assessment of the impact of those actions where relevant. Where possible, a quantitative assessment is made.

The specific pieces of legislation considered in scope of the legislative initiative are listed below. For some pieces of legislation only a limited set of specific actions proposed in this document is considered applicable. Those legislations are situated in the pharmaceuticals sector and are listed in a separate list below.

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[14] Proposal for a regulation of the European Union and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC. COM(2022) 142 final.

The development of the legislative proposal and this staff working document was supported by a study titled 'Study on streamlining chemicals data flows, increasing data interoperability, dissemination, re-use and the use of all available data, and on the establishment of a data generation mechanism for the purpose of safety assessments in the context of the European chemicals regulatory framework'. The proposal for the establishment of a common data platform was supported by a feasibility study on a common open data platform on chemical safety data[15] and builds on an earlier project initiated by the European Parliament to assess the feasibility of consolidating the chemical data collected by the institutions, bodies and agencies of the European Union. The proposal for the early warning and action system for emerging chemical risks was supported by a study titled 'Pilot of an EU early warning system for emerging chemical risks to the environment'[16].

List of EU legislation in scope of this initiative

1. Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40)
2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)
3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)
4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)
5. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)
6. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)
7. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)
8. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)
9. 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)
10. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)

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15 Feasibility study on a common open platform on chemical safety data - Publications Office of the EU (europa.eu)

16 Pilot of an EU early warning system for emerging chemical risks to the environment.

11. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)
12. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)
13. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)
14. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)
15. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 047, 18.2.2004, p. 1)
16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)
17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)
18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)
19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)
20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)
21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)
22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)
23. Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 070, 9.3.2006, p. 12)
24. Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances (OJ L 94, 1.4.2006, p. 32)
25. Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs (OJ L 364, 20.12.2006, p. 25)
26. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)
27. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency,

amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)

28. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)
29. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)
30. Commission Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 088, 29.3.2007, p. 29)
31. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)
32. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)
33. Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (OJ L 109, 19.4.2008, p. 11)
34. Commission Regulation (EC) No 429/2008 of 25 April 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 (OJ L 133, 22.5.2008, p. 1)
35. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)
36. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)
37. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)
38. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)
39. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)
40. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)

41. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)
42. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)
43. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)
44. 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 Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)
45. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)
46. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)
47. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)
48. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)
49. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)
50. Commission Regulation (EC) No 1169/2009 of 30 November 2009 amending Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (OJ L 314, 1.12.2009, p. 34)
51. Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (OJ L 314, 1.12.2009, p. 36)
52. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)
53. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)

54. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)
55. Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 080, 26.3.2010, p. 19)
56. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)
57. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)
58. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council implementing Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064, 11.3.2011, p. 15)
59. Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127)
60. 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)
61. Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods (OJ L 296, 15.11.2011, p. 29)
62. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)
63. Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2)
64. Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1)
65. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)

66. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)
67. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)
68. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)
69. Commission Implementing Decision 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (OJ L 22, 25.1.2013, p. 25)
70. Commission Regulation (EU) No 101/2013 of 4 February 2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcasses (OJ L 34, 5.2.2013, p. 1)
71. Commission Regulation EU No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1)
72. Commission Regulation EU 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation EC No 1107/2009 concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85)
73. Commission Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1)
74. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)
75. Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (OJ L 333, 12.12.2013, p. 54)
76. Commission Regulation (EU) No 119/2014 of 7 February 2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium (III) lactate tri-hydrate added to foods (OJ L 39, 8.2.2014, p. 44)
77. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)

78. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)
79. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)
80. Commission Regulation (EU) 2015/403 of 11 March 2015 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Ephedra species and Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) (OJ L 67, 12.3.2015, p. 4)
81. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)
82. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)
83. Commission Regulation (EU) 2017/644 of 28 March 2007 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 and repealing Regulation (EU) No 589/2014 (OJ L 92, 6.4.2017, p. 9)
84. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)
85. Regulation (EU) 2017/745 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)
86. Commission Regulation (EU) 2017/1203 of 5 July 2017 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements (OJ L 173, 6.7.2017, p. 9)
87. Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU)

2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72)

88. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)
89. Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5)
90. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).
91. Commission Regulation (EU) 2019/650 of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) (OJ L 110, 25.4.2019, p. 21)
92. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)
93. 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)
94. Commission Implementing Regulation EU 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20)
95. Commission Implementing Regulation (EU) 2020/1824 of 2 December 2020 amending Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 406, 3.12.2020, p. 51)
96. 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)
97. Regulation EU 2021/428 of 10 March 2021 adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 84, 11.3.2021, p. 25)
98. Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3)
99. Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103)

List of Union legislation only partly in scope of this initiative[17]

1. Directive 2001/83/EC on the Community code relating to medicinal products for human use
2. Regulation (EC) No 726/2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
3. Regulation (EU) 2019/6 on veterinary medicinal products
4. Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin

[17] Only specific types of data will be brought within the scope of the regulation and included in the common data platform for chemicals.

2. PROBLEM DEFINITION

2.1. What is/are the problems?

The EU regulatory framework for hazard and risk assessment and management of chemicals is comprehensive. It consists of many pieces of legislation, addressing the production and placing on the market of chemicals and chemical products, emissions of chemicals, protection of workers' health and safety of consumer products, foodstuff and feedstuff, and the environment. A high volume of technical and scientific work supports he implementation of the individual legislative acts. Sustained EU contribution is provided also for flanking measures[18] supporting policy objectives on chemicals in addition to legislative tools.

Depending on the legislation, the work is initiated by various actors, at different points in time, using different data and involving different actors (EU agencies, scientific committees, expert groups, Commission services and contractors). This situation sometimes leads to **inefficient use of resources** and **slow procedures**. Differences in knowledge base across pieces of legislation and incomplete knowledge bases may result in **inconsistent outcomes** for the same chemical**.** Similarly, different dissemination rules across pieces of legislation for the same chemical may result in **different degrees of transparency**. As a consequence, **the predictability** for stakeholders and the general public is reduced.

Despite the comprehensive and advanced EU regulatory framework for chemicals there is a growing concern that it lacks the relevant mechanisms to adequately address emerging chemical risks in a timely manner. There are numerous examples of the long timespan between a signal of a risk and the adoption of adequate measures to address that risk[19]. These examples also illustrate the difficulty to get emerging chemical risks such as nanomaterials, PFAS and endocrine disruptors on the radar of policy makers and governmental risk assessors.

An overview of the identified problems is given in Table 1 below.

Table 1 – overview of identified problems

Overall problem	Specific problems
	Chemicals data is scattered
	Chemicals data is not always interoperable

[18] While this general description could fit many activities supported through instruments like LIFE or COSME, the noteworthy example is the existing Commission's continued contribution to operation of EUON-European Observatory for nanomaterials, set as an alternative non-legislative solution to at the time considered EU registry of nanomaterials. EUON is operated by ECHA, commissioning studies, and compiling available information to increase and communicate knowledge on nanomaterials and increase transparency regarding their presence in the market. Commission staff working document: impact assessment accompanying the document Commission Implementing Decision on a Delegation Agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME programme. SWD (2017) 138 final..

[19] EEA: Late lessons from early warnings: the precautionary principle 1896–2000, Luxembourg: Office for Official Publications of the European Communities, 2001

2.1.1. Information is difficult to find, or share	
	Chemicals data is not always accessible
2.1.2. Knowledge base is incomplete	Academic data are insufficiently considered
	Lack of availability of certain types of chemicals data
	Not all study results are reported by duty holders
	Lack of mechanism to identify emerging chemical risks

2.1.1. Information is difficult to find, share or use

The fitness check of the most relevant chemical legislation (excluding REACH)[20] ('Fitness Check') found that there are **shortcomings in the findability, accessibility, interoperability and availability of good-quality and reliable data and in sharing and using data across legislative silos**. Stakeholders have complained about this in the past (e.g. regarding inefficiencies caused by double reporting requirements, difficulties to identify and access data, inconsistencies between outcomes of safety assessments because they are based on different datasets - which are frequently not interoperable - and not considering all available data in safety assessments). There is a lack of awareness of interested parties (EU bodies, authorities, industry, NGOs) of what information is available and where and how the existing data can be used and accessed, and use rights are sometimes too restrictive. Unnecessary duplication of effort in data generation still occurs in some instances due to a lack of data sharing as a result of various factors including confidentiality and intellectual property rights. Technical obstacles, such as different data formats and different vocabularies for the same chemical under different pieces of legislation, make data handling inefficient and are seen as contributing obstacles to the one substance, one assessment approach.

Chemicals data is scattered and some information flows are suboptimal
Through the EU's comprehensive chemicals legislative framework copious amounts of information about chemicals, their use and their occurrence are generated and collected by various stakeholders, including industry, the Commission, EU agencies and Member States. However, individual data streams resulting from the implementation of individual pieces of legislation are **not always interconnected and are hosted or stored in different databases and in different locations**.
In addition, some information flows are not optimal, e.g. because information is flowing to an agency which does **not necessarily have the best expertise** or does not have the type of data or the specific piece of legislation in its mandate. Also, some information is collected at Member State level but not shared with other Member States or EU agencies. This is particularly the case for raw data on monitoring of chemicals in the environment. Another example is the **lack of long-term structures** to store and assess data from EU-

[20] Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions finding of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps, and weaknesses. COM (2019) 264 final.

funded research projects or for certain voluntarily shared information, such as groundwater data on emerging pollutants.
All this makes it difficult for safety assessors and other stakeholders to know which information is available for a particular chemical and to find that information. Without a clear overview of what data is available and to which chemicals characteristics it relates, the EU safety assessor may not be able to use the existing wealth of information to its full potential. This may lead to inefficient assessments and decision making, but also to incoherent outcomes of different assessments of the same chemical, which in turn has a negative impact on the predictability for duty holders and the EU citizen's trust in the sound and scientific underpinning of the EU's assessment activities.

Chemicals data is not always interoperable
The feasibility study on a common open platform on chemical safety data[21] revealed that slightly over 50% of the considered sources of chemicals data (i.e., different platforms, databases or systems related to chemicals information) provide data in a comparatively structured way (e.g., tables, etc), while the remaining sources use less structured formats (such as reports) to provide data. The analysis done in the context of the study supporting this legislative initiative on chemicals information was in line with the findings of that feasibility study. **Many different - not always well-defined - formats are used**. It is recognised that the importance of harmonised formats and controlled vocabularies has increased over the last years.
For monitoring data, the support to the Fitness Check of monitoring and reporting obligations arising from EU environmental legislation[22] states that almost half of the identified reporting obligations have no format requirement. It should be noted, however, that not all monitoring data considered in that study are related to chemicals.

Chemicals data is not always accessible and re-usable
Differences exist in transparency rules governing the dissemination[23] of chemicals data across pieces of legislation. Such differences, as well as different interpretations of the same rules by different agencies or authorities, create a legal obstacle for sharing data among authorities. An agency with less stringent transparency rules may not be able to share its data with an agency with stronger transparency rules, because the latter would have to disseminate the information following its transparency rules while the agency with less stringent transparency rules does not have permission to disseminate such data. This obstacle hinders coherence and efficiency of chemicals safety assessments, as authorities are not always aware of or cannot see data held by other authorities and can therefore also not consider it in their assessment. Differences in transparency rules across pieces of legislation and agencies might also be seen as incoherent by the general public.

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21 Feasibility study on a common open platform on chemical safety data.

22 Study to support the Fitness Check of environmental monitoring and reporting obligations: a summary of public consultation responses.

23 For the purpose of this initiative and staff working document, *data dissemination* is considered as the process of making information available to the general public, while *data sharing* is a term used for making data available to authorities. *Transparency* is about openness of data and information to the general public and *transparency rules* thus govern the degree of dissemination of data and information to the general public. Finally, *data re-use* refers to the use of data by actors which differ from the originator or owner of the data.

In order to ensure the coherence and effectiveness of chemical safety assessments across legislative silos in line with the objectives of the one substance, one assessment approach, it is important that authorities have the right to re-use data in the assessments where relevant[24].

2.1.2. Knowledge base is incomplete

The knowledge base for regulatory safety assessments is not always complete. This may have different reasons: duty holders may **not report all results of the studies** they commission or carry out, **academic data are not always sufficiently considered,** and **the current legal framework does not allow for or does not standardly require the generation of certain data**.

Lack of availability of certain types of chemicals data
Different mechanisms and systems exist at EU and Member State level to request or generate data (via measurements or via non-testing and modelling methodologies) required for chemical safety and risk assessments, either under legislative frameworks or within other contexts. Still, not all chemicals on the market and/or occurring in the environment have currently been sufficiently characterised in terms of their toxicological properties and/or exposure sources and pathways or are regularly monitored. In addition, the lack of robust data on the environmental performance of chemicals throughout their lifecycle limits the extent to which the impacts of chemicals on the environment are understood, and therefore hinders the EU's ability to take targeted action to improve the sustainability of the industry by managing and reducing the environmental impact of chemicals. The sheer number of chemicals on the market represents an immense knowledge challenge, and the expected future rise in chemical production and use risks further widening the 'unknown territory of chemical risks'. Under Regulation (EC) 178/2002, the European Food Safety Authority ('EFSA') is given the means to perform all the tasks required to enable it to carry out its role. This includes a mandate for the EFSA to carry out scientific studies where necessary. **Such mandate or possibility does not exist for other agencies dealing with chemicals.**

Academic data are insufficiently considered
The fitness check concluded that there is a need to improve the consideration of academic data when carrying out chemical safety assessments. 'Academic data' is taken to mean chemicals related data derived from scientific studies published in peer-reviewed literature. In EU chemicals legislation, the consideration of academic data is usually not explicitly addressed but rather subsumed in the requirement to consider all available, relevant information. Academic studies are often not carried out according to the quality standards to which EU legislation refers, such as Good Laboratory Practice (GLP) and OECD test guidelines. This makes comparison difficult to data that are generated using such standard

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[24] For the purpose of this initiative, re-use focuses **on the re-use of data by authorities** (authorities are taken to mean the Commission, EU agencies and Member State competent authorities) (although data may come from different sources, such as from authorities, industry, or research activities). Re-use of data between private parties is not considered. This, however, does not constitute any barrier for industry to agree on business-to-business re-use for specific legal obligations or other purposes, as is already the case today.

test guidelines. Despite peer review, the appropriateness of data published in academic journals for use in regulatory processes can be variable, meaning scrutiny is required to ensure that the data is relevant and reliable for regulatory risk assessment purposes. This evaluation of the reliability and relevance of academic data is a burdensome process. The European Commission highlighted in the fitness check the importance of academic data in the early identification of new information and data on hazards and pointed out the lack of tools for the continuous monitoring of scientific papers and publications. This may slow down the reaction time of regulation to risks and means that early warning signals may be missed.

Not all study results are reported by duty holders
Under certain pieces of chemicals legislation, the industry needs to either seek regulatory approval or submit a registration before placing a chemical on the EU market. The registration/approval is typically obtained upon the submission of a dossier including supporting studies that are required by law. These supporting studies are commissioned with laboratories or carried out in-house. For assessors to be able to carry out their tasks properly, it is necessary that they have knowledge of all studies performed by an applicant or registrant. **Yet, duty holders may withhold unfavourable results without assessors ever being aware of this**. Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain ("Transparency Regulation") which amended Regulation (EC) 178/2002 introduced the requirement for duty holders to notify studies to the EFSA when they are commissioned or carried out with a view to submitting an application. The potential problem of not including certain studies in a dossier or application is likely not unique to the food sector and may equally occur in the rest of the chemicals sector.

2.1.3. Lack of mechanism to identify emerging chemical risks

The identification of new, emerging risks constitutes a major challenge to tackle. While it is important to ensure the prevention and management of existing risks, it is also essential to be able to anticipate as soon as possible to unforeseen consequences related to the use of chemicals and their release into the environment and to ensure that emerging risks are properly addressed in a timely manner by EU policy and decision makers. Some initiatives and projects already exist to this end, but are not comprehensive; their scope is limited or their funding is time-limited.

Even with an increase of the available information on early warning signals for the scientific community and experts, there is no procedure at EU level for a systematic collaboration with policy makers, regulatory agencies and monitoring organisations to facilitate timely follow-up actions. As chemicals production is expected to continue to grow, new and legacy chemicals will continue to be released into the environment, adding to the total chemical burden on ecosystems and people. Unidentified risks of chemicals will continue to be a growing concern due the increasing speed at which novel chemicals and products are placed on the market.

2.2. What are the problem drivers?

This section describes the underlying causes (or "drivers") of the issues and problems described in section 2.1. Drivers are **regulatory failures and technical obstacles**.

Specific problem	Drivers
Information is difficult to find or share: chemicals data is scattered and some information flows are suboptimal	• Pieces of legislation on chemicals are typically tailored to their specific objective without interconnection between them. Information is hosted or stored in different locations without a link or interaction between the locations or an overview of where chemicals data can be found
Information is difficult to find or share: chemicals data is not always interoperable	• Different pieces of legislation impose different or no standard formats and different or no controlled vocabularies
Information is difficult to find or share or use: chemicals data is not always accessible and usable	• Different pieces of legislation have different transparency rules. In addition, because of uncertainty on how to interpret confidentiality rules in some pieces of legislation, EU agencies apply precautionary measures and refrain from sharing information with other agencies or Member State competent authorities altogether • In many pieces of chemicals legislation, the use of information for purposes other than those of the specific legislation at hand is not considered.
Incomplete knowledge base: lack of availability of certain types of chemicals data	• There is a lack of possibility for the Commission or an EU agency to conduct studies where necessary to support the implementation and development of Union chemicals legislation or policy • Reporting mechanisms, common data formats and controlled vocabularies for information related to environmental sustainability are lacking
Incomplete knowledge base: academic data are insufficiently considered	• While some pieces of legislation require the uptake of 'all available, relevant information', thus including information coming from literature searches, experience shows that such literature searches are not always carried out • In other pieces of legislation, there is no – direct or indirect – legal requirement to include information resulting from literature searches • Chemicals data from peer reviewed publications is not always fit for use in a regulatory context; the information is usually generated with a predominant research purpose in mind and study designs and reporting do not always take into account regulatory needs. This may be the result of insufficient knowledge by the research community of regulatory needs and/or of the lack of incentives to produce peer reviewed publications which are also fit for use in a regulatory context
Incomplete knowledge base: not all study results are reported by duty holders	• A mechanism allowing to check whether studies that are carried out or commissioned are also effectively included in a regulatory procedure or dossier is lacking
Incomplete knowledge base: lack of mechanism to identify emerging chemical risks	• The coordination of the identification and assessment of early warning signals of emerging chemical risks to enable policy or regulatory follow up activities is inadequate

3. OBJECTIVES: WHAT IS TO BE ACHIEVED?

3.1. General objectives

This initiative pursues a better-informed, more robust scientific decision-making in the EU that would allow to achieve a high level of protection of human health and the environment. It aims to give broader access to and encourage the use by public authorities in the performance of regulatory functions and fulfilment of their missions of data on chemicals in the environment and on the presence and risk of chemicals in humans. In addition, it aims at improving the functioning and effectiveness of the governance of the internal market for chemicals as the common data platform by providing information on planned, ongoing and completed regulatory processes on chemicals as well as information on legal obligations under Union acts on chemicals.

3.2. Specific objectives

The initiative should achieve the specific objectives detailed in Table 2 below linked to the problems and their respective drivers.

Table 2 – Specific objectives related to the identified problems and their respective drivers

Problem	Objective
Chemicals data is scattered and some information flows are suboptimal	Establish a central platform containing or linking to chemicals data resulting from the implementation of EU chemicals legislation and from national and international implementation and research programs
Chemicals data is not always interoperable	Enable findability and interoperability of chemicals data
Chemicals data is not always assessable and usable	Make chemicals data available in a transparent manner to different types of users and enable use of the information by Member States, EU agencies and the Commission under pre-defined conditions
Academic studies are insufficiently considered	Improve the uptake of academic studies in chemicals safety and risk assessments
Lack of availability of certain types of chemicals data	Establish a mechanism for EU agencies to obtain adequate data and information
Duty holders may not report all study results	Ensure that information is shared on planned studies before they are being carried out
Lack of mechanism to identify emerging chemical risks	Establish an EU early warning and action system for emerging chemical risks

3.2.1. Objectives related to the problem that chemicals data is scattered and some information flows are suboptimal

Bring together chemicals data: The objective is to establish a central platform containing or linking to chemicals data resulting from the implementation of EU chemicals legislation and from national and international implementation and research programs. This calls for an efficient flow of information from EU agencies, the Commission, and in one particular instance also the Member States, to such platform. This objective builds on the project initiated by the European Parliament to assess the feasibility of consolidating the chemicals data collected by the institutions, bodies and agencies of the European Union.

3.2.2. Objectives related to the problem that chemicals data is not always interoperable

Ensure interoperability of chemicals data: The objective is to enable findability, harmonisation and interoperability of chemicals data by encoding them in standard formats and by using controlled vocabularies.

3.2.3. Objectives related to the problem that chemicals data is not always accessible and usable

Make chemicals data accessible and usable: The objective is to make chemicals data available in a transparent manner to different types of users and to enable use of the data by Member States, EU agencies and the Commission under pre-defined conditions.

3.2.4. Objectives related to the problem that academic data is insufficiently considered

Improve the uptake of academic studies: The objective is to improve the uptake of academic studies in chemicals safety and risk assessments. This calls for new or strengthened regulatory requirements and clarity for researchers and publishers on what type of information and reporting is relevant and necessary for use for regulatory purposes.

3.2.5. Objectives related to the problem that there is a lack of availability of certain types of chemicals data

Establish a data generation mechanism: The objective is to establish a mechanism for EU agencies to obtain adequate data and information required for the assessment of safety and impacts of chemicals in an efficient and coherent way, while maintaining the principle that the burden of proof of the safety of chemicals is on industry.

3.2.6. Objectives related to the problem that duty holders may not report all study results

Ensure notification of studies before they are commissioned or carried out: The objective is to ensure that information is shared on planned studies before they are being carried out and commissioned and before it is known whether results are favourable or not.

3.2.7. Objectives related to the problem that a mechanism is lacking for the identification of emerging chemical risks

Establish an EU early warning and action system for emerging chemical risks: The objective is to establish a proactive and systematic approach to the identification of

emerging risks by developing and compiling early warning signals and drawing up summary reports to inform policy and regulatory follow up activities.

4. WHAT ARE THE AVAILABLE OPTIONS?

4.1. What is the baseline from which options are assessed?

In the absence of this legislative initiative, the current data submission practices, data flows and data hosting and storage practices under existing chemicals legislation would continue to apply. The same accounts for existing practices with regard to the uptake of academic data, the use of data generation mechanisms and the application of study notification requirements. In the sections below, a short description is given of what this means more concretely. Given the vast number of pieces of legislation covered by this initiative, a detailed description of the current practice for each piece of legislation would lead us too far for the purpose of a staff working document, so for some sections (in particular the one related to data flows) examples are given to demonstrate concrete issues and practices. More detailed information on the current practice under the various pieces of legislation is given in the study supporting this initiative.

4.1.1. Data flows

A comprehensive assessment of the status of the chemicals data landscape was made in the feasibility study on a common open platform on chemical safety data[25]. There is a large amount of chemicals data in databases, much of it compiled following legal provisions and used in own processes but also disseminated by EU agencies and the Commission for transparency and public use. Comprehensive IT development has taken place in the agencies, optimizing tools used for internal data within sectors, in specific circumstances also using common building blocks (e.g. IUCLID for information on chemical hazards). The Information Platform on Chemical Monitoring (IPCHEM[26]) was developed for use across sectors but is limited to chemical occurrence data.

Effective common access to different types of chemicals data across those IT infrastructures has however not been enabled and is therefore also not systematically applied in EU chemicals assessments. Also, any *ad hoc* integration of information is hampered by different use conditions and differences in data formats and controlled vocabularies. There is inefficiency and duplication as individual projects repeat the same efforts merging and curating certain data across sectors for specific needs (e.g. the validation of predictive tools). There is also loss of coherence or there is even divergence between assessments of the same substances or groups of substances due to differences in the datasets used.

Different information types and datasets relevant for chemical safety assessments are collected under the various pieces of EU chemicals legislation in the scope of this initiative. Depending on the legislation, the **obligation to collect information** is on business operators, Member States and/or EU agencies.

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25 Feasibility study on a common open platform on chemical safety data.

26 Information Platform for Chemical Monitoring (IPCHEM).

Although not always the case, the data is usually **reported** to a Member State, EU agency or the Commission. Data flows are usually determined in legislation and typically have a **recipient** with a mandate or expertise corresponding to the type of data (e.g. data on food related chemicals typically flows to the EFSA, while information on medicinal chemicals and products typically flows to the EMA).

Information may be submitted in a **standard format** (imposed through legislation or deployed in practice) or without any specified format.

Data are typically hosted or stored in **databases** that are established and maintained by the receiving parties (Member States, EU agencies, Commission), without interaction or a link necessarily between the different existing databases, repositories, platforms etc.

Rules for the **dissemination and use** of chemicals data may be specified in specific pieces of legislation. Today, information on chemicals is already made **publicly available** by the Member States, EU agencies and the Commission. Various pieces of legislation (e.g., Regulation (EC) 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies ('Aarhus Regulation'); Directive (EU) 2019/1024 on open data and the re-use of public sector information ('Open Data Directive')) are in place that ensure a high level of transparency and data dissemination. The Aarhus Regulation, for example, sets as its objective to enable public access to environmental information, which may include, for example, chemicals monitoring data, either following a request or by active dissemination by the authorities.

Additional rights on access to documents enshrined in Regulation (EC) No 1049/2001[27] and, where environmental information is concerned, the rights enshrined in Regulation (EC) No 1367/2006[28] and Directive 2003/4/EC[29] enable further routes of access to chemicals data, save to data deemed confidential under those legislations.

The use of chemicals data owned or generated by **public authorities** and public undertakings is already possible today by virtue of a number of pieces of legislation. This includes arrangements[30] set under the Open Data Directive[31], which sets minimum rules on the use of data held by the public sector and of publicly funded research data made publicly available through repositories, as well as its Implementing Regulation on high-

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27 Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents. OJ L 145, 31.5.2001, p. 43–48.

28 Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. OJ L 264 25.9.2006, p. 13.

29 Directive 2003/4/EC of the European Parliament and of the Council (The Freedom of Access to Information). OJ L 41, 14.2.2003, p. 26–32.

30 Those arrangements include terms applicable to re-use, formats of data and metadata and technical arrangements for dissemination of the public data.

31 Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information. OJ L 172, 26.6.2019, p. 56 – 83.

value datasets[32]. In addition, the Data Governance Act[33] aims to facilitate the voluntary sharing of data by individuals and businesses and harmonises conditions for the use of certain public sector data, without altering material rights on the data or established data access and usage rights. Given existing sectoral legislation, with regard to the creation of the Green Deal data space, the revision of the INSPIRE Directive[34] will enable further open availability and use of spatial and environmental data. This initiative aims to make it easier for EU public authorities, businesses and citizens to support the transition to a greener and carbon-neutral economy and reducing administrative burden. It is expected to support reusable data services on a large scale to assist in collecting, sharing, processing and analysing large volumes of data relevant for assuring compliance with environmental legislation and priority European Green Deal actions. It will streamline reporting and burden reduction through better use of existing data, automatic reporting generation through data mining and business intelligence.[35]

The aim of the legislative initiative at hand is not to change information requirements of individual pieces of chemicals legislation, nor is it to change the way in which chemical safety assessments are to be conducted. One purpose is however to identify and address **inefficiencies in data flows and obstacles to an effective chemicals regulatory framework.** The following issues and practices under the current regulatory framework have been identified:

- Besides data collected and generated under EU legislation, data are being held at **Member State level** and not necessarily shared with other Member States or EU authorities or agencies. This is particularly the case for monitoring data on chemicals in the environment. For example, under Directive 2000/60/EC establishing a framework for the Community action in the field of water policy ('Water Framework Directive') there is a legal obligation for Member States to report to the Commission when there is an exceedance of environmental quality standards. To that end, monitoring activities are carried out in water bodies, but the results of those activities may never be communicated to the EU level if no exceedances occur. Yet, such **monitoring data** can be useful in the context of other safety assessments.
- An example of an inefficiency in data collection obligations is the **multiple reporting** of the same monitoring data of persistent organic pollutants in water as part of the implementation of Regulation (EU) 2019/1021 on persistent organic pollutants ('POPs Regulation), the Stockholm Convention on persistent organic pollutants' effectiveness evaluation and as part of a bigger set of data under the Water Framework Directive implementation reporting, Water Framework

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32 Commission Implementing Regulation (EU) 2023/138 of 21 December 2022 laying down a list of specific high-value datasets and the arrangements for their publication and re-use (Text with EEA relevance). OJ L 19, 20.1.2023, p. 43 – 75.

33 Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724. OJ L 152, 3.6.2022, p. 1–44.

34 Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). OJ L 108, 25.4.2007, p. 1–14.

35 Proposal for a regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act). COM (2022) 68 final, explanatory memorandum.

Directive pollutants prioritisation exercise and the EEA's State of the Environment reporting.

- Another issue relates to the management of data and information systems: in case of parallel initiatives there is **not always sufficient coordination**, such as in the developments of IPCHEM, Reportnet 2.0 and 3.0[36] and WISE[37].
- **Monitoring data** are often reported in **different formats with different meta-data structures**, which are developed separately from each other for separate data collection purposes (e.g. EFSA defines the format for the collection of data in food, EEA sets the format for the collection of data for state of the environment reporting or air monitoring network and the Commission prescribes the format for the collection of data under the Water Framework Directive prioritisation exercise). OECD harmonised templates OHT 301 – 306 for use and exposure information include the possibility to report certain monitoring information, but the formats do not capture individual monitoring data, but their aggregates. The Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain ('Transparency Regulation') empowers the Commission for the food sector to establish standard data formats by means of implementing acts based on a proposal from EFSA. There are currently no standard formats for information related to regulatory processes (as disseminated today for a very limited number of legislations through ECHA's public activities coordination tool (PACT)[38].
- Some monitoring data on chemicals are **not appropriately stored**, e.g. stored on compact discs as part of physical archives.
- Today, there is **no harmonised identity** of chemical substances. Various names and abbreviations are used in various systems and under various pieces of legislation.
- As regards **data dissemination and transparency**, outside of the generally applicable confidentiality and transparency frameworks, which apply to information held by EU bodies across all legislative frameworks, each regulatory regime may introduce its own confidentiality and transparency scheme specifying for example which categories of data are always to be made available to the public, data which can be claimed confidential and data for which a legal presumption of confidentiality is introduced. As an example, the Transparency Regulation obliges EFSA to disseminate a wide range of information. EFSA shall make publicly available all information on which it bases its scientific outputs, where the term "scientific output" is subject to a broad interpretation and includes all scientific opinions, reports and guidelines. The possibility of data submitters to claim confidentiality is limited to a closed list of information and all other information is to be made publicly available. Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ('REACH') and Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products ('Biocidal Products Regulation') only foresee automatic dissemination by the ECHA for a limited number of specific categories of information listed in those Regulations. Other EU bodies either have their own

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36 Reportnet 2.0 and 3.0.

37 Water Information System for Europe (WISE).

38 Public Activities Coordination Tool (PACT).

confidentiality regime (e.g. EMA) or apply only general confidentiality schemes (e.g. EEA).

4.1.2. Academic studies

For the purposes of this initiative, 'academic data' is taken to mean hazard, occurrence and exposure data derived from **scientific studies published in peer-reviewed literature** that are not carried out specifically to inform regulatory assessments. Such data are typically generated by scientists from academia (or research organisations) who often use non-standard (non-guideline) experimental (animal and non-animal) or computational methods, without necessarily complying with any recognised quality system.

An assessment was made of **legal requirements for business operators** to consider academic data in chemical safety assessments for the pieces of EU legislation in scope of this initiative. A screening was done for wordings and formulations that address such requirements: "available data/information/sources/knowledge"; "academic"; "scientific and technical data"; "scientific data/literature/research". That screening yielded 11 pieces of legislation that include a requirement for the uptake of academic data by business operators in their regulatory dossiers. An overview of those pieces of legislation and requirements is given in Table 3.

Besides legal requirements, many other types of resources have been developed in recent years to improve the uptake of academic data for regulatory purposes. An **OECD project** of the Working Party for Hazard Assessment (WPHA) was recently initiated on the development of a guidance setting minimum quality and reporting requirements to help researchers design, perform and report studies and the development of a search guide for finding and retrieving academic data. The project started in 2022 and is foreseen to end by 2024.

Table 3 – Overview of pieces of EU legislation with a requirement for industry duty holders to consider academic data

Legislation	Article and wording
Regulation (EU) No 1107/2009 concerning the placing of plant protection products on the market	**Article 8 Dossiers** […] (5) **Scientific peer-reviewed open literature**, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.
	ANNEX II Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter I [...] 3.6. Impact on human health

	3.6.2 An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, **including a review of the scientific literature**, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B. [3.6.3, 3.6.4, 3.6.5: Same text for carcinogenicity, reproductive toxicity and endocrine disruption for human health, respectively] 3.8.2. […] The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effect in humans in accordance with the fifth paragraph shall be based on all of the following points: (1) all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action: […] (b) other scientific data selected applying a systematic review methodology, in particular following guidance on **literature** data which is listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products	**ANNEX II INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES** **Title 1, Table, 8.13.3.** The assessment of endocrine disruption shall comprise the following tiers: (a) An assessment of the available information from the following studies and any other relevant information, including in vitro and in silico methods: [...] (viii) A systematic review of the **literature** including studies on mammals and non-mammalian organisms; […]
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	**Article 5 General provisions on data required for risk assessment** […] 2. The application dossier shall include all the available data relevant for the purpose of the risk assessment (i.e. **full published papers of all references cited** or full copies of the original unpublished studies). […] 4. The documentation on the procedure followed when gathering the data shall be provided, including **the literature search strategies (assumptions made, key words used, databases used, time period covered, limitation criteria, etc.)** and a comprehensive outcome of such search.

Regulation (EC) No 1332/2008 on food enzymes **Regulation (EC) No 1333/2008 on food additives** **Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods**	**Article 6 General conditions for inclusion of food enzymes in the Community list** A food enzyme may be included in the Community list only if it meets the following conditions and, where relevant, other legitimate factors: (a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed; […] (!the authorisation procedure for being included in list refers to 1331/2008, so **literature search is implied**) **Article 14 Information obligation** 1. A producer or user of a food additive [enzyme/flavouring] shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive [enzyme/ flavouring] substance.
Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin	**Article 7 Requirements relating to applications for MRLs** 1. The applicant shall include in an application for an MRL the following particulars and documents: […] (c) a comprehensive overview of relevant concerns raised in **the available scientific literature** about the plant protection product and/or its residue; […]
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	**ANNEX II GENERAL REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3** […] 3.2.2.4. Chronic oral toxicity studies (including carcinogenicity studies) To investigate the chronic toxic potential and carcinogenic potential, a chronic oral toxicity study must be carried out in at least one species, and shall be of at least 12 months' duration. The species chosen shall be the most appropriate **on the basis of all available scientific data**, including the results of the 90-day studies. (There are also several references to the use of literature data as proof of evidence; yet, it concerns a possibility to use literature data, not an obligation)
Regulation (EC) No 1223/2009 on cosmetic products	**Article 10 Safety assessment** 1. In order to demonstrate that a cosmetic product complies with Article 3, 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 responsible person shall ensure that: […]

	(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data **from all existing sources**; **ANNEX I COSMETIC PRODUCT SAFETY REPORT** **PART A – Cosmetic product safety information** […] 9. Undesirable effects and serious undesirable effects **All available data** on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.
REACH	**Article 3 Definitions** […] 27. full study report: means a complete and comprehensive description of the activity performed to generate the information. **This covers the complete scientific paper as published in the literature** describing the study performed or the full report prepared by the test house describing the study performed; 28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report; 29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study; […]
	ANNEX I GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS 1.0 Introduction 1.0.5. For any effect for which no relevant information is available, the relevant section shall contain the sentence: 'This information is not available'. The justification, including **reference to any literature search carried** out, shall be included in the technical dossier. 3.0. Introduction 3.0.3. For any environmental sphere, for which no effect information is available, the relevant section of the chemical safety report shall contain the sentence: 'This information is not available'. The justification, including **reference to any literature research** carried out, shall be included in the technical dossier. […] 3.1. Step 1: Evaluation of information 3.1.1. The evaluation of **all available information** shall comprise: […] — the hazard identification based on **all available information,**

[…]

5.1. Step1: Development of exposure scenarios

5.1.1. Exposure scenarios as described in Sections 0.7 and 0.8 shall be generated. Exposure scenarios are the core of the process to carry out a chemical safety assessment. The chemical safety assessment process may be iterative. The first assessment will be based on the required minimum and **all available hazard information** and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario).

ANNEX II REQUIREMENTS FOR THE COMPLETION OF SAFETY DATA SHEETS

9.1. Information on basic physical and chemical properties

[…]

(c) Odour - A qualitative description of the odour shall be given if it is wellknown or described **in the literature**.

16. SECTION 16: Other information

This section of the safety data sheet shall contain other information that is not included in sections 1 to 15, including information on the revision of the safety data sheet such as:

[…]

(c) **key literature references** and sources for data;

ANNEX VI INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

[…]

STEP 1 – GATHERING AND SHARING EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, **this would include a literature search for relevant information on the substance**.

Wherever practicable, registrations should be submitted jointly, in accordance with Articles 11 or 19. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance including on all nanoforms of the substance that are covered by the registration, regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other

	substances, in vivo and in vitro testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests. In addition, information on exposure, use and risk management measures in accordance with article 10 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information. **ANNEX VII STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE** […] Before new tests are carried out to determine the properties listed in this Annex, **all available** in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. (same wording in Annex VIII, IX, X) **ANNEX XIII CRITERIA FOR THE IDENTIFICATION OF PERSISNTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES** […] A weight-of-evidence determination means that **all available information** bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, readacross), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well **documented case reports and observations**. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.
Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	**Article 5 Identification and examination of available information on substances** 1. Manufacturers, importers and downstream users of a substance shall identify the relevant available information for the purposes of determining whether the substance entails a physical, health or environ-mental hazard as set out in Annex I, and, in particular, the following: […] (d) any new scientific information;

	(e) any other information generated under internationally recognised chemical programmes.

4.1.3. Data generation mechanisms

A few regulatory processes and other initiatives exist today to obtain or generate (additional) data, from industry duty holders, through EU agencies or national authorities or via the research community.

Transparency Regulation – verification tool

Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain ('Transparency Regulation') amends Regulation (EC) 178/2002 laying down the general principles and requirements of food law ('General Food Law') and establishes a **verification tool** (Article 32d of the General Food Law) allowing the Commission – *in exceptional circumstances of serious controversies or conflicting results* – to mandate the EFSA to commission additional studies with the objective of verifying evidence used in the context of risk assessment. The studies commissioned may have a wider scope than the evidence subject to verification, for example, in cases where new scientific developments become available. The verification tool is financed by the EU budget. An annual budget is foreseen of EUR 24-40 million for grant and procurement activities. This budget is used for verification studies (at the date of writing of this Staff Working Document no verification study has been commissioned) but also for activities related to EFSA's obligations under Article 32 of the General Food Law (scientific studies).

General Food Law – scientific studies

Pursuant to Article 32 of the General Food Law, EFSA, using the best independent scientific resources available, has the obligation to **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 by regular commissioning of scientific studies managed by the Science Studies and Project Identification and Development Office (SPIDO). The goals of these projects are to:

- enhance EFSA's capacity to identify studies or projects benefitting regulatory processes and science
- fill knowledge gaps to ensure preparedness for:
    - possible divergences on sensitive matters ('verification' studies)
    - future risk assessment requirements due to evolving scientific knowledge and legislation
- enhance capacity building and build partnerships

No specific budget is foreseen for the EFSA for these activities. In practice, the budget allocated to the EFSA for verification studies is used for the conduct of scientific studies in the absence of any need of or request for a verification study.

REACH Regulation - substance evaluation

Regulation (EC) 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') regulates the manufacture and use of chemical substances, aiming to ensure a high level of protection of human health and the environment. Under REACH, it is generally expected that necessary and adequate hazard data is compiled (and as necessary generated) following standard information requirements for the registration of chemicals. A completeness check and compliance check ensure that such information is indeed submitted in a registration dossier.

Under the **substance evaluation** process, the evaluating Member State has the possibility to request ECHA to issue a decision requiring the registrant(s) of a substance to provide further information to verify/clarify a specific risk-based concern. This request of the MS takes the form of a draft decision submitted to and adopted by the ECHA's Member State Committee. The information that may be requested in the decision may go beyond the standard information requirements of REACH. For example, registrants may need to provide studies specific to mode of action, endocrine disruption properties, higher tier hazard information even if all registrants have registered at lower tonnages, or monitoring of concentration levels in organisms or the environment. The registrant has to submit the information required to ECHA by the deadline set.

Water Framework Directive – watch list

Directive 2013/39/EU as regards priority substances in the field of water policy requires the Commission to establish a **watch list of substances for which EU-wide monitoring data is to be gathered**, based on which the risk of the substances can be determined and a conclusion can be drawn as to whether Environmental Quality Standards (EQS) should be set for them at EU level. A specific procedure is laid down in Directive 2013/39/EU to add substances to the surface water watch list. The number of substances that can be added at each update of the watch list depends on how many substances are deleted from it, as the length of the watch list is currently restricted to 13 substances. Member States are obliged to monitor the substances on the surface water watch list at least once a year and report their data annually. The watch list is reviewed every two years and substances can be on the list for up to four years. When enough reliable monitoring data on a substance has been gathered to conduct a risk assessment, this substance is removed from the watch list. If a risk has been identified, the substance will become a candidate for designation as a priority substance under Directive 2000/60/EC establishing a framework for Community action in the field of water policy ('Water Framework Directive', entailing the derivation or refinement of an EQS.

A similar watch list approach for groundwater was introduced in Directive 2006/118/EC on the protection of groundwater against pollution and deterioration ('Groundwater Directive'). However, monitoring of the substances on the groundwater watch list is voluntary, which leads to an incomplete picture of the situation.

The Water Framework Directive and its daughter directives mentioned above were recently reviewed and a proposal[39] for amending the directives was published. Regarding the watch list systems, the main proposed changes are making monitoring of the substances on the groundwater watch list mandatory for the MS and streamlining the process of reviewing monitoring data and updating the watch lists.

Land Use and Coverage/Area frame Survey (LUCAS) - soil survey

LUCAS is an in-situ survey designed to provide **harmonized statistics on land cover and land use** across the EU. The LUCAS campaign in 2022 observed 400,000 point locations in the EU, half of them in the field while and the other half through photointerpretation. The LUCAS 2022 soil survey was carried out at a subset of 41,000 locations for which topsoil samples were collected and analysed for (standard) physical and chemical parameters. The results give a general overview of the soil characteristics, and give insight in soil health and e.g., resilience of the soil related to chemical risk assessment. Also, the socio-economic land use might be useful to give an indication of vulnerability of the location and the activities carried out (residential, public space, …) in relation to the potential impact of chemical accidents.

The results of the LUCAS soil survey support policy needs of a variety of EU policies like the Soil Strategy for 2030, the Common Agricultural Policy, the EU Farm2Fork strategy, the Circular Economy Action Plan, Climate Law, and EU policies in the area of biodiversity and land degradation neutrality, the sustainable development goals, Europe in a wider world and the Green Agenda for the Western Balkans[40].

Before a new soil survey campaign is undertaken, the Joint Research Centre assesses the different policy needs and adapts the data to be gathered in the surveys accordingly, e.g., if new parameters are needed. Data generation under the LUCAS soil survey is recurrent. It is not linked to a specific legislation but the results contribute to multiple policy needs of a variety of EU policies. LUCAS soil is funded from the EU budget and is performed under the surveillance of ESTAT and the JRC.

H2020, Horizon Europe and co-funded European partnerships

Several projects funded under the European Union's Horizon Europe framework have led to the generation of information that may be relevant in a Union chemicals regulatory or policy context. For example, the European Human Biomonitoring Initiative (HBM4EU[41]- a joint European human biomonitoring (HBM) initiative running from 2017 to 2022, collected existing as well as new human biomonitoring datasets and harmonised data collection and management approaches. Other examples are EU-funded H2020 and

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39 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.

40 Jones, A., Fernandes-Ugalde, O., Scarpa, S. & Eiselt, B. (2021) LUCAS 2022, EUR 30331 EN, Publications Office of the European Union, Luxembourg., 2021, ISBN 978-92-76-21079-5, doi:10.2760/74624, JRC121253, pp. 46.

41 https://cordis.europa.eu/project/id/733032

Horizon Europe projects coordinated in clusters of projects (e.g. NanoSafety Cluster[42], CUSP Cluster[43] and IDEAL Cluster[44], which share a common theme of improving tools, skills and knowledge.

The co-funded public-public Partnership for the Assessment of Risks from Chemicals (PARC)[45] (in which the EU together with public partners commit to jointly support the development and implementation of a programme of research and innovation activities that significantly contributes to achieving EU policy priorities) was selected for funding for the 2022-2029 period.

These large EU-funded research initiatives help support the implementation of the European Union's Chemicals Strategy for Sustainability, paving the way for the "zero pollution" ambition announced in the European Green Deal.

EUON – European Union Observatory for nanomaterials

While having a very specific setting and scope, in its core, the European Union Observatory for nanomaterials is a data generation (and dissemination) mechanism, dedicated at present to nanomaterials, a subclass of chemicals considered at times to warrant an additional survey to support the development and implementation of and confidence in chemicals policies when addressing the innovative and rapidly evolving field of nanotechnology, introducing new materials on which general knowledge and understanding and appreciation of potential risks may not have been sufficiently informed through the standard reporting channels.

As first-generation (passive) nanomaterials are getting increasingly mainstreamed also in reporting e.g. following implementation of nano-specific provisions in product legislation (food law, cosmetics, medical devices, biocidal products) and through an update of REACH registration obligations with nanoform-specific requirements in 2018, further generation of active nanomaterials is slowly entering the market, alongside other classes of complex materials dubbed ‘advanced’ due to their rational design of structural features, often at nanoscale, that bring new and enhanced properties. The present approach by the Observatory to search the market for available information and launch dedicated studies on particular aspects on properties, presence and use of nanomaterials can be naturally extended with innovation.

4.1.4. Notification of studies

Transparency Regulation – notification of studies

The Transparency Regulation lays down rules for **the food sector** on the transparency and sustainability of the EU risk assessment in the food chain. The Transparency Regulation

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42 EU NanoSafety Cluster – The NanoSafety Community

43 CUSP cluster - The European Research Cluster to Understand the Health Impacts of Micro- and Nanoplastics (cusp-research.eu)

44 Home - IDEAL CLUSTER

45 https://cordis.europa.eu/project/id/101057014

introduces a study notification mechanism in Article 32b and in Article 32(c)(1) in the General Food Law.

The purpose of the notification provision is to ensure that all relevant available data is taken into account in a regulatory dossier (an application or notification dossier in this case). To that end, all studies that are being commissioned or carried out in the context of the preparation of an application or notification are to be notified. The following information needs to be notified: title of study, scope of study, study type, study design, actual or planned start date, completion date, business operator, and lab or testing facility.

An application or notification which is supported by studies that have not been previously notified in accordance with the Regulation will not be considered valid or admissible unless a valid justification is provided for the non-notification of the study. Likewise, an application which is not supported by studies that have been previously notified in accordance with the Transparency Regulation will not be considered valid or admissible, unless a valid justification is provided for the non-inclusion of the study in the application dossier. In case the justification provided is considered invalid, the applicant will be requested to submit any missing data relating to any supporting studies. In addition, a six months standstill will be applied before the newly submitted application or notification is assessed.

Information on notified studies is stored in a database hosted by EFSA. The notified information will be made public only in cases where a corresponding valid application was submitted to EFSA. EFSA publishes the extract of the relevant studies from the database at the moment the validity of the application is confirmed. Prior to doing that, the applicant gets the opportunity to claim possible data confidential.

REACH – testing proposals

REACH does not create advance notification obligations for those who are generating data that may eventually be used in registration. However, if information required according to Annex IX or X to REACH is not available and needs to be generated by a registrant, the registrant needs to submit a testing proposal to the ECHA. The purpose of the notification mechanism for testing proposals is to avoid unnecessary testing in general on vertebrate animals (through a public consultation organised by the ECHA on the testing proposal), to ensure that proposed tests meet real information needs, to ensure that the best use has been made of existing information and that the most adequate test is performed to fulfil information requirements for risk assessment and hazard classification.

After the public consultation period, the ECHA examines the testing proposal and adopts a decision. In the decision, ECHA can either require the registrant to carry out the proposed test as set out in the testing proposal or modify the testing conditions and/or impose additional requirements. ECHA may also decide to reject the testing proposal or set a deadline to perform and provide the test results.

Directive on the protection of animals – notification of studies

Directive 2010/63/EU on the protection of animals used for scientific purposes includes provisions on the evaluation and authorisation of projects involving the use of animals.

The purpose of those provisions is to protect animals from being used for scientific purposes.

To start a scientific project using living animals, an application must be submitted and authorisation received. Information to be notified includes at least (a) the project proposal; (b) a non-technical project summary; and (c) information on the elements set out in Annex VI of the Directive, which include the relevance and justification of use of animals and procedures, application of methods to replace, reduce and refine the use of animals in procedures, and competence of people included in the project.

In practice, applications are not submitted for single, separate well defined studies, but a 'project' is taken to cover all activities in the course of a period of ca. five years and making use of living animals.

Directive on good clinical practice – notification of studies

Directive 2001/20/EC relating to the implementation of good clinical practice in the context of clinical trials on medicinal products for human use stipulates principles with regard to performing clinical trials on medicinal products for human use. The Directive discusses a notification mechanism in Articles 8, 9 and 10.

The purpose of the notification provision is to collect and assess applications from organisations that seek approval for the commencement of a clinical trial. These organisations are referred to as sponsors and could be individuals, companies, institutions or other organisations which take the responsibility for the initiation, management and/or financing of a clinical trial. They are obliged to notify the competent authority. Only approved requests for authorisation allow sponsors to conduct a clinical trial.

Information to be notified includes the following:

- Trial identification information
- Identification of the sponsor responsible for the request
- Applicant identification information
- Information on each investigational medicinal product (IMP)
- General information on the trial
- Population of trial subjects
- Clinical trial sites/investigators in the Member State concerned by the request
- Competent authority/ethics committee in the Member State concerned by the request
- Signature of the applicant in the Member State

The sponsor may only start a clinical trial if the competent authority in the Member State concerned did not see any grounds for non-acceptance, and once the ethics committee has issued a favourable opinion on the application.

Good laboratory practice

Good laboratory practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Its purpose is to ensure the quality and integrity of the safety data submitted to regulatory authorities ('GLP receiving authorities'). The principles of GLP are applied to the non-clinical safety testing of test items contained in a range of products. The application of GLP is required by a variety of different product-specific legislation.

Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances is one of the two core Union GLP Directives together with Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP).

4.1.5. Identification of emerging chemical risks

Several initiatives exist in the EU aiming at the identification of potential environmental and health risks of chemicals in use in the EU.

EFSA emerging risks exchange network (EREN)

EREN serves to facilitate the exchange of information between the EFSA and Member States on potential emerging risks relating to food and feed safety, including for animal health. During regular meetings, the EREN members work out an expert opinion on emerging issues, in specific areas of interest for the EFSA, covering also emerging chemicals in the food/feed chain and drivers of and interactions with emerging biological risks. The EREN also discusses and proposes follow-up actions for the EFSA.

Norman Network

The NORMAN network enhances the exchange of information on substances posing a potential risk to the environment and encourages the validation and harmonisation of common measurement methods and monitoring tools so that the requirements of risk assessors and risk managers can be better met. It specifically seeks both to promote and to benefit from the synergies between research teams from different countries in the field of emerging substances.

Horizon Europe and co-funded European partnership

The co-funded public-public European Partnership for the Assessment of Risks from Chemicals (PARC)[46] aims to develop a scientific and technical basis for an early warning system on chemical risks. The work involves the development and validation of early warning monitoring tools for humans, the environment and products combining exposure and hazard data as well as machine learning for patterns to identify new hazardous substances, their sources and transformation products. The substances from the early

[46] European Partnership for Risk of Chemicals (PARC).

warning tools and framework are ranked based on their potential risks and integrative models and are made publicly available.

The Horizon Europe cluster of projects CUSP[47], aims at understanding the complex relationships between exposure to micro- and nano plastics and human health. The cluster works on the development of methodologies for risk assessment that consider the whole life cycle of chemicals and develops risk evaluation frameworks tailored to the different sources, fate, exposure route and scenarios, hazardous effects and risk indicators for micro- and nano plastics.

4.2. Description of how problems can be addressed

4.2.1. Addressing the problem that chemicals data is scattered and some information flows are suboptimal

In order to bring together chemicals data, the only viable and effective option identified was the establishment of an IT infrastructure, serving as a central platform from where such information can be accessed as interoperable data and supported by data services facilitating use cases such as chemical assessments by authorities. Such a common data platform on chemicals (CDPC) is foreseen to be established by the ECHA. Complementary to the establishment of the platform, and in order to increase efficiency and coherence, a number of information flows was considered for redirection.

Establishment of common data platform on chemicals

The feasibility and added value of establishing an EU common data platform on chemicals have been evaluated by a comprehensive "Feasibility study on a common open platform on chemical safety data"[48], supported by the European Parliament.

The study, while framed from the beginning on a single premise of establishing a new IT platform on chemicals, has cast its analysis very widely to ensure the appreciation of the extent of the problem and opportunities such platform is aiming to address. It analysed the baseline (no action) vs. the added value of different ways to establish and populate the platform, and estimated resources required to develop and govern it. Seventy existing information systems were analysed/screened and 100 stakeholders from different groups were interviewed for, or contributed to, the analysis. Details of the analysis are available in the final study report and summarized well in an executive summary.

Even with the expected evolution in IT services and availability of chemicals data in digital form, **there is no existing platform that addresses** (or would be able to address with minimal effort) **the stated objectives**. A one-off solution merging current datasets also does not make much sense from an efficiency or sustained usefulness perspective. The only meaningful solution is a platform dynamic in terms of content and services provided,

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47 CUSP cluster - The European Research Cluster to Understand the Health Impacts of Micro- and Nanoplastics (cusp-research.eu)

48 European Commission, Directorate-General for Environment, *Feasibility study on a common open platform on chemical safety data*, Publications Office of the European Union, 2022.

establishing rules and controlled vocabularies for repeated ingestion of data, responding in time to the use cases supported, and opportunities with regard to individual datasets which may require changes either to their formats or sharing and use conditions, before they can be efficiently integrated.

Such a platform should from the onset be designed as an integral part of the EU Green Deal Data Space[49] and exploit work done on IT building blocks from existing platforms and formats (e.g. IUCLID). There are different technical solutions available for the IT infrastructure behind the platform: options rotate mainly around different ways of addressing data infrastructure (consolidated or federated models), security (ability to form secure enclaves), and functionalities (basic vs. advanced such as analytics and insights, interface support). Considering extensions are always an option but may come at the cost of inefficiency and time, four different possibilities were evaluated, providing recommendation for a stronger, flexible architecture with full support to federated access but enabling local database service solution as well, and a list of initial functionalities to be supported in a minimum viable product.

The study was used as a basis for further elaboration of a technical implementation plan including the delineation of tasks, governance and resource estimates for setting up such a platform by the Commission services and the agencies[50]. It was prepared by a dedicated subgroup of the inter-service group on one substance, one assessment and driven by a working vision:

> *The platform aims to become a sustainable, single access point for chemicals related data and information at EU level. It should facilitate the sharing, access, re-use and dissemination of information on chemicals and allow for, e.g., improvement of quality and coherence of chemical assessments, identification of chemicals of concern, grouping of chemicals based on inherent properties, identification of candidates/ideas for enforcement campaigns and the search for substitutes. This IT infrastructure, set as an integral element of the European Green Deal Data Space, is expected to be a key technical enabler for access to data and information on planned and concluded regulatory actions related to chemicals across the different EU legislative regimes.*

The platform is expected to serve the widest possible community, with robust governance and providing reliable service and with the **ability to evolve**, addressing new use cases and stakeholder expectations, ingesting new relevant datasets, develop functionalities and respond to its developing ecosystem of tools and applications.

ECHA has been identified as the appropriate agency designated to establish and manage the platform, apply a governance scheme that is prepared and adopted with other EU agencies and the Commission, and actively seek input from other stakeholder/users of the platform to maximize its utility. ECHA is thus responsible for

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49 Green Deal Dataspace.

50 The Project Initiation Document will represent part of the Staff Working Document in support of the legal proposal. It already includes consideration of technical solutions regarding architecture, governance scheme, tasks for ECHA as the manager of the platform as well as expected tasks for the agencies, serving as data providers responsible to prepare individual identified datasets ready for ingestion in the platform within the timeline set as part of the initial "minimum viable product".

‘**the container**’, the technical implementation of the IT infrastructure set to provide access to the information, and coordination of the necessary common work established through governance (e.g. agreements on interoperability).

The information (i.e. **content**) is brought to ECHA by **data providers**. It is expected that data providers themselves make the effort to ensure the data is ready for ingestion in the platform i.e. follows the appropriate format, respects agreed controlled vocabularies and includes the necessary context information to make integration possible.

With further consideration on practical implementability and governance, and the datasets identified in the supporting study for a minimum viable product, it is considered that the scope of data providers should, at least in the initial implementation, be limited only to the **Commission and the EU agencies**; an **obligation** established for these actors can ensure that the information they hold is prepared for ingestion and sent to ECHA to introduce in the platform (ECHA has the same obligation on its own datasets). This obligation directly applies to main datasets compiled or generated as part of their legal obligations, e.g. REACH registration or information on regulatory processes and substance-specific activities. Future data such as information generated through a data generation mechanism (see section 4.1.3) or new datasets with chemicals data established as part of any potential further legal obligations would automatically fall under such obligation. As with other datasets that might be agreed for the inclusion in the platform, ingestion in the platform would be a planned activity covered in its implementation plan.

In addition, at the request of the Commission, the data providers would be expected to **host and maintain** - and correspondingly provide to the platform - also further data corresponding to their mandate and the type of data they already hold, e.g. the EEA would cover occurrence data for the environment and human biomonitoring data (see also section 4.2.1).

The scheme indicated does not exclude the possibility to include further datasets, for example specific datasets prepared at national level or international organisation. The approach however includes an agreement in accordance with the procedure set in the governance scheme and its inclusion in the implementation plan. The responsible to prepare the dataset for ingestion and to coordinate with ECHA will however always remain one of the EU agencies or the Commission, becoming ‘a patron’ by establishing a dataflow from the original data owner based on the type of data to be included (e.g. ECHA typically on hazard data, EEA typically on occurrence data, EFSA on food-related data etc.).

The content as well as functionalities of the existing **Information Platform for Chemical Monitoring** (IPCHEM) are to be integrated into the EU-CDPC in a phased manner to prevent any disruption to its current function.

Information compiled from different sources may include **confidential data** and may have **specific conditions of use**. The platform will ensure that context information will allow the identification of the data’s origin, will allow differentiated access (Commission, EU agencies and competent authorities *vs.* general public), will apply the originator principle to the content available in the platform, and will describe conditions under which use of the data by the Commission, EU agencies and competent authorities is allowed.

A list of functionalities was developed in the feasibility study[51] considered appropriate to inform the initial development and estimates of resources required. Standard data services (search etc.) are already well covered by standard features of IT building blocks expected to be applied. Whether they will be effective is however very dependent on the application of controlled vocabularies (in particular relating to substance identity) to the datasets in the platform. Developing rules and vocabularies and the preparation of the datasets before ingestion by the data providers are considered critical parts of the task but cannot be specified in detail in the legal text. There are however some clear **dedicated products,** tools/functionalities underpinned by specific curated data that will exist only in the platform and have been identified in advance as required to support the overarching one substance, one assessment use case. Their sustained availability needs to be ensured by specific listing, as they are not covered by other legal instruments. Some precursors of these products may already exist:

1. **Repository of reference values**

   ECHA will be expected to maintain a repository with reference values and relevant metadata information. While EU agencies (ECHA, EFSA, EMA, EU-OSHA) would be expected to provide ECHA any derived reference value, additional work and curation are also considered to ensure continuous updated availability of further selection of reference values established via national activities or international organisations. Within the platform, the repository may become associated with the chemicals legislation finder (see below).

2. **Database of notified studies**

   Based on the information generated through established legal provisions under the Transparency Regulation, the ECHA will compile potential new notification information (see section 4.2.6) and make it available within the platform in accordance with the relevant conditions of dissemination and use.

3. **Information on regulatory processes** ECHA shall manage a database with information on regulatory processes related to chemical safety assessments as well as substance-specific activities that are planned, ongoing or completed by Member States, Union institutions or agencies. While the obligation to share this information in the platform between the agencies is already established by default, the provision sets a specific obligation on ECHA to compile this information and provide dedicated functionalities supporting effective exchange and coordination, when appropriate.

4. **Information on the obligations under EU acts on chemicals**

   ECHA is presently already providing information on regulatory processes on its dissemination platform through the EU Chemicals Legislation Finder[52], supporting

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51 Feasibility study on a common open platform on chemical safety data - Publications Office of the EU (europa.eu)

52 EU Chemicals Legislation Finder (EUCLEF).

any user in identifying all legal provisions applicable to a specific chemical substance. Introducing it as a dedicated product under the common data platform will establish its availability as ECHA's legal obligation, while at the same time push its integration with other information available in the platform for further added value.

5. Database on environmental sustainability related information

Recognised as an upcoming need based on ongoing initiatives[53], a database on environmental sustainability related information, including data on resources, emissions and relevant by-products of a chemical, will be included in the platform. The ECHA should establish that database, collect relevant data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service.

6. Repository of standard formats and controlled vocabularies

Setting standard formats and controlled vocabularies is an extensive exercise spanning across different activities, including work with international organisations, and is supported by different agencies, covering very different types of chemicals data with different solutions employed. At the same time, it is pivotal work supporting the integration of information in the platform itself and therefore a crucial task under its governance. Organised access to this standardisation work on the platform directly serves platform data providers, facilitates one substance, one assessment actions on harmonisation of data and methods between the EU chemical assessors, and serves the wider chemical community. The scope is to be understood in the wider sense and includes for example the preparation of a curated set of substance names and identifiers used to support integration in the platform.

Redirection of information flows

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53 Proposal for a regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC (Ecodesign Regulation) (COM (2022) 142 final.); Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC, and Directive 2013/34/EU as regards corporate sustainability reporting (Corporate Sustainable Reporting Directive) (OJ L 322, 16.12.2022, p. 15 – 80.); Proposal for a directive of the European Parliament and of the Council on corporate sustainability due diligence and amending Directive (EU) 2019/1937 (Corporate Social Responsible Directive) (COM (2022) 71 final.); The Commission Recommendation of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials (C (2022) 8854 final.); The Commission Recommendation on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations (C (2021) 9332 final.); and Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (EU taxonomy Regulation) (OJ L 198, 22.6.2020, p. 13 – 43.) all include references or announced expectation for the submission of information on sustainability, for which data and tools will be required.

Table 4 gives an overview of the foreseen (re)direction or strengthening of information flows. More detailed descriptions are given further in the text.

Table 4 – Overview of information flows to be (re-)directed or strengthened

Information type	Currently flows to	Redirection foreseen to
Environmental monitoring data	Commission (IPCHEM managed by JRC)	EEA
Food and feed related monitoring data	Commission (IPCHEM managed by JRC)	EFSA
Human biomonitoring data	Commission (IPCHEM managed by JRC)	EEA
Indoor air monitoring data	Commission (IPCHEM managed by JRC)	EEA
Workplace monitoring data	Commission (IPCHEM managed by JRC)[54]	ECHA
Hazard data on food contact materials	Commission	EFSA
Regulatory process-related information	ECHA	ECHA; requirement to be strengthened to add more legislations to the list of legislations on which process-related information is disseminated

(i) Monitoring data

The information flow for **environmental monitoring data** starts mostly at Member State level. **Reporting by Member States** is currently typically done with specific time intervals to the Commission, which stores most of the information in the Information Platform for Chemical Monitoring (IPCHEM), while the concrete handling of the data is done by the EEA. A re-allocation of tasks and obligations is foreseen under the proposal for a regulation on re-attribution of technical and scientific tasks to the Union agencies to reflect and follow today's concrete practice.

Considering the establishment of the common data platform on chemicals and based on the different agencies' mandate and expertise, the aim is to eventually absorb IPCHEM into the common data platform and establish the following general information flows for monitoring information:

- **Environmental monitoring** data flows to the EEA, from where it is made available to the ECHA for integration in the common data platform
- **Food and feed related monitoring** data flows to the EFSA, from where it is made available to the ECHA for integration in the common data platform

[54] No established systematic data flow at EU level. Setting one under IPCHEM is an ongoing project between JRC and EU-OSHA.

- **Human biomonitoring** data flows to the EEA, from where it is made available to the ECHA for integration in the common data platform
- **Indoor air monitoring** data flows to the EEA, from where it is made available to the ECHA for integration in the common data platform

Besides these regulated data flows, a solution is needed for the handling and hosting of **orphan chemicals monitoring data** contained in IPCHEM, such as data generated within the context of research projects or implementation plans and outside the context of any legal obligations. The most efficient solution identified is to **empower the Commission to request an agency** to host and maintain such data based on its mandate and expertise, from where it is made available to the ECHA for integration in the common data platform.

(ii) Process-related data

The **Activities Coordination Tool (ACT**) and its public version, PACT, is a voluntarily established information system developed and operated by the ECHA which provides an up-to-date overview of all planned and ongoing initiatives on chemicals by authorities under Regulation (EC) 1907/2006 concerning the Registration, Authorisation and Restriction of Chemicals (REACH) ('REACH') and Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures ('CLP'). PACT increases the transparency and predictability of authorities' work leading up to the more formal processes under REACH and CLP, as early information allows stakeholders to better predict which substances may be addressed by which formal risk management route in the future. Similarly, the tool promotes the coordination of safety assessment activities across EU legislation, as authorities are informed about each other's plans and intentions.

A similar tool is the **OpenEFSA portal**[55], a single public interface for all information related to EFSA's scientific work. Risk assessment processes can be followed from the receipt of a dossier to the adoption of an opinion with the dissemination of the status of assessments, dossier and studies (non-confidential versions), meeting agenda, info on experts etc.

(P)ACT and OpenEFSA disseminate very similar information, although some differences exist (some of the information shared through OpenEFSA does not apply to the regulatory processes covered by (P)ACT). An overview of the information disseminated through both interfaces is given in Table 5.

Table 5 – overview of dissemination of information through PACT and OpenEFSA

Information	Disseminated via PACT	Disseminated via OpenEFSA
Submitter or responsible actor for the process or activity*	Yes	Yes
Status of the process or activity	Yes	Yes
Outcome of the process or activity	Yes	Yes
Where applicable, date of intention, completion, and latest update	Yes	Yes
Where applicable, reports or opinions adopted as an outcome of the process or activity	Yes	Yes

55 Open EFSA (europa.eu)

Supporting information for the process or activity	Yes	Yes
Substance name, EC number, CAS number, and additional information on the substance	Yes	Yes**
Concern related to the substance	Yes	No
Pre-submission advice	No	Yes
Regulations related to the substance application	No	Yes
Where applicable, the mandate number	No	Yes***
Where applicable, the dossier number	No	Yes****
Food domain	No	Yes

* For the pieces of legislation currently covered by (P)ACT, the submitter or responsible actor is typically a Member State or the Commission; in OpenEFSA, the submitter is typically an applicant (business operator)
** In OpenEFSA, all applications received by the EFSA are also given an application number which is communicated to the applicant.
*** An attached link allows to view whether the mandate is external or internal, the requestor, the subject of the mandate, and the initiation and decision date. Additionally, it allows viewing other submissions under the same mandate, their status and food domain.
**** An attached link (if provided) allows to view the general information of the dossier (food domain, submitters, the subject of the dossier), administrative information of the dossier (this can be the scope, applicant's name, information if data-sharing agreement is in place, existing authorisation in the related EU legislation, additional information), public summary of the dossier, and general information on the technical dossier (excluding sections claimed confidential).

In order to support and consolidate a one substance, one assessment approach, and taking into consideration the fact that ECHA will also set up and host the common data platform on chemicals, it is appropriate to **formalise the (P)ACT system** and **progressively add relevant pieces of chemicals legislation**. The information from the OpenEFSA portal would consequently be made available through (P)ACT. As to the concrete information to be disseminated, a list of minimum information would be specified, to which additional types of information can be specified for dissemination, based on agreements reached in the common data platform's steering committee.

Based on an assessment of pieces of chemicals legislation, Table 6 lists the acts that are considered for inclusion in the (P)ACT approach based on the acts' coverage of safety assessment processes and initiatives (the table also provides an indication of processes in those pieces of legislation relevant for (P)ACT.

Table 6 – Legislations considered for inclusion in (P)ACT

Legislation to be included in (P)ACT	Processes to be covered ad minimum
Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)	Safety assessment
Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)	- Setting EU OELs; - Setting national OELs
Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work	- Setting EU OELs; - Setting national OELs

(fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)	
Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)	Review of exemptions
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)	Environmental safety assessment of product
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)	- Development of scientific opinion by EFSA (not already covered by GFL related legislation) - Scientific and technical assistance, scientific studies and collection of data
Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	Safety assessment
Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	Safety assessment
Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)	Environmental safety assessment of product
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	Safety assessment
Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	Assessment of ambient air concentrations and deposition rates
Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)	Safety assessment as part of the reviewing, amending, setting, deleting of MRLs
Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 070, 9.3.2006, p. 12)	Safety assessment

Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs (OJ L 364, 20.12.2006, p. 25)	Safety assessment
Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)	- Limit value derivation EU and national - Addition/removal of substances to watch list
Commission Regulation (EC) No 429/2008 of 25 April 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 (OJ L 133, 22.5.2008, p. 1)	Safety assessment
Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)	- Data generation and assessment (dossier and substance evaluation) - Assessment of regulatory needs - Regulatory risk management – harmonised classification and labelling SVHC identification, recommendations for inclusion in the Authorisation List, restrictions
Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	- EQS derivation EU and national - Addition/removal of substances to watch list
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	Harmonised classification and labelling
Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	Safety assessment
Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	Safety assessment

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	Safety assessment
Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)	Safety assessment
Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	Safety assessment
Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)	Safety assessment as part of the reviewing, amending, setting or deleting of MRLs
Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	Safety assessment
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)	Safety assessment as part of the substance (re-)approval process
Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)	Setting new OELs
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	Safety assessment
Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 015, 20.1.2010, p. 1)	Safety assessment as part of the reviewing, amending, setting or deleting of MRLs
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)	Review of exemptions

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	Evaluation of active substance
Commission Regulation (EU) 2017/644 of 28 March 2007 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 and repealing Regulation (EU) No 589/2014 (OJ L 92, 6.4.2017, p. 9)	Safety assessment
Commission Regulation (EU) 2017/880 of 23 May 2017 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 135, 24.5.2017, p. 1)	Safety assessment as part of the reviewing, amending, setting or deleting of MRLs
Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC (OJ L 79, 22.3.2018, p 16)	Safety assessment as part of the reviewing, amending, setting or deleting of MRLs
Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5)	Safety assessment as part of the reviewing, amending, setting or deleting of MRLs
Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1)	Safety assessment of product
Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43)	Safety assessment of product
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)	- Proposal to list substance under Stockholm Convention on persistent organic pollutants - Listing of substances in any of the Annexes - Setting of unintentional trace contaminant limit

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)	Safety assessment of contact materials

4.2.2. Addressing the problem that chemicals data is not always interoperable

In order to ensure that chemicals data is interoperable, the only viable and effective approach is **imposing the use of standard data formats and controlled vocabularies** for the transfer of information by the EU agencies to the common data platform and in particular imposing the use of IUCLID for the transfer of chemicals data by the EFSA for a limited number of specific pieces of legislation. A particular focus needs to be given to the establishment and use of a common set of substance identifiers across chemicals legislation. This would not necessarily prohibit and limit the use of specific substance identifiers commonly used in specific sectors (e.g. International Nomenclature of Cosmetic Ingredients (INCI) in the cosmetics sector); indeed, such specific identifiers could be added for specific data sets.

A mandate would be created for **EU agencies to establish such formats and controlled vocabularies**, which would also be made available through the CDPC. The use of those formats and vocabularies would be made obligatory for the provision of information to the CDPC.

(i) Progressive move to the use of IUCLID

Several pieces of EU legislation already require the use of IUCLID and other relevant OECD harmonised templates (OHTs). IUCLID consists of templates on core data (e.g. physical and chemical properties, ecotoxicological / toxicological information), OHTs and templates related to specific regulatory activities (e.g. Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products, REACH and Regulation (EC) 1107/2008 concerning the placing of plant protection products on the market). IUCLID and OHTs specifically are based on formats which are the result of harmonisation reached at OECD level, as well as between regulatory programmes.

Based on a categorisation of chemicals legislation according to the datasets[56] they are linked to and the possibility for coverage by an OHT, the following pieces of Union legislation were identified as suitable candidates for a progressive move to the use of IUCLID:

- Regulation (EC) No 1831/2003 on additives for use in animal nutrition
- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food
- Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

[56] Sets of information considered were the following: substance identity; hazard properties; physico-chemical data; information on use of chemicals; volume data and speciation thereof; exposure data; occurrence and monitoring data; emission; legislative and process related information; agency reports/agency opinions.

- Regulation (EC) No 1332/2008 on food enzymes
- Regulation (EC) No 1333/2008 on food additives
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
- Regulation (EC) No 1223/2009 on cosmetic products
- 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
- Directive 2009/48/EC on the safety of toys

(ii) Other standard data formats, and controlled vocabularies

For some data categories IUCLID is not appropriate for use and the adoption of new OHTs would be required. This is for example the case for exposure and use related information as well as monitoring data. The most effective and efficient approach is to **mandate EU agencies to establish standard formats** for data they receive under the various pieces of legislation based on their mandate and expertise. Data received under those pieces of legislation would need to be provided to the ECHA in the established standard format for integration in the common data platform on chemicals. In order to ensure coherence to the extent possible between different data formats, **agencies would be required to cooperate** when establishing formats. A similar approach is considered to be the best possible way forward for the establishment and use of controlled vocabularies.

4.2.3. Addressing the problem that chemicals data is not always accessible

Data sharing and data dissemination

To address the issue of different **transparency** rules and the limited availability/accessibility of data across the chemicals regulatory framework two possible options were identified:

Option	Description of option
1	Harmonise transparency rules across the chemicals regulatory framework
2	Apply the originator principle

1. *Apply harmonised transparency rules across the chemicals regulatory framework*

Under this option, the transparency rules applicable under the Transparency Regulation (and applicable to all chemicals subject to the General Food Law) **would be extended to the entire chemicals regulatory framework**. This would **include the rules relating to confidentiality claims**. This would mean that for chemicals outside the applicability domain of the General Food Law, besides the information that is already made public today, additional information might need to be disseminated, and more importantly, that requirements for the verification of confidentiality claims may change.

This option would address the objective of increasing the general public's trust in the scientific underpinning of EU decision making in the chemicals regulatory field. In addition, it would remove the obstacle for sharing data among authorities stemming from different transparency rules.

2. *Apply the originator principle*

Under this option, no horizontal harmonisation of transparency rules would be established, but the approach would be taken that **the specific legislation under which data arrives first determines the transparency rules**; every subsequent use of that data would have to follow the same (original) rules.

This principle allows authorities to have access to all available data, including confidential data, without the risk that when the data is being re-used and therefore brought in the scope of another piece of legislation, the transparency rules of that latter piece of legislation are applied and information may be disclosed that would not be disclosed under the original legislation. Such approach also gives legal certainty to the original data submitters that the data they claimed confidential (i.e., not for dissemination to the general public) remains confidential upon re-use.

This option would address the abovementioned obstacles to data sharing between authorities, but would not change the current dissemination practice to the general public.

Data use

The entities enabled by means of this proposal to use the information contained in the common data platform are public authorities (Commission, EU agencies, and Member State competent authorities), and not private parties.

Specific **conditions** will need to be set for the use of information by public authorities. Indeed, if information owned by a private party is used by a public authority for the fulfilment of legal duties of another private party, and without a financial compensation mechanism in place, this would constitute **free riding** of the latter duty holder on the information paid for by the former. In order to prevent this, a clear condition will need to be set that public authorities cannot use privately owned information **for the fulfillment of** legal obligations, including filling in data gaps in the regulatory dossiers of other duty holders. Similar conditions already exist under specific EU acts, e.g. Article 20(1) of Regulation (EC) No 1831/2003 on additives for use in animal nutrition[57] and Article 31 of Regulation (EC) No 1829/2003 on genetically modified food and feed[58].

4.2.4. Addressing the problem that there is no default generation or submission of certain types of chemicals data

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[57] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. (OJ L 268, 18.10.2003, p. 29)

[58] Regulation (EC) no 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)

A data generation mechanism (DGM) should allow the Commission and EU agencies, and possibly national authorities, to obtain adequate data and information required for the assessment of safety and impacts of known and emerging chemicals in an efficient and coherent way, while maintaining the principle that the burden of proof of the safety of chemicals is on industry. A data generation mechanism could cater for the situation where it is not legally possible to request data from industry or where there is an explicit reason why data should be generated by a non-industrial stakeholder.

For the options identified below,

– ‘data generation’ will be understood as the intentional production of new data through testing, monitoring, or modelling; in specific cases the data generation may be complemented with the collection of existing data, e.g., through a literature search.

– the term ‘data’ means any data used for chemical risk assessments, such as chemical identity, physicochemical properties, hazard data or occurrence data. It is not only to be understood as measurements or test data, but also includes results of computer modelling. It does not include information on processes about the assessments, e.g., application for REACH authorisation, initiation of harmonised classification, etc.

When establishing a DGM, the following scope and conditions are considered essential:

- The DGM should enable the Commission and EU agencies and possibly also national authorities to carry out or commission testing or monitoring.
- The DGM can be used to:
    - inform regulatory processes in which data are missing;
    - verify the effectiveness of legal measures;
    - generate additional data to provide additional evidence in exceptional cases of serious controversy on a specific substance or dossier.
- The DGM is complementary to any existing obligatory data generation – this means that the burden of proof remains on the original duty holder and the DGM cannot be used to fulfil any legal obligation towards data generation or provision.
- The DGM should consider other existing similar tools or mechanisms to ensure that synergies are exploited and that resources are used efficiently.
- The data generated for a specific purpose (use case) should be available for re-use in the larger context of chemicals policy and legislation.
- The DGM cannot be used for predominant research purposes or for the validation of methods.

Examples of use cases for a DGM are listed below. A prerequisite for a DGM is that the data generation is technically feasible, and that suitable methods and analytical protocols are available.

- Absence of unequivocal data on hazards for human health or the environment in a dossier for harmonised classification and labelling (CLH)
- Absence of data or insufficient data on toxicokinetics, metabolism and distribution for risk assessment of a group of structurally similar substances; this data need is encountered by ECHA under the assessment of regulatory needs (ARN) procedure
- Data gap filling on mechanistic information on toxicity (from *in vitro* assays) to support grouping of structurally similar chemicals
- High throughput screening for specified endpoints, *e.g.*, endocrine disruption
- Need for human toxicity reference values as basis for substance prioritisation e.g. under Directive (EU) 2020/2184 on the quality of water intended for human consumption
- Lack of data on chronic ecotoxicity for prioritisation of substances for inclusion in the watch list for surface water under Directive 2000/60/EC establishing a framework for Community action in the field of water policy
- Avoiding regrettable substitution by substances yet at lower tonnage levels or not (yet) marketed but within a chemical group with known members of hazard of concern e.g., already on the REACH Candidate List for Authorisation
- Lack of information on intrinsic properties including hazard data for substances not registered under REACH such as chemicals whose production has ceased, or that are produced unintentionally
- Need for an early warning and action system for chemicals, to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research.
- Lack of soil monitoring data for specified substances of concern, and identification of potential time trends. Currently, soil monitoring is done in the Land Use/Cover area frame statistical Survey (LUCAS)[59]. This is highly unstable as it depends on the financial resources currently put in place by the respective Commission services. Soil monitoring is also done in initiatives at Member State level.
- Need for monitoring data (water, soil, biota) in pristine, remote areas for the assessment of the long-range transport potential of persistent organic pollutants candidates under the Stockholm Convention, as well as for classification as PMT (Persistent, Mobile and Toxic)
- Need for surface water monitoring data beyond the substances on the watch lists of Directive 2000/60/EC, for specified substances of potential concern, to examine whether inclusion in the watch list would be recommendable
- Need for air monitoring data for specified substances of potential concern, to examine whether inclusion in the legislation on air quality would be recommendable
- Lack of deposition data on environmental contaminants (e.g., polycyclic aromatic hydrocarbons (PAH's), phthalates, and other chemicals for which dietary intake is the major exposure route).
- Human biomonitoring (HBM) data for prioritised substances/groups of concern can be used to generate time trends for following up the effectiveness of regulatory actions and policies.
- Lack of indoor air quality monitoring data; there are some activities already at Member State level, but an EU-wide mechanism could ensure coordination and higher relevance to the EU policies.

[59] Database - Land cover/use statistics - Eurostat (europa.eu)

- Support to activities such as EUON[60] that periodically compile targeted information on properties, uses and presence on the market for selected classes of materials (e.g. nanomaterials) for increased transparency

For the establishment of a data generation mechanism, two options were identified.

1. *Data generation mechanism with explicit governance structure and centralised submission and assessment procedures*

Under this option, a centralised system for the submission of testing ideas and for the assessment/prioritisation of submissions would be established as well as a clear governance structure. Member States would have the right to submit study requests, as well as the Commission and EU agencies. The entire chemicals regulatory framework would be covered.

The following aspects and procedural steps are addressed under this option:

- **Submission of requests.** A study request needs to comprise a rationale, a proposal for testing, a preliminary cost estimate and the estimated timeline.
- **Eligibility check of all requests.** Incoming requests are checked for completeness and for the fulfilment of any set formal requirements.
- **Assessment of all requests (prioritisation, resource availability).** All requests for data generation need to be assessed for prioritisation and resource availability, so that a recommendation is available whether the data generation should be executed or not.
- **Decision on what requests are approved.** To move from the assessment to the execution of a data generation request different options exist. In particular, considerations on whether the data generation is done on the basis of a (multi)-annual work programme or on a rolling basis result in different sub-options.

The following procedural steps can be distinguished in which responsibilities would need to be assigned at the execution stage of data generation:

- **Sample acquisition.** Depending on the type of data to be generated, the sample acquisition might need support from industry or Member States.
- **Commission study.** In this step the envisaged study is commissioned.
- **Management and follow-up of study.** As soon as the study is carried out somebody needs to be responsible for the management and follow up of the

[60] Home - European Observatory for Nanomaterials (europa.eu)

study. This covers contacts with potential laboratories, checking of results and related activities.

- **Dissemination of study results.** Once the data are generated it needs to be ensured that the data are made publicly available. This is to be done through the common data platform.

Submission of requests: Besides the European Commission, EU agencies should be allowed to submit requests. Furthermore, under this option, Member States (MS) would also be allowed to submit requests, because they are frequently involved in risk assessment processes for chemicals.

A request should comprise a rationale, a proposal for testing, a preliminary cost estimate as well as the estimated timeline. The rationale should summarise the current knowledge and latest relevant findings to justify the request. A testing proposal needs to show the technical feasibility and should also indicate the involvement of national or EU reference laboratories if necessary as well as possibilities for appropriate sample acquisition.

Governing body: the Commission would have the administrative and financial responsibility for the process and mandate EU agencies according to their expertise and mandate for the assessment of study requests as well as for the execution of the data generation. In case a high number of requests is submitted a prioritisation will be necessary, so prioritisation criteria will need to be identified. The process could be along the following lines:

- The Commission receives all study requests and distributes them to the agency with the specific expertise for the request (mainly EMA, ECHA, EFSA and EEA but potentially also others like EU-OSHA). The EU agencies assess the conformity of the request and report back to the Commission on the outcome.

- For the final decision on approval of requests, an expert working group could be involved, where the Commission, EU agencies and Member States are represented.

For the prioritisation, a scoring system could be set up that takes into account hazardous properties, exposure (including environmental, consumer and occupational exposure pathways), regulatory demand, societal concern, and overall feasibility (technical, financial).

Upon approval of a specific study request, the agency mandated by the Commission is responsible for the commissioning and follow-up of the study:

- ensure the acquisition of samples in close collaboration with industry or Member States where relevant;
- commission the testing via appropriate laboratories;
- receive the results from the laboratory;
- feed generated data into the common data platform on chemicals;
- inform the Commission and the data requestor on the availability of the data;

– propose any follow up actions concerning the data to the expert working group where relevant.

Sample acquisition: in order to be able to carry out data generation appropriate samples are needed. Considerations on the possibilities for sample acquisition and any necessity to involve national and /or EU reference laboratories should be part of the data generation request.

For tests related to industrial chemicals, the **involvement of industry** could be beneficial. This is particularly important in order to agree on appropriate samples as regards composition so that data generated is useful and suitable for risk assessments. In case of monitoring programs Member States could support sample acquisition.

Admission structure: A **(multi-) annual work program** allows planning safety for all actors involved and a better prioritisation of requests in general, so that the budget can be spent on the most important activities. However, a minor part of the budget could be reserved for urgent / interdependent requests as an ***ad hoc* response mechanism**. The admission structure in the form of a (multi-) annual work programme implies a defined timeline with set deadlines for the submission and assessment of study requests.

Budget and resources: most likely the budget would have to come from the **community budget**. Indeed, there will be data generation procedures in which the data needs cannot be allocated to one or several specific chemicals (e.g., substances registered under REACH) and thus cannot be directly linked to specific industry organisations, from which a fee could be requested. Such cases comprise data generation in which substances are grouped or substances are monitored which are not REACH registered in the EU; also non-target screening methods cannot be linked directly to a specific company or duty holder.

2. Obligation on ECHA to commission scientific studies for the performance of its mission
In this option, an obligation would be conferred on ECHA similar to the one on EFSA under Article 32 of Regulation (EC) 178/2002:

Article 32

Scientific studies

1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

EFSA would continue the operation of their mechanism to commission scientific studies, which is focused on the food sector. ECHA would be mandated to commission scientific studies for the performance of its mission, i.e. to support the implementation and evaluation of chemicals legislation within the mandate of ECHA. In addition, the Commission would be empowered to request ECHA to commission such studies as well.

This option would also foresee a requirement for ECHA and EFSA 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.

4.2.5. Addressing the problem of an insufficient uptake of academic data

Three options were identified for an improved uptake of academic data. The options are not necessarily all mutually exclusive.

Option	Description of option
1	Legal obligation on EU agencies
2	Legal obligation on industry duty holders
3	Rely on OECD guidance

1. Legal obligation on EU agencies

A legal requirement would be put on EU agencies to perform a literature search on a **regular basis.** Searches could be limited to specific (categories of) chemicals. Results of the search are made available to duty holders in a structured way through a repository so they can be taken into account in their safety assessment duties.

Under **one sub-option**, the repository would contain the **links to scientific papers** with relevant information on a substance. This sub-option would make it clear to duty holders which academic studies to explore as a minimum for their legal obligations. This could help implement the obligation to consider all available information by defining a minimum set of information to consider.

Under a **second sub-option**, an agency would **extract the information** from the relevant scientific papers and **make it available in a repository** (made available through the common data platform on chemicals), comparable to the Endocrine Active Substance Information System EASIS[61]. This would allow duty holders not only to know which academic studies to consider but would make the use of data very easy for them.

2. Legal obligation on industry duty holders

Under **one sub-option**, a new legal obligation would be created for the **entire chemicals' regulatory framework** to collect and consider academic data and to document the search and its outcomes.

In some legislations the requirement to consider academic data is already clearly specified e.g., for the assessment of endocrine disrupting properties of biocidal products and plant

[61] Endocrine Active Substances Information System (EASIS).

protection products under Regulation 528/2012[62] and Regulation 1107/2009[63] respectively. For the authorisation of food improvement agents[64], the documentation on the data gathering procedure also needs to be submitted, including the literature search strategy (i.e., the assumptions made, key words used, databases used, the time period covered, limitation criteria etc.) and the comprehensive outcome of the search.

A consistent legal obligation would also apply to legislation where **the decision-maker** is required to gather the relevant information for setting or reviewing limits in the field of e.g., occupational exposure, protection of air and water and consumer protection, e.g., by limits for certain substances in cosmetics but also for processes like REACH restrictions or the nomination of persistent organic pollutants.

Care should be taken to avoid putting an **inappropriate focus** on academic database searches: in some processes, other approaches to collect relevant information are used in addition to or even instead of the classical literature search, e.g. calls for evidence or other consultation activities. In some processes, monitoring data and grey literature might be the actual relevant sources. Furthermore, some processes, e.g., REACH restrictions or the setting of an environmental quality standard (EQS), are well established processes and include an additional consultation step by an independent committee. Against this background, it can be argued that the quality of the uptake of the relevant information is already ensured, and an additional obligation is not needed.

Under a **second sub-option**, **existing** legal obligations would be **strengthened**.

Regulation (EU) No 234/2011 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[65] requires the following documentation as part of the general provisions on data required for risk assessment according to Article 5:

The documentation of the procedure followed when gathering the data shall be provided, including the literature search strategies (assumptions made, key words used, databases used, time period covered, limitation criteria, etc.) and a comprehensive outcome of such search.

The **documentation requirement** ensures that the collection and consideration of academic data actually takes place and can be retraced and verified.

A requirement like the one above could be put in place for other legislations. Focus could be put in the first place on instances where industry has an information collection and submission obligation, e.g., for registration under REACH, notification under CLP or for

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62 Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products. OJ L 167 27.6.2012, p. 1.

63 Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/ EEC and 91/414 EEC. OJ L 309 24.11.2009, p. 1.

64 Commission Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 064 11.3.2011, p. 15.

65 EUR-Lex - 32011R0234 - EN - EUR-Lex (europa.eu)

cosmetic products, or approval and authorisation processes for plant protection products and biocidal products.

A choice is also to be made between a requirement to only provide a **summary of the search strategy** and a requirement to provide a summary of the search strategy as well as an **overview of the outcome** of the search.

3. Rely on OECD guidance

The Commission initiated an OECD project under the Working Party for Hazard Assessment (WPHA) on developing (i) a **guidance** setting minimum quality and reporting requirements to help researchers to design, perform and report studies in a way that is acceptable for the regulatory assessment and (ii) a **search guide** for finding and retrieving relevant academic data. The project is foreseen to end by the end of 2024.

A follow-up to the development of the guidance document would be the adoption of an OECD **recommendation** to research funders of the member countries and publishers to require the use of the guidance setting minimum quality and reporting requirements for data generation and reporting.

Under this option, no action is needed in the context of the legislative proposal at hand. While the adoption of both documents and the potential OECD recommendation will not create any legal obligation, they will independently contribute to an improvement in the uptake of academic data. This would therefore be **complementary to any legal obligations** that may be introduced.

4.2.6. Addressing the problem that duty holders may not report all study results

To ensure that the EU risk assessor has knowledge of all studies performed by an applicant, the Transparency Regulation contains a requirement to **notify studies that are commissioned or intended to be carried out** in the context of the preparation of an application for approval process in the food chain, at pre-submission phase. Besides the applicant (business operator), where a study is commissioned with a laboratory, the contracted laboratory is also required to notify. 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 procedural consequences in case of non-compliance.

Under the current initiative it was evaluated whether there is a need for and added value of such a notification mechanism beyond the food sector (the outcome of this evaluation is reflected in the summary of the stakeholder consultation in Annex 2). In addition, we developed different options for the establishment of such notification requirement.

Five aspects were considered for the design of the options for extending the study notification requirement. Different combinations of different possibilities for each of the five aspects led to the identification of three main options.

- **Scope**. The scope of the extension of the study notification obligation to the rest of the chemicals sector should be scaled to ensure maximal effectiveness and maintain a positive benefit/cost ratio. The most effective option would be to require **all studies** commissioned or conducted to support a regulatory process to be notified when commissioned or carried out. In order to understand what is considered to be a 'study', the Transparency Regulation and its related guidance documents were used as a reference. A study thus means an experiment or set of experiments in which a chemical substance or mixture, or a group of chemical substances or mixtures, is examined under laboratory conditions or in the environment to obtain data with respect to the properties or the safety of that substance or mixture, or group of substances or mixtures. This full coverage would affect the **whole chemicals sector** and generate the most study notifications but would also result in a more significant total compliance cost for the industry (operators and laboratories) compared to a narrower scope. Other possibilities for this aspect include requiring notification only for **specific groups or sectors of chemicals** (e.g. only substances subject to REACH registration requirement) and/or for **specific studies.**

- **Database setup**. The **existing EFSA database** (holding study notifications done under the Transparency Regulation) could be the starting point for the extended requirement. It could receive and store new notifications, which would be accessible by the relevant assessors to cross-check the notifications and the studies in a regulatory dossier. The advantage of this choice would be to leverage the already existing register infrastructure.

  Alternatively, a **central repository**, part of the common data platform on chemicals, accessible to all relevant assessors and linked to regulatory dossiers, could be set up. Monitoring and enforcement of study notifications would be carried out by the entity in charge of the assessment or regulatory process.

  A third possibility could be to operate the **two databases** separately and independently from each other: EFSA continues to operate its existing database and ECHA would set up a database for the remainder of the study notifications. Notifications made to EFSA would in any event also be made available through the common data platform on chemicals once a decision is taken by the EFSA on the disclosure of the studies accompanying an application in accordance with the confidentiality rules under the Transparency Regulation.

- **Sanctions**. In the case of missing study notifications or missing studies in a dossier, the same sanctions as under Article 32b (4) Transparency Regulation could be considered: applications are considered invalid or inadmissible when supported by studies not previously notified, or *vice versa*, when notified studies are not taken up in the dossier, without valid justification. Applicants may resubmit the application after notifying the missing study or including the missing study results and after a **6-month waiting period** (after notification or inclusion of the study).

  This type of sanction, which essentially entails a delay in market access, can however not be applied to all pieces of legislation. For example, the REACH registration process is not a market approval or authorisation process like the

processes covered by the Transparency Regulation. Once companies have registered their substances, they can place their substance on the market and do not need to wait for any approval or authorisation by an EU body. In those cases, **standard enforcement activities** by Member States are considered to apply.

- **Transparency**. With regard to making the notification information publicly available, a balance needs to be struck between transparency on the one hand and protection of innovation and competitiveness on the other. One possible way to deal with this is to carefully choose the timing of the publication of information. Once a regulatory dossier relating to a notified study is submitted, it appears appropriate to also publish the notification information. This approach is similar to the one under the Transparency Regulation.

  The **assessor** would in any case have access to the information from the moment of notification. This serves to inform the assessor on what is to come in terms of assessment work as well as on the progress in a procedure.

- **Content**. The base option is the specification in Article 32 of the Transparency Regulation: title and scope of any study carried out by the applicant to support an application or a notification, as well as the laboratory or testing facility if the study is commissioned, and its starting and planned completion dates (for laboratories: the scope, planned start and end date, and commissioning operator).

Based on different combinations of the dimensions described above, three options were identified. These options are presented below, ranked according to the magnitude of the induced changes compared to the status quo (no notification requirement), with option A bringing about least changes and option C most. A combination of elements is possible, thus creating more options.

	Option A	Option B	Option C
Scope	Subset of the chemicals: substances subject to REACH registration Laboratories co-notify	Whole chemicals sector Laboratories co-notify	Whole chemicals sector Laboratories co-notify
Database set-up	Dual notification databases Food sector notifications to EFSA database Rest of notifications to new ECHA database All notifications accessible through common data platform	All notifications go to existing EFSA notification database All notifications accessible through common data platform	One notification database under common data platform (i.e. food sector notification moves from EFSA to ECHA) All notifications accessible through common data platform

Transparency	Made public when notified	Pre-defined redaction rules and publication when ensuing application/registration is considered admissible (same as Transparency Regulation).	Pre-defined redaction rules and publication when ensuing application/registration is considered admissible (same as Transparency Regulation).
Sanctions	Standard enforcement activities by Member States	Market access delay where relevant (same as under Transparency Regulation) + standard enforcement activities by Member States	Market access delay where relevant (same as under Transparency Regulation) + standard enforcement activities by Member States
Content	Substance identity, notifier identity, study title, study scope, and timing of study (same as under Transparency Regulation).	Substance identity, notifier identity, study title, study scope, and timing of study (same as under Transparency Regulation).	Substance identity, notifier identity, study title, study scope and timing of study (same as under Transparency Regulation) + information specific to the type of substance or regulatory process where relevant

1. *Policy option A*

Under this option the requirement to notify studies would be extended to substances subject to REACH registration. A notification database would be set up and managed by ECHA in parallel with the existing database at EFSA. All notifications would be made available through the common data platform on chemicals. Non-compliance would be dealt with under normal enforcement by Member States. The notification requirement applies to both the applicant and the contracted laboratory where applicable (co-notification). The content of the notification would be the same as under the Transparency Regulation, i.e., substance identity, notifier identity, study title, study scope and timing of study. The information would be made public at the moment of notification.

2. *Policy option B*

This option has a broader scope than option A: it includes all regulatory processes in the chemicals sector. The existing EFSA notification database would serve as a single notification point. All notifications would be made available through the common data platform. Individual agencies/competent authorities would be responsible for monitoring study notifications. In case of non-compliance (missing study notification), besides standard enforcement by Member States, a market access delay would be applied where relevant. The content of the notification is the same as in option A but would be made public according to pre-defined redaction rules, and only when an ensuing regulatory dossier is considered admissible (like under the Transparency Regulation).

3. *Policy option C*

In comparison with option B, this option expands the content of the notification with more information specific to the type of chemicals examined in the study. All notifications, including those made under the Transparency Regulation, would go to the ECHA and would be made available through the common data platform.

4.2.7. Addressing the problem that there is no mechanism for the identification of emerging chemical risks

To ensure coordination in the generation, compilation and evaluation of early warning signals of emerging chemical risks to enable policy or regulatory follow up actions, the only viable and effective option identified was the establishment of an EU early warning and action system, serving as an EU umbrella system based on inputs from EU agencies, national early warning systems, national and EU initiatives, and the scientific community.

A proactive and systematic approach to the identification of emerging risks would be established, with the European Environmental Agency acting as the leader. The system would consist of the collection of early warning signals, the identification of potential emerging risks from chemicals, and a report on the findings of those activities, all to be presented to the Commission, relevant EU agencies and Member State competent authorities for identification and discussion of potential regulatory or policy follow-up. The system would be developed progressively. Initially, it would rely on existing early warning systems and signals, such as the EFSA's emerging risks exchange network (EREN), national warning systems (e.g. SamTox, SIGNAAL), as well as relevant existing data and information made available by EFSA, ECHA, EEA, EMA, EU-OSHA and the Commission. 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 explored and utilised as appropriate.

The European Environmental Agency would make all information on early warning signals for emerging chemical risks it holds or hosts, as well as the summary report available to the ECHA for integration in the common data platform on chemicals.

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)

5. WHAT ARE THE IMPACTS OF THE IDENTIFIED OPTIONS?

5.1. Addressing the problem that information is difficult to find, share or re-use and some information flows are suboptimal

Establishment of common data platform on chemicals

The platform will exploit opportunities with existing data through the creation of new services and a significant extension of the possibility to use data through an enhanced interoperability of individual datasets as well as their integrated access. The latter is further augmented through the sustained embedded availability of targeted dedicated services such as a repository of reference values and information on regulatory processes.

The **sustainable benefit** of the platform will come from these functionalities, applied over the content that will be included in the platform. The platform will operationalise the ambition of the one-substance one-assessment approach, supporting **quality and mutual coherence** of assessments performed. Bringing together chemicals data in one place will increase findability and simplify access, which is beneficial for all users (citizens, industry in particular SME and microenterprises with less access to professional services, Member State competent authorities and EU agencies). 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, it 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 it 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** in accordance with the objectives of the chemicals strategy for sustainability.

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.

The dedicated service 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. The 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.

The dedicated service 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.

While the database of environmental sustainability information is only being designed, and information is only started to be generated in more systemic manner and the regulatory tools mandating use of such data are still very limited, it is clear from the trends that ensuring in advance a common focus can dramatically increase efficiency in collection, validation, verification and consistency of sustainability information on chemicals, and its use both in regulatory and non-regulatory domain.

The establishment and operation of the platform will not impose any costs on industry. Business operators will have to continue to fulfil their legal obligations as they are doing today under relevant specific pieces of legislation. The platform is not associated with any new information requirements or other obligations for industry.

The establishment of the platform will however 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 systems/capabilities, principally on 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.

The platform's development is centred around three main elements:

- design and construction of a **data container**, i.e. the technical platform solution and the data definitions and ingestion mechanisms that enable it to receive data. While ECHA will be responsible for the IT infrastructure of the data container, other agencies will need to be involved in cooperation (and – depending on the data type – lead) on setting data definitions and supporting the general governance of the platform covering the determination of basic functionalities (ingestion, use and outputs, dedicated products featuring in the platform) and further evolution inter alia.
- **data content** activities: data transformation, curation and confidentiality assessment as well as the upload of integrated datasets will remain the responsibility of the data source owners (i.e. agencies), unless explicitly agreed

otherwise, based on commonly agreed rules and vocabularies and supported as appropriate with ingestion tools. For data source owners, this work will overlap with the work on formats and controlled vocabularies of their datasets and the organisation of related dataflows from original data providers (e.g. industry registrants, applicants, Member States).

- preparation of **dedicated services** available in the platform will include work on technical platform functionality as well as on data content. Examples of dedicated services are a repository of reference values, information on legal obligations, and a database on study notifications (see also section 4.2.1).

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 public cloud environment where the platform is expected to be hosted. It will follow the "intentional architecture, emergent designs" principle, leading to the 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 / context data according to platform requirements
- Mapping and conversion to agreed formats, use of controlled vocabularies
- Incorporation of agreed substance identifiers, controlled vocabularies and tagging (e.g. origin)
- Indication of confidentiality of information
- Quality control after conversion
- Mechanisms for (periodic) ingestion by the platform; updates, versioning

While a significant part of the preparation of 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. Extensive resources are already employed in current IT/data infrastructures of the agencies. The common data platform on chemicals is however a new infrastructure that in spite of longer term benefits requires investment for its development and additional work on existing datasets, and needs some overhead for operations.

Table 7 provides an overview of the estimated resources required for the development of the platform and integration of the datasets identified in a minimum viable product[66].

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66 Outlined in the Feasibility study[21] and further refined in the Project Initiation Document accompanying this Staff Working Document, the Minimum Viable Product (MVP) is the planned initial implementation of the common data platform and comprises the operating IT infrastructure that is delivering initial functionalities (e.g. basic database search, access to data, export) providing an integrated experience across the initial datasets contained in the platform (minimum viable dataset) and initial set of dedicated services (PACT, legal obligations database, repository of reference values etc.) with own further functionalities. The minimum viable dataset includes the following datasets, organised according to the Union agency responsible for integration:

Detailed resource estimates for agencies were made in the context of the proposal for a regulation on the re-attribution of scientific and technical work between EU Agencies and can be found in section 9 of the accompanying staff working document.

Table 7 – Overview of resource estimates for minimum viable product of common data platform

	FTEs				Operational costs (EUR)			
Activity	**Y1**	**Y2**	**Y3**	**Y4**	**Y1**	**Y2**	**Y3**	**Y4**
Common data platform	21	21	21	9	950	3 442	4 077	1 300
IPCHEM	1	3	3	3	0	200	380	230
Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0
Repository of limit values	1	1	1	1	0	650	650	200
Information on the obligations under Union acts on chemicals	0	0	0	0	0	0	0	0
Environmental sustainability information	0	1	1	1	0	0	0	0

- **ECHA REACH** (registration data industrial chemicals, incl. chemical safety reports); **ECHA CLP** (Classification and Labelling inventory); **ECHA BPR** (different datasets related to biocidal active substance approval process, authorised products and product-substance combinations); **ECHA Prior Informed Consent** (substances subject to Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals); **ECHA Persistent Organic Pollutants (POP); ECHA regulatory processes information** (present ECHA PACT)**; EU Chemicals Legislation Finder (EUCLEF); HBLVR** (under development, dataset underpinning repository of reference values)
- **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** (pesticides, veterinary medicinal product residues and contaminants data, measurements in food/feed); **EFSA OpenEFSA** (EFSA's scientific work, processes); **EFSA EU_PPP Agency IUCLID** (plant protection products, IUCLID dossiers submitted by applicants);
- **EEA Air Quality; EEA Waterbase Water Quality** (nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters, including records reported under the Water Framework Directive Watch List for chemicals in surface waters); **EEA Waterbase emissions** (emissions of nutrients and hazardous substances to water, reported by EEA member countries and cooperating countries, including data on yearly riverine input loads to transitional, coastal and marine waters); **EEA Industrial emissions** (as reported under E-PRTR Regulation and Industrial Emissions Directive, from releases to emissions, permit information etc.); **EEA National Emission reductions Commitments (NEC) Directive emission inventory data** (emissions of certain air pollutants);
- **EMA human medicinal products data** (environmental risk assessment and non-clinical toxicological data); **EMA Veterinary medicinal products** (environmental risk assessment and **maximum residue limit** (values and MRL assessment data)
- **IPCHEM, presently managed by JRC, including a number of chemical monitoring datasets** structured into four modules: Environmental monitoring, Human Bio-Monitoring, Food and Feed, Products and Indoor Air, to be integrated in the platform by joint undertaking by JRC, ECHA and EEA;

SUM	**23**	**26**	**26**	**14**	**950**	**4 292**	**5 107**	**1 730**

Redirection of information flows

Redirection of information to certain EU agencies could be foreseen for a limited number of information flows (see section 4.2.1, Table 4) in accordance with EU agencies' mandate and expertise. Such redirection is expected to have a beneficial impact on the efficiency and effectiveness of data handling and data interpretation and as such also a **positive impact on the efficiency and effectiveness on chemical safety assessments**.

5.2. Standard data formats

In order to ensure that chemicals data is interoperable, the only viable and effective option that was identified is **imposing the use of standard data formats and controlled vocabularies** for the transfer of data by EU agencies to the common data platform and in particular the use of IUCLID for a limited number of specific legislations. The agencies would be required to set standard formats and controlled vocabularies for the information in their mandate or expertise and to cooperate with other agencies setting formats and vocabularies in order to progressively move towards a maximisation of interoperability between different datasets.

Under this option, there would be no impact on duty holders under the respective individual pieces of chemicals legislation, as they would continue to submit information as they are doing today. The expectation is that in the longer term the formats and vocabularies set by the EU agencies would not only be used for the transfer of data from the agencies to the common data platform, but gradually also for the submission of data by the duty holders under the individual pieces of legislation.

The requirement for agencies to develop and agree on standard formats and controlled vocabularies implies additional effort required from them compared to today. The resource impact of this requirement is subsumed under the resource estimates for the setup and operation of the common data platform, provided in section 5.1.

The use of standard formats and controlled vocabularies will have a positive impact on the interoperability of information, thus increasing the findability of information. 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 and have a positive impact on the effectiveness, efficiency and coherence of chemical safety assessments.

5.3. Transparency and use of chemicals data contained in the common data platform

Dissemination and sharing of chemicals data

Table 18 in Annex 3 provides an overview of relevant rules relating to transparency and confidentiality under various pieces of legislation. Today there is already a very high degree of transparency and dissemination of information under the various pieces of

chemicals legislation in the scope of this initiative. **Strengthening the transparency rules** even more in the sense of requiring more information to be disseminated will only lead to a **marginally larger amount of information** becoming publicly available. Assuming that the general public is not specialised in interpreting chemicals data, any positive impact on EU citizens' trust in the scientific underpinning of chemical safety assessments is therefore also expected to be marginal.

With regard to **confidentiality claims**, the table in Annex 3 shows that while the General Food Law specifies the information that can be claimed confidential (Article 39(2)), it also stipulates that that list of information is without prejudice to any sectoral Union law (Article 39(3)). So, already at the level of food legislation there is no real harmonisation of provisions related to confidentiality. As such, it can also be questioned to what extent the very question of harmonising confidentiality rules across the chemicals regulatory framework is a valid one.

If it is still considered however to 'harmonise' confidentiality rules, from the table it is apparent that **the approach to confidentiality claims under different legislations and by different Union agencies is different**. Harmonisation of rules on confidentiality claims along the provisions of the General Food Law would imply a **significant additional administrative burden on the ECHA to systematically verify all submitted claims**. Indeed, Article 39b of the General Food Law requires the EFSA to do a concrete and individual examination of each confidentiality claim. In contrast, legislation in the mandate of the ECHA, such as the REACH Regulation or the Regulation on Biocidal Products refer to information, the disclosure of which shall normally be considered to undermine the protection of commercial interests. In other words, instead of a systematic verification of a confidentiality claim under the General Food Law, under REACH and the Regulation on Biocidal Products there is a **general assumption** of what constitutes confidential information and what not. As a result, the ECHA does not systematically verify every incoming confidentiality claim, but only in cases of clear need (e.g. in case of a request made under Regulation (EC) 1049/2001 regarding public access to European Parliament, Council and Commission documents or when a request is made by another agency for data sharing).

Harmonising transparency and confidentiality rules may thus be expected to lead to an increase in the number of confidentiality claims submitted by duty holders, causing **more costs and burden** for duty holders, as well as a higher burden for the agencies to systematically verify such claims.

Taking into account the above, the added value of disseminating only marginally more information than is currently the case through the harmonisation of transparency provisions may **not outweigh** the costs and burden incurred by duty holders and agencies for the submission and assessment of confidentiality claims.

In contrast, while the **originator principle** will not change the amount of information shared with the general public, it is also not expected to lead to an increase in the submission of confidentiality claims. The principle allows for data sharing between authorities, which is a prerequisite for data use, and as such is considered to **indirectly contribute to the efficiency, effectiveness and coherence of chemical safety assessments**.

Use of chemicals data contained in the common data platform

The use of chemicals data contained in the common data platform will **broaden and streamline** the evidence base for EU safety assessors and will therefore have a positive impact on the effectiveness, efficiency and coherence of chemicals safety assessment and thus on the protection of human health and the environment from chemicals as well as EU citizens' trust in the scientific underpinning of EU decision-making on chemicals, as a broader and more.

Since re-use will only be enabled for public authorities under strict conditions and not for private parties, no impact is expected on the competitiveness of chemicals companies.

5.4. Addressing the problem that there is no default generation or submission of certain types of chemicals data

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 necessary for a robust scientific assessment.

Table 8 re-iterates the two options identified for the establishment of a data generation mechanism with an indication of expected impacts.

Table 8 – Options for the establishment of a data generation mechanism with expected impacts

	Option 1 – DGM with explicit governance and centralised procedures	Option 2 – obligation on ECHA
Agencies involved	All EU agencies involved in chemicals related legislation (ECHA, EEA, EFSA, ECHA, EMA, EU-OSHA)	ECHA
Scope	All EU chemicals legislation in the scope of the overall legislative proposal	EU chemicals legislation and activities in ECHA's mandate and expertise
Right of initiative for Member States	Yes	No
Administrative burden	High – complex and long decision-making process with several different actors involved (Member States, EU agencies, Commission, expert working group)	Low - study initiation at ECHA's own initiative or at the request of the Commission
Possibility to request sample from industry	Yes	Yes
Resources required	• Multiple of the amount under option 2 if larger scope is taken into account and similar coverage of legislations in scope is assumed • A fixed number of FTEs for each agency involved and for the Commission without any foresight on which agencies would have to	• Operational costs variable in first three years, then EUR 5

	deal with a larger or smaller number of study requests	million annually as of the fourth year[67] • 1 FTE in the first year, thereafter 2 FTEs per year

Option 1 – DGM with explicit governance and centralised procedures

This option is expected to have a high effectiveness given its very broad scope (virtually any study relating to or supporting chemicals policy or implementation of Union chemicals legislation can be requested) and the fact that Member States can also submit study requests besides EU agencies and the Commission.

The broad scope and high possible number of initiators call for the establishment of procedures and an expert group to assign, assess, and prioritise study requests, which may have a negative impact on the efficiency of this option. Similarly, the broad scope will require a significant amount of resources, in the form of (i) human resources at the agencies to support the mechanism and (ii) financial resources to finance the studies. If the approach is taken that a good representation is to be had of all chemicals legislation and activities in scope of the DGM, a considerable budget will be required to allow for the necessary studies.

Option 2 – Obligation on ECHA to commission scientific studies for the performance of its mission

Since under this option an obligation would be conferred only on the ECHA, the scope of this option is automatically limited to chemicals legislation and activities in the mandate or expertise of the ECHA. This gives the option a medium effectiveness, but also a high efficiency (the latter not only because of the involvement of only one agency and the limited number of legal acts in scope, which requires less elaborate procedures, but also because of the fact that Member States cannot submit study requests under this option).

As regards resource requirements, for (i) human resources, the ECHA would require 1 FTE in the first year and 2 FTEs per year thereafter. In addition, ECHA would require EUR 0 in the first year, EUR 1 million in the second year, EUR 3 million in the third year and EUR 5 million annually from the fourth year onwards.

5.5. Addressing the problem of an insufficient uptake of academic data

Table 9 reiterates the options identified.

Table 9 – Options to address the problem of an insufficient uptake of academic data

Option	Description of option
1	Legal obligation on EU agencies
2	Legal obligation on industry duty holders

[67] Estimated operational costs year 1: EUR 0; year 2: EUR 1 million; year 3: EUR 3 million; year 4 and onwards: EUR 5 million. Detailed resource estimates were made in the context of the proposal for a regulation on the re-attribution of scientific and technical work between EU Agencies and can be found in section 9 of the accompanying staff working document.

3	Rely on OECD guidance

Option 1 – Legal obligation on EU agencies

This option has the disadvantage that by putting the obligation on agencies, the **burden of proof is shifted**. In addition, performing a search on a chemical without any specific regulatory context or problem definition may be challenging or may result in the retrieval of many publications, not all of which may prove to be relevant for a specific case at hand, thus leading to **inefficiencies**.

In addition, such obligation would lead to a **significant burden and cost for the agencies**. As a reference, resource estimations provided by the administrative team for populating the EASIS database were in the range of 0.5 – 1 FTEs per year for the entry of 1,000 studies in the database (including quality control). Over the last few years about 400-600 relevant studies were added to the platform per year. In a stakeholder consultation it was indicated by industry that this number could already be reached for one data-rich substance, such as glyphosate or titanium dioxide.

A similarly high resource requirement was indicated in a stakeholder consultation for the nomination of a substance as a persistent organic pollutant under the Stockholm Convention: for the gathering of academic studies as well as monitoring grey literature (including monitoring reports and other forms of governmental reports and/or databases), a Member State stated that 1 man year is required.

Requiring searches to be carried out on a selection of specific (categories of) chemicals instead of all possible chemicals would reduce the burden, but several thousands of academic studies can still be expected to be resulting from such obligation. The proportionality of this option would largely depend on the extent of the use of the information for risk management or regulatory purposes.

Option 2 – Legal obligation on industry duty holders

In case of the introduction of an obligation horizontally across the chemicals regulatory framework (**sub-option 1**), the impact on industry duty holders would be **significant**. The amount of time spent on a literature search can be expected to be similar to that spent by an EU agency per substance. The difference with the first option is that in case of an obligation on EU agencies (option 1), the agencies would have to cover a multitude of chemicals whereas in case of an obligation on industry duty holders (option 2) that number would be more limited per duty holder.

Where already existing requirements to consider academic data are strengthened by requiring the documentation of the search (**sub-option 2**) the assessment of the impact on industry duty holders depends on the baseline taken: (i) if it is assumed that a search is already done today given that there is an existing requirement, a documentation of that search will only have a **marginal impact** in terms of costs; (ii) if it is assumed that a search is often not done even though there already is a requirement (i.e. if non-compliance is assumed), then the introduction of a documentation requirement could have a **significant**

impact as the situation would change from 'no literature search' today to 'literature search + documentation' under the new provisions.

No significant administrative burden is expected for the EU agencies under either sub-option as the additional information found through the literature search would likely constitute a minor part compared to the rest of the regulatory dossier provided by the industry.

Option 3 – Rely on OECD guidance

Under this policy option, no action is needed in the context of the legislative proposal. While the adoption of both the guidance document and search guide and a potential OECD recommendation will not create any legal obligation, it will independently contribute to an improvement in the uptake of academic data. This will therefore be complementary to any legal obligations that may be introduced. Adoption of the aforementioned documents will also promote international harmonisation of assessment approaches and increased interoperability of workflows implemented by regulatory bodies for the identification, evaluation and reporting of academic data.

In view of the fact that this option does not consist in a legal obligation, but is guidance only, its effectiveness is difficult to predict.

5.6. Addressing the problem that duty holders may not report all study results

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.

Table 10 re-iterates the options identified.

Table 10 – Options to address the problem that duty holders may not report all study results

	Option A	Option B	Option C
Scope	Subset of the chemicals: substances subject to REACH registration Laboratories co-notify	Whole chemicals sector Laboratories co-notify	Whole chemicals sector Laboratories co-notify
Database set-up	Dual notification databases Food sector notifications to EFSA database Rest of notifications to new ECHA database All notifications accessible through common data platform	All notifications go to existing EFSA notification database All notifications accessible through common data platform	One notification database under common data platform (i.e. food sector notification moves from EFSA to ECHA) All notifications accessible through common data platform
Transparency	Made public when notified	Pre-defined redaction rules and publication	Pre-defined redaction rules and publication when ensuing

		when ensuing application/registration is considered admissible (same as Transparency Regulation)	application/registration is considered admissible (same as Transparency Regulation)
Sanctions	Standard enforcement activities by Member States	Market access delay were relevant (same as under Transparency Regulation) Standard enforcement activities by Member States for all other cases	Market access delay were relevant (same as under Transparency Regulation) Standard enforcement activities by Member States for all other cases
Content	Substance identity, notifier identity, study title, study scope, and timing of study (same as under Transparency Regulation)	Substance identity, notifier identity, study title, study scope, and timing of study (same as under Transparency Regulation).	Substance identity, notifier identity, study title, study scope and timing of study (same as under Transparency Regulation) + information specific to the type of substance or regulatory process where relevant

Option A

No major impediments are discerned for the **feasibility** of option A. While the scope is limited, it is not expected that this necessarily increases the feasibility of the establishment of the required IT infrastructure, as it may be assumed that once the IT setup is developed it can be used for notification under all pieces of chemicals legislation, regardless how little or how many.

The use of two separate notification databases – the existing one at EFSA for notifications under the Transparency Regulation and one at ECHA for the notification of testing on chemicals subject to REACH implies a duplication of effort while use could be made of the already existing database. ECHA will need to set up a new database and processes and use the new information (cross-check of study notifications) in its processes, while EFSA will continue its activities as usual. On the other hand, ECHA is known to have ample experience in designing and setting up IT systems. Moreover, as ECHA will be responsible for setting up and hosting the common data platform and the making available of study notification information through it, there is something to be said for establishing the database of study notifications (for studies not subject to a notification obligation under the Transparency Regulation) at the ECHA. Presumably, the IT system and design used by EFSA can be re-used at ECHA, with small adjustments as necessary. **Additional resources** would be required **within ECHA** to manage both the users (training, helpdesk support, analysis of information) and the technical solution.

Industry duty holders will need to update their internal planning and processes to include the notification requirement in their workflows. An **adjustment/setup cost** may therefore

be expected. In addition, there will be a labour cost for preparing and submitting notifications. This will entail a digital form with a limited number of fields to be filled out corresponding to the information required. It is estimated that notification will take between **15 and 30 minutes per study**.

Based on an estimated number of 16 708[68] companies in the EU with REACH obligations, 100 laboratories and a generous 7 person days per company/laboratory to adjust workflows and update internal planning and processes, a o**ne-off total setup cost for the entire EU** is calculated of ca. **EUR 26 million**. **Annual costs of notification** are estimated to amount to ca. **EUR 109 000 for the entire EU**, based on 7 500 estimated notifications and a notification time of 30 minutes. Calculations and figures are given in Table 11.

An important indirect cost impacting industry under option A is the potential competitiveness **impact of the confidentiality parameters** when set to "published when notification submitted". This cannot be monetised in a robust way, but the lack of confidentiality might deter research and development investments or spur divestments out of the EU which would lead to a lower economic output of the sector.

The extent of the **benefits**[69] of this option is a function of the scope and compliance rate. The scope in option A is limited to chemicals subject to REACH registration, while the compliance rate can be assumed to be driven by the deterrent role of sanctions. For this option, it is not possible to impose a market access delay as is the case under the Transparency Regulation, as the REACH registration process does not require any pre-market approval or authorisation, so enforcement and sanctions are expected to be determined by Member States. Sanctions could for example take the form of financial penalties. Since there is no systematic check or evaluation of each REACH registration dossier, it is not unrealistic to assume a certain degree of non-compliance, in line with non-compliance rates for other elements related to REACH implementation.

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68 These estimations were calculated in the study supporting this initiative. The estimated number of companies in the EU with REACH obligations is based on REACH registration statistics. The estimated number of laboratories is based on the assumption that in each Member State, a REACH registrant/applicant has on average at least three laboratory options (>=3 x 27 = approx. 100). The estimated number of study notifications is based on studies requested in REACH substance evaluation (~ 950), studies in new REACH registrations of new substances (~ 3,600), and studies in REACH registration updates where the tonnage band is increased (~ 450; for lower tier only, as higher tier is covered by testing proposals evaluated by ECHA). This estimation does not take into account any upcoming changes in REACH information and/or registration requirements.

69 The benefit of all options is a more effective risk assessment system in the chemicals sector, through an increased transparency on the planning of studies to support a regulatory process in chemicals legislation. As a result, authorities are informed of the existence of relevant studies for regulatory processes.

Table 11 – Estimated direct costs for EU industry of a notification requirement under option A

Business operators (Direct Costs)		EUR 25 787 547
Direct costs after 1 year		EUR 25 787 547
One-off		**EUR 25 678 422**
1. Adjust notification requirements in internal planning and processes *Total costs = p (fixed adjustment costs) * q (number of duty holders within scope)*		**EUR 25 678 422**
p (fixed adjustment costs)		EUR 1 527.80
Hourly salary	*EUR/h*	*29.1*
Hours per workday	*h/day*	*7.5*
Person days to adjust	*days*	*7*
q (# of companies and labs under REACH)		16 808
Companies commissioning/carrying out studies under the extended mechanism	*firms*	*16 708*
Laboratories facing an adjustment cost	*labs*	*100*
Recurrent		**EUR 109 125**
1. Labour cost of notifying each study *Total costs = p (labour cost) * q (number of studies notified)*		**EUR 109 125**
p (labour cost per notif.)		EUR 14.60
Hourly salary	*EUR/h*	*29.1*
Notification time requirement	*hours*	*0.5*
q (# of studies notified under REACH)		7 500
Studies to notify under the extended mechanism	*notifications/year*	*5 000*
Co-notification factor	*ratio*	*1.5*

Option B

No major impediments are discerned for the **feasibility** of option B. While the scope is very broad, it is not expected that this significantly decreases the feasibility of the establishment of the required IT infrastructure, as it may be assumed that once the IT setup is developed it can be used for notification under all pieces of chemicals legislation, regardless how little or how many, even though the system would have to be able to receive and host a larger number of notifications in case of a broader scope.

Using the existing notification database at EFSA to direct all notifications to is considered **an efficient approach**. There is no need to set up a new IT structure and staff dealing with the database and notifications is already available at EFSA. However, the ECHA will need to enable the making available of study notification information through the common data platform. The increased number of incoming notifications as a result of the establishment of a notification requirement for the entire chemicals regulatory framework may require a limited number of additional resources at EFSA.

Industry duty holders will need to update their internal planning and processes to include the notification requirement in their workflows. An **adjustment/setup cost** may therefore be expected. In addition, there will be a labour cost for preparing and submitting notifications. This will entail a digital form with a limited number of fields to be filled out corresponding to the information required. It is estimated that notification will take between **15 and 30 minutes per study**.

Based on an estimated number of 23 391[70] companies in the EU with REACH obligations, 200 laboratories and a generous 7 person days per company/laboratory to adjust workflows and update internal planning and processes, a **one-off total setup cost for the entire EU** is calculated of ca. EUR 36 million. **Annual costs of notification** are estimated to amount to ca. **EUR 375 000 for the entire EU**, based on 25 800 estimated notifications and a notification time of 30 minutes. Calculations and figures are given in Table 12.

Research and development investments are not expected to be impacted, nor are divestments out of the EU expected, as dissemination of notification information is only done when a corresponding dossier linked to the relevant regulatory process is considered admissible.

The extent of the **benefits**[71] of this option is a function of the scope and compliance rate. The scope in option B is very wide, covering all chemicals legislation in scope of the legislative initiative, while the compliance rate can be assumed to be driven by the deterrent role of sanctions. Under this option, a market access delay as under the Transparency Regulation is imposed where relevant, while for all other cases, enforcement and sanctions are expected to be determined by Member States. Such sanctions could for example take the form of financial penalties. Since a market access delay is quite impactful, compliance rates could be considered to be relatively high. Yet, from a legal implementation point of view, addressing the complexity of amending h existing

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70 These estimations were calculated in the study supporting this initiative. The estimated number of companies in the EU with REACH obligations is based on REACH registration statistics (option A) and on the assumption that 40% more companies concerned than by REACH alone (expansion of scope under option B).

The estimated number of laboratories is based on the assumption that in each Member State, a REACH registrant/applicant has on average at least three laboratory options (>= 3 x 27 = approx. 100). That number was multiplied by two (=200)(expansion of scope). The estimated number of study notifications is based on studies requested annually under REACH substance evaluation (~ 950), studies in new REACH registrations of new substances (~ 3600), and studies in registration updates where the tonnage band is increased (~ 450; lower tier only, as higher tier is covered by testing proposals evaluated by the ECHA). In addition, the number is based on studies under all relevant chemical sector regulations (REACH ~500 + biocides 7 200 + others 5 000). This does not take account of upcoming changes in information/registration requirements.

71 The benefit of all options is a more effective risk assessment system in the chemicals sector, through an increased transparency on the planning of studies to support a regulatory process in chemicals legislation. As a result, authorities are informed of the existence of relevant studies for regulatory processes.

regulatory procedures and their established timelines may be too complex or simply impossible in a standalone Regulation.

Table 12 – Estimated direct costs for EU industry of a notification requirement under option B

Business operators (Direct Costs)		EUR 36 416 846
Direct costs after 1 year		EUR 36 416 846
One-off		**EUR 36 041 456**
1. Adjust notification requirements in internal planning and processes *Total costs = p (fixed adjustment costs) * q (number of firms within scope)*		**EUR 36 041 456**
p (fixed adjustment costs)		EUR 1 527.80
Hourly salary	*EUR/h*	*29.1*
Hours per workday	*h/day*	*7.5*
Person/days to adjust	*days*	*7*
q (# of firms and labs under REACH)		23 591
Firms commissioning/carrying out studies under the extended mechanism	*firms*	*23 391*
Laboratories facing an adjustment cost	*labs*	*200*
Recurrent		**EUR 375 390**
1. Labour cost of notifying each study *Total costs = p (labour cost) * q (number of studies notified)*		**EUR 375 390**
p (labour cost per notif.)		EUR 14.60
Hourly salary	*EUR/h*	*29.1*
Notification time requirement	*hours*	*0.5*
q (# of studies notified under REACH)		25 800
Studies to notify under the extended mechanism	*notifications/year*	*17 200*
Co-notification factor	*ratio*	*1.5*

Option C

No major impediments are discerned for the **feasibility** of option C. While the scope is very broad, it is not expected that this significantly decreases the feasibility of the establishment of the required IT infrastructure, as it may be assumed that once the IT setup is developed it can be used for notification under all pieces of chemicals legislation, regardless how little or how many, even though the system would have to be able to receive and host a larger number of notifications in case of a broader scope.

A single notification database at ECHA will eventually be an efficient approach, but in the short term there would be an **efficiency loss** associated with the setup of a new database at ECHA, the abolishment of the existing EFSA database and the transfer of existing notifications to the ECHA database.

Industry duty holders will need to update their internal planning and processes to include the notification requirement in their workflows. An **adjustment/setup cost** may therefore be expected. In addition, there will be a labour cost for preparing and submitting

notifications. This will entail a digital form with a limited number of fields to be filled out corresponding to the information required. It is estimated that notification will take between **15 and 30 minutes per study and possibly up to 60 minutes per study** for specific pieces of legislation where specific information is requested in addition.

Based on an estimated number of 23 391[72] companies in the EU with REACH obligations, 200 laboratories and a generous 7 person days per company/laboratory to adjust workflows and update internal planning and processes, a **one-off total setup cost for the entire EU** is calculated of ca. EUR 36 million. **Annual costs of notification** are estimated to amount to ca. **EUR 750 000 for the entire EU**, based on 25 800 estimated notifications and a notification time of 60 minutes. Calculations and figures are given in Table 13.

Research and development investments are not expected to be impacted, nor are divestments out of the EU expected, as dissemination of notification information is only done when a corresponding dossier linked to the relevant regulatory process is considered admissible.

The extent of the **benefits**[73] of this option is a function of the scope and compliance rate. The scope in option C is very wide, covering all chemicals legislation in scope of the legislative initiative, and the compliance rate can be assumed to be driven by the deterrent role of sanctions. Under this option, a market access delay as under the Transparency Regulation is imposed where relevant together with additional penalties, while for all other cases, enforcement and sanctions are expected to be determined by Member States. Such sanctions could for example take the form of financial penalties. Since a market access delay is quite impactful, compliance rates could be considered to be relatively high. Yet, from a legal implementation point of view, addressing the complexity of amending existing regulatory procedures and their established timelines may be too complex or simply impossible in a standalone Regulation.

Table 13 – Estimated direct costs for EU industry of a notification requirement under option C

Business operators (Direct Costs)		EUR 36 792 236
Direct costs after 1 year		EUR 36 792 236
One-off		**EUR 36 041 456**
1. Adjust notification requirements in internal planning and processes *Total costs = p (fixed adjustment costs) * q (number of firms within scope)*		**EUR 36 041 456**
p (fixed adjustment costs)		EUR 1 527.80
Hourly salary	*EUR/h*	*29.1*
Hours per workday	*h/day*	*7.5*

72 For assumptions and calculations made, see footnote with related explanations for option B

73 The benefit of all options is a more effective risk assessment system in the chemicals sector, through an increased transparency on the planning of studies to support a regulatory process in chemicals. legislation. As a result, authorities are informed of the existence of relevant studies for regulatory processes.

Person/days to adjust	*days*	*7*
q (# of firms and labs under REACH) *Firms commissioning/carrying out studies under the extended mechanism*	*firms*	23 591 *23 391*
Laboratories facing an adjustment cost	*labs*	*200*
Recurrent		**EUR 750 780**
1. Labour cost of notifying each study *Total costs = p (labour cost) * q (number of studies notified)*		**EUR 750 780**
p (labour cost per notif.) *Hourly salary*	*EUR/h*	EUR 29.10 *29.1*
Notification time requirement	*hours*	*1*
q (# of studies notified under REACH) *Studies to notify under the extended mechanism*	*notifications/year*	25 800 *17 200*
Co-notification factor	*ratio*	*1.5*

5.7. Addressing the problem that a mechanism is lacking for the identification of emerging chemical risks

Establishment of an EU early warning and action system for emerging chemical risks

The establishment of 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.

Putting the EEA in the lead on an early warning and action system will provide synergies with existing workstreams, as early identification of emerging risks is one of the activities of the EEA (e.g. for waste), and with the agency's work on indicators, including work on the zero-pollution indicator framework. Work on an early warning system can be considered as a natural expansion of the EEA's work on the framework on indicators for chemicals, as several indicators can serve also as early warning signals. In addition, the EEA (and also the 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.

The work will require additional resources for EEA. EEA will need as of the first year 1 FTE per year and an operational budget for the first year of EUR 0, for the second year EUR 300 000 and as of the third year and thereafter EUR 150 000 per year. Resources needed for other agencies would be minimal: the EFSA already operates the emerging risks exchange network (EREN), while the ECHA develops indicators for chemicals - the existing allocated resources should cover also the activity related to the early warning system - and EMA and EU-OSHA would only have to contribute with existing information they already hold.

6. COMPARISON OF OPTIONS AND IDENTIFICATION OF PREFERRED OPTION

Note: **detailed resource estimates for agencies for the various preferred options were made in the context of the proposal for a regulation on the re-attribution of scientific and technical work between EU Agencies and can be found in the accompanying staff working document.**

6.1. Addressing the problem that chemicals data is scattered and some information flows are suboptimal

Establishment of a common data platform on chemicals

As indicated in section 4.2.1., only **one viable option** was identified to address the problem in an effective and efficient manner. That option is the **establishment of a common data platform** on chemicals. Given the ECHA's mandate and overall expertise, it is considered that the **ECHA is the most suitable EU agency** to establish such platform. Other relevant EU agencies and the Commission should be part of the platform steering committee to agree on a governance scheme and rolling implementation plans.

6.2. Addressing the problem that chemicals data is not always interoperable

As indicated in section 4.2.2., only **one viable option** was identified to address in an effective and efficient manner the problem that chemicals data is not always interoperable. That option is **establishing standard data formats and controlled vocabularies** and making their use obligatory. Given the specificities of some pieces of legislation and the fact that different EU agencies have different, specific mandates and expertise, the logical approach is to **require the relevant EU agencies to develop such formats and vocabularies** for the chemicals data and legislation in their mandate or expertise.

6.3. Addressing the problem that chemicals data is not always accessible

Dissemination and sharing of data

Two options were identified: (i) apply the transparency rules under the Transparency Regulation horizontally to all chemicals legislation in the scope of this initiative and (ii) apply the originator principle.

Overall, already today there is a very high degree of transparency and dissemination of information under the various pieces of chemicals legislation in the scope of this initiative. Strengthening the transparency rules even more will only lead to a **marginally larger amount of information** becoming publicly available. The added value of such additional dissemination may be limited for the general public, the majority of which may not be expected to have an in-depth knowledge and expertise on chemicals data. Moreover, in view of the fact that some EU agencies do not systematically verify every incoming confidentiality claim, but only in cases of clear need (e.g. in case of a request made under Regulation (EC) 1049/2001 regarding public access to European Parliament, Council and Commission documents or when a request is made by another agency for data sharing), strengthening transparency rules horizontally may be expected to lead to an increase in the number of confidentiality claims submitted by duty holders, causing **more costs and burden** for those duty holders, as well as a higher burden for those agencies to

systematically verify such claims. As a result, it can be expected that the added value of disseminating only marginally more information than is currently the case will **not outweigh** the costs incurred by duty holders for the submission of confidentiality claims.

In contrast, the originator principle avoids this imbalance between added value and incurred costs and is thus **more proportionate**, while still allowing data sharing between public authorities as a first and necessary step towards the re-use of data. Based on this, **option 2 (apply the originator principle) is considered the preferred option.**

6.4. Addressing the problem that there is no default generation or submission of certain types of chemicals data

Two options were identified: (i) establishing a data generation mechanism with explicit governance and centralised submission and assessment procedures ('option 1') and (ii) conferring an obligation on ECHA to commission scientific studies for the performance of its mission ('option 2'). A qualitative comparison of both options is given in Table 14.

Table 14 – comparison of options for data generation

	Option 1 – DGM with explicit governance and centralised procedures	Option 2 – obligation on ECHA
Agencies involved	All EU agencies involved in chemicals related legislation (ECHA, EEA, EFSA, ECHA, EMA, EU-OSHA)	ECHA
Scope	All Union chemicals legislation in the scope of the overall legislative proposal	Union chemicals legislation and activities in ECHA's mandate and expertise
Right of initiative for Member States	Yes	No
Administrative burden	High – complex and long decision-making process with several different actors involved (Member States, EU agencies, Commission, expert working group)	Low - study initiation at ECHA's own initiative or at the request of the Commission
Possibility to request sample from industry	Yes	Yes
Resources required	• Multiple of the amount under option 2 if larger scope is taken into account and similar coverage of legislations in scope is assumed • A fixed number of FTEs for each agency involved and for the Commission without any foresight on which agencies would have to	• Operational costs variable in first three years, then EUR 5 million annually as of the fourth year[74] • 1 FTE in the first year, thereafter 2 FTEs per year

[74] Estimated operational costs year 1: EUR 0; year 2: EUR 1 million; year 3: EUR 3 million; year 4 and onwards: EUR 5 million. Detailed resource estimates were made in the context of the proposal for a regulation on the re-attribution of scientific and technical work between EU Agencies and can be found in section 9 of the accompanying staff working document.

	deal with a larger or smaller number of study requests	

The two options are considerably different mainly in terms of scope, resource requirements and administrative burden. Taking into account the fact that data generation is already possible for food related chemicals by virtue of Article 32 of the General Food Law, and the process of substance evaluation under REACH also allows for the request of additional data generation, **it appears reasonable to accept a more narrowly scoped data generation mechanism in return for significantly lower resource requirements and administrative burden**. Moreover, in the spirit of a coherent approach to the implementation of chemicals legislation and the delivery of high-quality chemicals assessments, it only seems logical to give the same possibility to ECHA as EFSA already has today to conduct scientific studies for the performance of its mission.

Therefore, **option 2 (conferring an obligation on ECHA to commission scientific studies for the performance of its mission) is the preferred option**.

As a specific side-note, it is considered that EUON as an existing data generation mechanism run presently by ECHA should be using the same data generation mechanism with outputs construed as a database within the common data platform for maximum efficiency and impact.

6.5. Addressing the problem of an insufficient uptake of academic data

Table 15 reiterates the options identified.

Table 15 – Options to address the problem of an insufficient uptake of academic data

Option	Description of option
1	Legal obligation on EU agencies
2	Legal obligation on industry duty holders
3	Rely on OECD guidance

Options 1 and 2 imply the introduction of new or the strengthening of existing legal obligations, while option 3 operates from a non-regulatory guidance or incentivisation angle. The first two options can therefore be expected to be more effective than the last one. Yet, the third option can be considered complementary to any legal obligation adopted.

When comparing options 1 and 2, option 1 clearly has two main disadvantages, notably (i) the fact that the burden of proof is reversed and as such the option goes against one of the basic principles assumed under the chemicals regulatory framework, and (ii) it comes with a large resource requirement for the agencies subject to the obligation as they would need to cover all chemicals in scope.

Taking into account these considerations, **option 2 is the preferred option, while option 3 is evidently supported in addition**. Within option 2, a strengthening of existing requirements through the obligation to provide a documentation of the search carried out

is preferred (**sub-option 2**), as it will have considerable effectiveness (the documentation needs to be included in the regulatory dossier) while costs and burden will be limited as the legal requirement to do a literature search already exists.

Considering it unlikely, however, that the requirement can be caught in one standard phrasing in a standalone regulation and apply appropriately to several different pieces of legislation with requirements relating to a literature search with specific contexts, actors etc. it is believed to be **suboptimal to address the problem through the proposed regulation on chemicals data. It should rather be covered through targeted amendments of individual legislative texts**.

6.6. Addressing the problem that duty holders may not report all study results

A comparative overview of the impacts of the three options identified is given in Table 16.

Table 16 – comparative overview of the impacts of the three identified options

	Option A	Option B	Option C
Feasibility	High	High	High
Effectiveness	Lowest	Highest	Highest
Efficiency	Lowest	Highest	Medium
Resource requirements of EFSA and/or ECHA	Medium	Medium	Medium
Negative impact on competitiveness of duty holders	High	Low	Low
Financial impact on duty holders	Medium	Medium	Highest
Combined impact on duty holders (competitiveness + financial)	Highest	Lowest	Medium

No major impediments are discerned for the **feasibility** of any of the identified options. In terms of legal implementation, however, introducing a market access delay sanction as currently laid out for the food sector in Article 32d of Regulation (EU) 2018/1725 in a self-standing regulation for several different regulatory processes under specific pieces of legislation with their own procedures and timelines is considered far-reaching and not specific enough to address disparities between the various regulatory processes requiring the carrying out of studies under the acts listed in Annex I. . It is considered therefore that, Member States' defined penalties and measures implementing those penalties would facilitate a more process-specific tailored approach and incentivise compliance with the study notification requirement. The agencies responsible for handling respective dossiers should, to this end, cooperate with Member State enforcement authorities on exchanging information and best practices.

In terms of **effectiveness** – determined by the scope (legislations covered) and sanctions – option A scores lowest, as it covers only studies on substances subject to REACH

registration and does not allow for market access delay in case of incompliance. In contrast, both options B and C cover studies conducted under all chemicals legislations in scope of the legislative initiative and impose a market access delay in case of incompliance where possible (i.e. in cases where approval or authorisation is required before a chemical can be placed on the market). **Option C and B can therefore be considered equally effective, and both options are clearly more effective than option A.**

The concrete practicalities of the submission of a notification by a duty holder will be the same under the three options; notifications will need to be submitted via an electronic form. Differences in **efficiency** of the notification system are thus determined by the setup of the notification database and the related resources required by the relevant agencies. The three options score quite similar in this respect with advantages and disadvantages associated with all of them, in the short, middle and/or longer term.

Both options B and C ultimately lead to the deployment of one single database: under option B all notifications are directed to EFSA's existing database, while under option C all notifications have to be sent to a central database at the ECHA. Option C would thus require the transfer of the existing notifications in EFSA's database to the ECHA. As such, option B would need the least additional resources in the short term. While the use of two databases in option A (continuation of existing EFSA database and establishment of new database at ECHA) appears to be the least efficient in the shorter term, the approach draws on advantages that both agencies have to offer: EFSA can continue their practice as usual, while ECHA has ample experience with setting up IT systems and is expected to set the notification system using own IT building blocks with relative ease and can do so in a way which optimises the linking and interoperability of the notification database with the common data platform.

Duty holders can be impacted in two ways: (i) all options are associated with financial costs related to the preparation and submission of notifications and (ii) depending on the dissemination policy, competitiveness may be impacted.

A one-off cost relates to the update of duty holders' internal planning and processes to include the notification requirement in their workflows. In addition, there are recurring costs associated with the actual notification of studies. The one-off setup cost is the same per company under all three options. Yet, since option A has a narrower scope and therefore affects a smaller number of business operators, the overall one-off cost for EU industry is lower in option A than in option B or C. With respect to the recurring costs related to the actual notifications, under option A and B the cost per notification is the same, while under option C that cost is expected to be higher because the information requirements for the notification may be more elaborate for specific pieces of legislation. At EU level, the total recurring annual cost for all EU duty holders together is lowest under option A because of that option's narrower scope. Option B and C have the same scope, but option C requires more information to be notified.

The dissemination policy may have a significant impact on competitiveness. Under option A, notification information is made public upon receipt of the notification, i.e. before a corresponding regulatory dossier is submitted. The availability of such information in an early stage may have serious detrimental effects on the competitive position of the business operator. Under options B and C, notification information is only disseminated if a

corresponding valid regulatory dossier has been submitted, thus avoiding any damage to competitiveness.

Combining both elements – financial impacts and impact on competitiveness – **option B has the least negative impact on duty holders, with option C performing only marginally less well and option A having the worst impact on duty holders, mainly due the damaging effects on competitiveness**.

Considering all elements described above, a **modified option B -** taking into account the legal implementation challenges relating to the market access delay sanction **- as specified below, is the preferred option**.

	Option B
Scope	Whole chemicals sector Laboratories co-notify
Database set-up	Notifications pursuant to Article 32b of the Transparency Regulation continue to go to existing EFSA notification database All other notifications go to ECHA notification database All notifications accessible through common data platform
Transparency	Pre-defined redaction rules and publication when ensuing application/registration is considered admissible (same as Transparency Regulation)
Sanctions	Standard enforcement activities by Member States
Content	Substance identity, notifier identity, study title, study scope, and timing of study (same as under Transparency Regulation).

6.7. Addressing the problem that a mechanism is lacking for the identification of emerging chemical risks

Establishment of an EU early warning and action system for emerging chemical risks

As indicated in section 4.2.7., the only viable and effective option identified is the establishment of an EU early warning and action system, serving as an EU umbrella system based on inputs from EU agencies, national early warning systems, national and EU initiatives and the scientific community to enable a timely implementation of risk reduction measures for the protection of human health and the environment.

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

The initiative on chemicals data is under the responsibility of DG Environment (ENV). It is included in Decide planning with reference PLAN/2022/479[75] and mentioned in the Commission work programme 2023 as one of the follow-up actions on the zero-pollution action plan.

2. ORGANISATION AND TIMING

The initiative on chemicals data was first announced in the Chemicals Strategy for Sustainability published in October 2020. A call for evidence[76] was published on 19 July 2022. To support the development of the legal proposal, a supporting study was launched on 16 May 2022 with a duration of one year and specific input was requested from the ECHA, EEA, EFSA, EMA, EU-OSHA and JRC.

An Inter-Service Steering Group (ISG) on One Substance, One Assessment was set up to which the following 10 services participated: BUDG, CNECT, EMPL, ENV, GROW, JRC, JUST, RTD, SANTE, SG. In addition, ECHA, EEA, EFSA, EMA and EU-OSHA were invited and participated as observers.

The ISG met 7 times in total, on 11 February 2021, 13 April 2021, 28 June 2021, 16 November 2021, 18 February 2022, 27 February 2023 and 9 March 2023.

In addition to the ISG meetings, interested services and agencies were involved in bilateral meetings and discussions on topics that were specifically in their remit or expertise.

3. EVIDENCE, SOURCES AND QUALITY

The evidence collected for this staff working document is based on a several sources, which can be summarised as follows:

- Fitness check of the most relevant chemical legislation (excluding REACH)[77]
- Supporting study on streamlining chemicals data flows, increasing data interoperability, dissemination, re-use and the use of all available data, and on the establishment of a data generation mechanism for the purpose of safety assessments in the context of the European chemicals regulatory framework
- Feasibility study on a common open platform on chemical safety data[78]

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75 Decide (europa.eu)

76 Chemical safety – better access to chemicals data for safety assessments (europa.eu).

77 Fitness Check of the most relevant chemical legislation (excluding REACH) (europa.eu)

78 Feasibility study on a common open platform on chemical safety data - Publications Office of the EU (europa.eu)

- Study on a pilot of an EU early warning system for emerging chemical risks to the environment[79]
- A comprehensive stakeholder consultation (see also Annex II)
- Ad-hoc support from CNECT, JRC, ECHA, EEA, EFSA, EMA

[79] Pilot of an EU early warning system for emerging chemical risks to the environment.

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

A call for evidence for this initiative was published on the Commission website 'Have your say'[80] on 19 July 2022. The public and stakeholders were invited to provide feedback on this initiative before 16 August 2022. In total, 68 submissions were received from business associations (35%), NGOs (16%), individual companies (15%), EU citizens (12%), public authorities (9%), others (4%), non-EU citizens (3%), academic/research institutions (3%), and trade unions (3%).

An extensive discussion was held with representatives of Member States and Union agencies at three meetings of the Expert Group on One Substance, One Assessment[81] held on 29 September 2021, 2-3 June 2022 and 30 March 2023, respectively.

Stakeholders were informed and consulted during the Information Session on One Substance, One Assessment with Stakeholders held on 1 June 2022. Around 800 participants followed this on-line event.

In the context of the supporting study a combination of tools and methods was used to gather views and data from different stakeholder groups:

- An online questionnaire targeting Member States yielded 15 responses
- An online questionnaire targeting academia, industry and NGOs yielded 65 responses
- 14 interviews were conducted with Commission services and EU agencies
- three online workshops were organised targeting all stakeholders on 15 November 2022, 19 January 2023 and 27 February 2023, respectively, and were attended by 44, 72 and 61 participants, respectively

In table 17 an overview is provided of the main objectives of the different consultation tools and the type and number of stakeholders contacted or consulted. For each problem or topic, a summary of the results is provided further below.

Table 17 – Overview of consultation tools

Tool	Objective	Targeted stakeholders	Stakeholders contacted	Stakeholders responded/participated
Call for evidence	Collect data and information on the initiative at large	All stakeholders, including EU citizens	N/A	68
Online questionnaire for Member States	Collect data and information from Member States on the initiative at large	27 Member States, Norway	76	15
Online questionnaire for other stakeholders	Collect data and information from stakeholders on the initiative at large	Academia, industry, industry and business associations, NGOs	707	65
Interviews	Obtain rich data and information on specific	European Commission services and agencies (also an industry	22	14

80 Chemical safety – better access to chemicals data for safety assessments (europa.eu).
81 Register of Commission expert groups and other similar entities (europa.eu)

	topics in the scope of the initiative	association and PARC coordinators)		
Targeted online workshops	Facilitate discussion on possible policy options among key stakeholders.	Academia, industry, industry and business associations, NGOs, European Commission services, Member States	115 (first online workshop) 166 (second online workshop)	44 (first workshop) 71 (second workshop)
Final online workshop	Present the findings from the second interim report of the study supporting the initiative and allow for its validation by stakeholders, such as authorities, NGOs and industry stakeholders.	Academia, industry, industry and business associations, NGOs, European Commission services, Member States	224	62

Feedback on the establishment of a common data platform on chemicals
Generally, there was a large support for the establishment of a common data platform on chemicals. Several public authorities stated that national authorities and EU agencies should make more data available and claimed that public authorities should have unrestricted access to all data in the platform. Industry emphasised the importance of maintaining the confidentiality of information upon sharing and re-use. NGOs advocated for full transparency of chemicals data for the general public. Some NGOs stated that obstacles related to intellectual property rights and confidentiality should be removed to allow a broader access to and re-use of information.

Feedback on options related to data formats
Several business associations emphasised that data formats should be developed in consultation with stakeholders and take account of existing initiatives. Academics mainly raised the point that it would be essential for them to have all data available for bulk download in a common format without the need for any specific new software. They highlighted the importance to report values for a given parameter in a consistent manner and in a constant unit. Several Member States reported that they support the principle to use the same data formats and tools across different pieces of legislation and across data holders as much as possible. Yet, the use of standard data formats should not increase the burden on industry or delay regulatory processes. One Member State found coordination with the OECD essential. Use should be made of OHTs (OECD harmonised templates). Another Member State proposed to move from human readable to FAIR and highly granular data, so it can be rendered and or aggregated in a human readable way.

Feedback on controlled vocabularies
The majority of the feedback received related to examples where different definitions of the same concept were identified among different legislations. EU agencies commonly agreed on the benefit of a controlled vocabulary. Industry associations indicated that controlled vocabularies should be developed in consultation with stakeholders and should take account of existing initiatives. With regard to substance identity, EU agencies, industry and Member States agreed that it is not possible to harmonise substance identity itself. EU agencies raised the idea to work towards a common set of identifiers, which can be used for all chemicals data sets. Sector-specific identifiers could be used in addition. Data sets should also be linked to the regulatory context in which they were generated, so that regulators are aware of the substance definition considered. Several Member States

indicated that besides substance identity, information on the purity of a substance is of similar importance. Common definitions for ‘substance’, ‘constituent’, ‘component’, ‘impurity’, ‘substance identity’, ‘intrinsic property’ were considered necessary to ensure interoperability of different datasets generated under different regulatory frameworks. Also, they strongly recommended the involvement of OECD.

Feedback on transparency and use of data

Academics indicated that disseminating more than what is already the case today may not be necessary for the general public, yet they did consider it necessary for scientific experts from academia to have access to more data in order to ensure that the public is protected sufficiently from any harms of chemicals. They noted that currently, their main legal obstacles to accessing information are confidential business information and the lack of access to full industry study reports. They supported harmonisation of transparency rules across the chemicals regulatory framework. NGOs called for better data access to enable them to perform analyses and find potentially harmful and under-regulated substances. They suggested limiting confidentiality claims to a minimum and applying fees to prevent default claims.

One NGO highlighted that the system that eventually will be set up must enable independent scientists to scrutinize industry studies, to ensure that adverse effects or indicators of adverse effects are not being overlooked. Today, only study summaries are available and in cases of controversies it is of public interest and important to enable access to raw data for independent parties on a confidential basis. Industry representatives welcomed the dissemination of assessment reports but highlighted the danger of disclosing proprietary and confidential business information that could endanger competitiveness and innovation. They suggested limiting transparency to chemicals already on the market and ensuring fair sharing of costs involved in the generation of test data. One industry sector expressed concerns that undifferentiated dissemination of data could facilitate counterfeiting and pose a risk to human health. Industry also suggested to work with a disclaimer prior to providing access to data in order to clarify the legal situation and ownership in order to protect against misuse. One company expressed support for the originator principle.

With regard to the use of chemicals data, some data providers expressed concern about how their data will be interpreted or used. While industry generally accepted data use for legal purposes by authorities, they highlighted the obstacles of fair cost sharing mechanisms, unfair competition, inappropriate use of data, and compromised data generation and sharing. A certain risk was perceived of inappropriate use of data as tests are designed for specific purposes and specific chemicals. One industry association welcomed the idea that data use should not support filling of data gaps in regulatory dossiers.

Stakeholder feedback on the establishment of a data generation mechanism

Divergent opinions were raised by several Member States, business associations, companies, NGOs, and one university on the scope of a data generation mechanism, ranging from ‘only in exceptional cases’, ‘solving doubts or unclarities in specific dossiers’, ‘targeted and specific data requests’, to ‘broad scope’ and ‘all testing of chemicals’. The university, several business associations and an individual expert also

emphasised the need to avoid overlap with existing systems. Existing data should be evaluated before new data are generated. One Union agency and a Member State also mentioned that data generation should be relevant for several Member States. One Union agency, one university and a Member State also stressed the importance of conformity with existing principles and obligations, such as the precautionary principle, the polluter pays principle or specific obligations for companies (such as to monitor the real-life fate and effects of their substances).

Several Member States and business associations indicated that a data generation mechanism should not be used to fill data gaps in dossiers or bypass difficulties in regulatory processes where the data request is in the scope of such processes. An NGO pointed out that a data generation mechanism could exclude data on substances covered in existing chemicals and chemical product regulations, and instead focus on low tonnage substances and substances with reduced information requirements under the REACH Regulation. On the other hand, a Member State mentioned that a data generation mechanism could be used to identify new chemicals for monitoring and to assess future regulatory needs. Another Member State pointed out that provisions should be foreseen to conduct vertebrate animal tests as a last resort only.

Several Member States indicated that all actors involved in regulatory safety assessments should be allowed to make study requests under a data generation mechanism. Academics claimed that it should also be possible for academia to submit study requests.Some Member States and a research consortium stressed the need for the generation of (bio)monitoring data.

Comments from a Member State, several business associations, and a university on the budget included the need for due reflection on the polluter pays principle, as well as the fact that it would be difficult to fund the data generation mechanism through industry fees, as it would be difficult to allocate them fairly.

Feedback on the establishment of a requirement to notify studies commissioned or carried out by business operators

Largely, respondents agreed that a study notification requirement would limit to a great extent the possibility to hide study results for the regulatory processes that the obligation would apply to. Industry stakeholders where generally against the extension of the notification mechanism while NGO and academia respondents were generally in favour.

Industry stakeholders moreover underlined the compliance costs implications and highlighted the need for proportionate action. Some Member States and EU agencies reported that a notification requirement would bring several indirect benefits related to information on progress throughout the regulatory process (decisions taken by the applicant, planning of future workload). Several business associations expressed concern about a notification requirement increasing administrative burden. In addition, they stated that notifications should ensure confidentiality and protect research and development activities. A few business associations stated that the notifications can hinder competitiveness because only laboratories located in the European Union would be obliged to co-notify.

ANNEX 3: TRANSPARENCY AND CONFIDENTIALITY RULES

Table 18 presents an overview of transparency and confidentiality related provisions under different legislations. Underlined text in bold is in particular relevant for the assessment made in section 5.3.

Table 18 - Overview of transparency and confidentiality related provisions under different legislations

Legislation	Transparency/dissemination	Confidentiality
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 (General Food Law) **and Regulation (EU) 2019/1381 on the**	Article 38 Transparency 1. The Authority shall carry out its activities with a high level of transparency. It shall in particular make public: *(a) agendas, participant lists and minutes of the Management Board, the Advisory Forum, the Scientific Committee and the Scientific Panels and their working groups;* *(b) all its scientific outputs, including the opinions of the Scientific Committee and the Scientific Panels after adoption, minority opinions and results of consultations performed during the risk assessment process always being included;* *(c) scientific data, studies and other information supporting applications, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;* *(d) the information on which its scientific outputs, including scientific opinions are based, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;*	Article 39 Confidentiality 1. By way of derogation from Article 38, the Authority shall not make public any information for which confidential treatment has been requested under the conditions laid down in this Article. 2. Upon the request of an applicant, the Authority **may grant confidential treatment only with respect to the following items** of information where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) the **manufacturing or production process**, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;* *(b) **commercial links** between a producer or importer and the applicant or the authorisation holder, where applicable;* *(c) **commercial information** revealing sourcing, market shares or business strategy of the applicant; and* *(d) **quantitative composition** of the subject matter of the request, except for information which is relevant to the assessment of safety.*

transparency and sustainability of the EU risk assessment in the food chain (Transparency Regulation)	*(e) the annual declarations of interest made by the members of the Management Board, the Executive Director and the members of the Advisory Forum, the Scientific Committee and the Scientific Panels, as well as the members of the working groups, and the declarations of interest made in relation to items on the agendas of meetings;* *(f) its scientific studies in accordance with Articles 32 and 32d;* *(g) the annual report of its activities;* *(h) requests from the European Parliament, from the Commission or from a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification;* *(i) a summary of the advice provided to potential applicants at pre-submission phase pursuant to Articles 32a and 32c.* Information referred to in the first subparagraph shall be made public without delay, with the exception of the information referred to in point (c) thereof, as far as applications are concerned, and in point (i) thereof, which shall be made public without delay once an application has been considered valid or admissible. The information referred to in the second subparagraph shall be made public in a dedicated section of the Authority's website. That dedicated section shall be publicly available and easily accessible. That information shall be available to be downloaded, printed and searched through in an electronic format. 1a. The disclosure of the information referred to in points (c), (d) and (i) of the first subparagraph of paragraph 1 to the public shall be without prejudice to: *(a) any existing rules concerning intellectual property rights which set out limitations on certain uses of the disclosed documents or their content; and*	3. The list of information referred to in paragraph 2 **shall be without prejudice to any sectoral Union law**. 4. Notwithstanding paragraphs 2 and 3: *(a) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to in paragraphs 2 and 3;* *(b) information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment, shall nevertheless be made public.* Article 39b Decision on confidentiality 1. The Authority shall: *(a) make public the non-confidential version of the application as submitted by the applicant without delay once that application has been considered valid or admissible;* *(b) proceed, without delay, to a **concrete and individual examination of the confidentiality request** in accordance with this Article;* *(c) inform the applicant in writing of its intention to disclose information and the reasons for that, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority, the applicant may state its views or withdraw its application within two weeks of the date on which it was notified of the Authority's position;* *(d) adopt a reasoned decision on the confidentiality request, taking into account the observations of the applicant, within 10 weeks of the date of receipt of the confidentiality request with respect to applications and without delay in the case of supplementary data and information; notify the applicant of its decision and provide information on the right to submit a confirmatory application in accordance with paragraph 2; and inform the Commission and the Member States, where appropriate, of its decision; and*

	(b) any provisions set out in Union law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules'). The disclosure to the public of the information referred to in point (c) of the first subparagraph of paragraph 1 shall not be considered to be explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules, and the Union shall not be responsible for its use by third parties. The Authority shall ensure that clear undertakings or signed statements are given to that effect by those who access the relevant information prior to its disclosure. 2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities. 3. The Authority shall lay down the practical arrangements for implementing the transparency rules referred to in paragraphs 1, 1a and 2 of this Article, taking into account Articles 39 to 39g and 41. Article 41 <u>Access to documents</u> 1. Notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation, Regulation (EC) No 1049/2001 of the European Parliament and of the Council (1) shall apply to documents held by the Authority. Where environmental information is concerned, Regulation (EC) No 1367/2006 of the European Parliament and of the Council (2) shall also apply. Directive 2003/4/EC of the European Parliament and of the Council (3) shall apply to environmental	*(e) make public any additional data and information for which the confidentiality request has not been accepted as justified at the earliest two weeks after the notification of its decision to the applicant has taken place pursuant to point (d).* Article 39c <u>Review of confidentiality</u> Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential may nevertheless be made public in accordance with point (b) of Article 39(4). Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply mutatis mutandis. Article 39d <u>Obligations with regard to confidentiality</u> 1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application or to a request by the European Parliament, by the Commission or by the Member States for a scientific output, including a scientific opinion, unless otherwise indicated in Union law. 2. The Commission and the Member States shall take the necessary measures so that information received by them under Union law for which confidential treatment has been requested is not made public until a decision on the confidentiality request has been taken by the Authority and has become final. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public. 3. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of information as granted by the Authority in accordance with Articles 39 to 39e. The application shall be considered withdrawn as of the moment the written request to that effect

	information held by Member States, notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation. 2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 by 27 March 2020, ensuring as wide access as possible to documents in its possession. 3. Decisions taken by the Authority pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the EC Treaty respectively.	is received by the competent body that had received the original application. Where the withdrawal of the application takes place before a final decision on the confidentiality request has been adopted by the Authority pursuant to, where appropriate, Article 39b(1) or (2), the Commission, the Member States and the Authority, shall not make public the information for which confidentiality has been requested. 4. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of the obligation of professional secrecy pursuant to Article 339 TFEU. 5. The Authority shall lay down in consultation with the Commission the practical arrangements for implementing the confidentiality rules laid down in Articles 39, 39a, 39b, 39e and in this Article, including arrangements concerning the submission and treatment of confidentiality requests with respect to information to be made public under Article 38, and taking into account Articles 39f and 39g. As regards Article 39b(2), the Authority shall ensure that appropriate separation of tasks is applied for the assessment of confirmatory applications.
Regulations related to biological hazards: **Regulation (EC) No 1069/2009 of laying down health rules as regards animal by-products and derived**	Regulation (EC) 2017/625 Article 85 <u>Transparency</u> 1. Member States shall ensure a high level of transparency on: (a) the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80, namely on: (i) the method and data used to establish these fees or charges; (ii) the amount of the fees or charges, applied to each category of operators and for each category of official controls or other official activities; (iii) the breakdown of the costs, as referred to in Article 81;	There is no mention of confidentiality in the legislation.

products not intended for human consumption ; Regulation (EC) No 852/2004 on the hygiene of foodstuffs; Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin; Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health	(b) the identity of the authorities or bodies responsible for the collection of the fees or charges. 2. Each competent authority shall make available to the public the information referred to in paragraph 1 of this Article for each reference period and the costs to the competent authority for which a fee or charge is due in accordance with point (a) of Article 79(1), Article 79(2) and Article 80. 3. Member States shall consult relevant stakeholders on the general methods used to calculate the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80.	

and plant protection products		
Regulation (EC) No 1831/2003 on additives for use in animal nutrition	Article 18 Transparency and confidentiality 1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002, which shall apply mutatis mutandis. 2. **In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and in this Article, the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential**, accompanied by verifiable justification. The Authority shall assess the confidentiality request submitted by the applicant. 3. In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority **may also grant confidential treatment with respect to the following items of information**, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) the **study plan** for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) of, and Annex I to, this Regulation; and* *(b) specifications of the **impurities** of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.*	See Article 18 in second column

	4. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002. Article 17 Community Register of Feed Additives 1. The Commission shall establish and keep up to date a Community Register of Feed Additives. 2. The Register shall be made available to the public Article 8 Opinion of the Authority 1. The Authority shall give an opinion within six months of receipt of a valid application. This time limit shall be extended whenever the Authority seeks supplementary information from the applicant under paragraph 2. 6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 18(2). Article 13 Modification, suspension and revocation of authorisations 1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out by this Regulation. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.	
	Article 19 Public Access	Article 20 Confidentiality

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food	1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002, which shall apply mutatis mutandis, and with Article 20 of this Regulation. 2. Member States shall process applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001. Article 10 Opinion of the Authority 1. The Authority shall give an opinion within six months of the receipt of a valid application, as to whether, under the intended conditions of use of the material or article in which it is used, the substance complies with the safety criteria laid down in Article 3 and, where they apply, Article 4. The Authority may extend the said period by a maximum period of a further six months. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States. 6. The Authority shall make its opinion public, after deletion of any information identified as confidential, in accordance with Article 20.	1. **In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002** and in this Article: *(a) the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification; and* *(b) the Authority shall assess the confidentiality request submitted by the applicant.* 2. **In addition** to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, **the Authority may also grant confidential treatment with respect to the following items of information**, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) any information provided in **detailed descriptions of starting substances and mixtures** used to manufacture the substance subject to the authorisation, the composition of mixtures, materials or articles in which the applicant intends to use that substance, the manufacturing methods of those mixtures, materials or articles, impurities, and migration testing results, except for information which is relevant to the assessment of safety;* *(b) the **trademark** under which the substance shall be marketed as well as the tradename of the mixtures, material or articles in which it shall be used, where applicable; and* *(c) **any other information deemed confidential** within the specific procedural rules referred to in point (n) of Article 5(1) of this Regulation.* 3. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.
Regulation (EC) No 1331/2008 establishing a common authorisation procedure	Article 11 Transparency Where the Commission requests the opinion of the Authority in accordance with Article 3(2) of this Regulation, the Authority shall make public without delay the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with	Article 12 Confidentiality 1. The applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification, upon submission of the application.

for food additives, food enzymes and food flavourings	Articles 38 to 39e of Regulation (EC) No 178/2002. The Authority shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.	2. Where an opinion by the Authority is required in accordance with Article 3(2) of this Regulation, **the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.** 3. **In addition** to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) where applicable, information provided in **detailed descriptions of starting substances and starting preparations** and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety;* *(b) where applicable, **detailed analytical information** on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety.* 4. Where an opinion by the Authority is not required in accordance with Article 3(2) of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 3 of this Article shall apply mutatis mutandis. 5. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.
Regulation (EC) No 1829/2003 on genetically modified food and feed	Article 29 Public access 1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions and opinions from the competent authorities referred to in Article 4 of Directive	Article 30 Confidentiality 1. **In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002** and this Article: *(a) the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification; and*

	2001/18/EC, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002 and taking into account Article 30 of this Regulation. 2. The Authority shall apply Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (1) when handling applications for access to documents held by the Authority. 3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001. Article 28 Community register 1. The Commission shall establish and maintain a Community register of genetically modified food and feed, hereinafter referred to as 'the Register'. 2. The Register shall be made available to the public.	*(b) the Authority shall assess the confidentiality request submitted by the applicant.* 2. **In addition** to the items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) **DNA sequence information**, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and* *(b) **breeding patterns and strategies.*** 3. The use of the detection methods and the reproduction of the reference materials, provided under Articles 5(3) and 17(3) for the purpose of applying this Regulation to GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise. 4. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002. Article 31 Data protection The scientific data and other information in the application dossier required under Article 5(3) and (5) and Article 17(3) and (5) may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used. On the expiry of this 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

Regulation (EU) 2015/2283 on novel foods	Article 23 Transparency and confidentiality 1. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002 and with this Article. 2. The applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification, upon submission of the application. 3. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002. 4. In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food*	Article 23 Transparency and confidentiality 1. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002 and with this Article. 2. The applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification, upon submission of the application. 3. Where the Commission requests the opinion of the Authority in accordance with Article 10(3) and Article 16 of this Regulation, **the Authority shall assess the confidentiality request submitted by the applicant in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002**. 4. **In addition** to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *(a) where applicable, information provided in **detailed descriptions of starting substances and starting preparations** and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety;* *(b) where applicable, **detailed analytical information** on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety.*

	categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety; *(b) where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety.* 5. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16 of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 4 of this Article shall apply mutatis mutandis. 6. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.	5. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16 of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39, 39a and 39d of Regulation (EC) No 178/2002 and paragraph 4 of this Article shall apply mutatis mutandis. 6. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.
Regulation (EC) No 1924/2006 on nutrition and health claims made on foods	There is no mention of transparency or dissemination of data in the legislation.	There is no mention of confidentiality in the legislation.
Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market	Article 10 <u>Public access to the dossiers</u> The Authority shall without delay make the dossiers referred to in Article 8, including any supplementary information supplied by the applicant, available to the public, with the exception of any information to which the rapporteur Member State has granted confidential treatment pursuant to Article 63. Article 16 <u>Public access to the information for renewal</u>	Article 63 <u>Confidentiality</u> 1. An applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification. 2. **<u>Confidential treatment may be granted only with respect to the following items of information</u>**, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree: *a) information referred to in Article 39(2) of* ***<u>Regulation (EC) No 178/2002;</u>***

	The Authority shall assess, without delay, any confidentiality request and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which confidential treatment has been requested and granted by the Authority pursuant to Article 63. The Authority, following consultations with the Member States, shall lay down practical arrangements to ensure the consistency of those assessments.	*(b) the specification of* ***impurity of the active substance*** *and the related* ***methods*** *of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities;* *(c)* ***results of production batches*** *of the active substance including impurities; and* *(d) information on the complete composition of a plant protection product.* 2a. Where the Authority assesses confidentiality requests under this Regulation, the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and paragraph 2 of this Article shall apply. 2b. Where Member States assess confidentiality requests under this Regulation, the following requirements and procedures apply: *(a) confidentiality treatment may only be granted with respect to information listed in paragraph 2;* *(b) where the Member State has decided which information is to be treated as confidential, it shall inform the applicant of its decision;* *(c) Member States, the Commission and the Authority shall take the necessary measures so that information for which confidential treatment has been granted is not made public;* *(d) Article 39e of Regulation (EC) No 178/2002 shall apply mutatis mutandis;* *(e) notwithstanding paragraph 2 and points (c) and (d) of this paragraph:* *(i) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Member State may disclose the information referred to in paragraph 2;* *(ii) information which forms part of the conclusions of the scientific outputs delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment shall nevertheless be made public. In that case, Article 39c of Regulation (EC) No 178/2002 shall apply;* *(f) if the applicant withdraws or has withdrawn an application, Member States, the Commission and the Authority shall respect the confidentiality as granted in accordance with this Article. Where the withdrawal of the application takes place before the Member State has decided on the relevant confidentiality request,*

		Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested. 3. This Article is without prejudice to Directive 2003/4/EC (1) and Regulations (EC) No 1049/2001 (2) and (EC) No 1367/2006 (3) of the European Parliament and of the Council.
Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency	Article 209 Rules on transparency To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in mixtures or in articles which is not of a confidential nature. Article 118 Access to information 1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency. 2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person: *(a) details of the full composition of a mixture;* *(b) without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or mixture, including information about its precise use as an intermediate;* *(c) the precise tonnage of the substance or mixture manufactured or placed on the market;*	Article 118 Access to information 1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency. 2. **Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person**: *(a) details of the **full composition of a mixture**;* *(b) without prejudice to Article 7(6) and Article 64(2), the precise **use, function or application** of a substance or mixture, including information about its precise use as an intermediate;* *(c) the precise **tonnage** of the substance or mixture manufactured or placed on the market;* *(d) links between a manufacturer or importer and his distributors or downstream users.* *Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.* 3. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request, by 1 June 2008. 4. Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

	(d) links between a manufacturer or importer and his distributors or downstream users. *Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.* 3. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request, by 1 June 2008. 4. Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively. Article 119 <u>Electronic public access</u> 1. The following information held by the Agency on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e): *(a) without prejudice to paragraph 2(f) and (g) of this Article, the name in the IUPAC nomenclature for substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:* *— hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;* *— hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;* *— hazard class 4.1;* *— hazard class 5.1;*	

	(b) if applicable, the name of the substance as given in EINECS; *(c) the classification and labelling of the substance;* *(d) physicochemical data concerning the substance and on pathways and environmental fate;* *(e) the result of each toxicological and ecotoxicological study;* *(f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;* *(g) the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;* *(h) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.* 2. The following information on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned: *(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;* *(b) the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;* *(c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);* *(d) information, other than that listed in paragraph 1, contained in the safety data sheet;* *(e) the trade name(s) of the substance;*	

	(f) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for non-phase-in substances referred to in paragraph 1(a) of this Article for a period of six years; *(g) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for substances referred to in paragraph 1(a) of this Article that are only used as one or more of the following:* *(i) as an intermediate;* *(ii) in scientific research and development;* *(iii) in product and process orientated research and development.*	
Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures,	Article 42 <u>The classification and labelling inventory</u> 1. The Agency shall establish and maintain a classification and labelling inventory in the form of a database. The information notified pursuant to Article 40(1) shall be included in the inventory, as well as information submitted as part of registrations under Regulation (EC) No 1907/2006. Information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006 shall be publicly accessible. The Agency shall grant access to the other information on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance with Article 29(1) of Regulation (EC) No 1907/2006. It shall grant access to such information to other parties subject to Article 118 of that Regulation. 2. The Agency shall update the inventory when it receives updated information in accordance with Article 40(2) or Article 41. 3. In addition to the information referred to in paragraph 1, the Agency shall, where applicable, include the following information in each entry:	Article 24 <u>Request for use of an alternative chemical name</u> 1. The manufacturer, importer or downstream user of a substance in a mixture may submit a request to the Agency to use an alternative chemical name which refers to that substance in a mixture either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation, where the substance meets the criteria set out in Part 1 of Annex I and where he can demonstrate that disclosure on the label or in the safety data sheet of the chemical identity of that substance puts the confidential nature of his business, in particular his intellectual property rights, at risk. 2. Any request referred to in paragraph 1 of this Article shall be made in the format referred to in Article 111 of Regulation (EC) No 1907/2006 and shall be accompanied by a fee. The level of the fees shall be determined by the Commission in accordance with the regulatory procedure referred to in Article 54(2) of this Regulation. A reduced fee shall be set for SMEs. 3. The Agency may require further information from the manufacturer, importer or downstream user making the request if such information is necessary to take a decision. If the Agency raises no objection within six weeks of the request or the

	(a) whether, in respect of the entry, there is harmonised classification and labelling at Community level by inclusion in Part 3 of Annex VI; *(b) whether, in respect of the entry, it is a joint entry between registrants of the same substance as referred to in Article 11(1) of Regulation (EC) No 1907/2006;* *(c) whether it is an agreed entry of two or more notifiers or registrants in accordance with Article 41;* *(d) whether the entry differs from another entry on the inventory for the same substance.* The information referred to in (a) shall be updated where a decision is taken in accordance with Article 37(5).	receipt of further required information, the use of the requested name shall be deemed to be allowed. 4. If the Agency does not accept the request, the practical arrangements referred to in Article 118(3) of Regulation (EC) No 1907/2006 shall apply. 5. The Agency shall inform competent authorities of the outcome of the request in accordance with paragraph 3 or 4 and provide them with the information submitted by the manufacturer, importer or downstream user. 6. Where new information shows that an alternative chemical name used does not provide sufficient information for necessary health and safety precautions to be taken at the workplace and to ensure that risks from handling the mixture can be controlled, the Agency shall review its decision on the use of that alternative chemical name. The Agency may withdraw its decision or amend it by a decision specifying which alternative chemical name is allowed to be used. If the Agency withdraws or amends its decision, the practical arrangements referred to in Article 118(3) of Regulation (EC) No 1907/2006 shall apply. 7. Where the use of an alternative chemical name has been allowed, but the classification of the substance in a mixture for which the alternative name is used no longer meets the criteria set out in section 1.4.1 of Annex I, the supplier of that substance in a mixture shall use the product identifier for the substance in accordance with Article 18 on the label and in the safety data sheet, and not the alternative chemical name. 8. For substances, whether on their own or in a mixture, where a justification in accordance with Article 10(a)(xi) of Regulation (EC) No 1907/2006 regarding information referred to in Article 119(2)(f) or (g) of that Regulation has been accepted as valid by the Agency, the manufacturer, importer or downstream user may use on the label and in the safety data sheet a name that will be made publicly available over the Internet. For those substances in a mixture for which Article 119(2)(f) or (g) of that Regulation no longer applies, the manufacturer, importer or downstream user may submit a request to the Agency to use an alternative chemical name as provided for in paragraph 1 of this Article.

		9. Where the supplier of a mixture, before 1 June 2015, has demonstrated under Article 15 of Directive 1999/45/EC that the disclosure of the chemical identity of a substance in a mixture puts the confidential nature of his business at risk, he can continue to use the agreed alternative name for the purposes of this Regulation. Article 45 <u>Appointment of bodies responsible for receiving information relating to emergency health response</u> 1. Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24. 2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used: *(a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency;* *(b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed. The information shall not be used for other purposes.* 3. The appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible. 4. The Commission is empowered to adopt delegated acts in accordance with Article 53a amending Annex VIII to further harmonise the information relating to emergency health response and preventative measures, following consultation with

		relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT).
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products	Article 67 Electronic public access 1. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the following up-to-date information held by the Agency or the Commission on that active substance shall be made publicly and easily available free of charge: *(a) where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;* *(b) if applicable, the name as given in the European Inventory of Existing Commercial Chemical Substances;* *(c) the classification and labelling, including whether the active substance meets any of the criteria set out in Article 5(1);* *(d) physicochemical endpoints and data on pathways and environmental fate and behaviour;* *(e) the result of each toxicological and ecotoxicological study;* *(f) acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI;* *(g) the guidance on safe use provided in accordance with Annexes II and III;* *(h) analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.*	Article 66 Confidentiality 1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (37) and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation. 2. The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned. **Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned**: *(a) details of the full composition of a biocidal product;* *(b) the precise tonnage of the active substance or biocidal product manufactured or made available on the market;* *(c) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;* *(d) names and addresses of persons involved in testing on vertebrates.* *However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph.* 3. Notwithstanding paragraph 2, after the authorisation has been granted, **access to the following information shall not in any case be refused**:

	2. From the date on which a biocidal product is authorised, the Agency shall make publicly and easily available free of charge the following up-to-date information: *(a) the terms and conditions of the authorisation;* *(b) the summary of the biocidal product characteristics; and* *(c) analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III.* 3. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on that active substance: *(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives of active substances which are known to be hazardous;* *(b) the study summaries or robust study summaries of studies submitted to support the approval of the active substance;* *(c) information, other than that listed in paragraph 1 of this Article, contained in the safety data sheet;* *(d) the trade name(s) of the substance;* *(e) the assessment report.* 4. From the date on which a biocidal product is authorised, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its	*(a) the name and address of the authorisation holder;* *(b) the name and address of the biocidal product manufacturer;* *(c) the name and address of the active substance manufacturer;* *(d) the content of the active substance or substances in the biocidal product and the name of the biocidal product;* *(e) physical and chemical data concerning the biocidal product;* *(f) any methods for rendering the active substance or biocidal product harmless;* *(g) a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;* *(h) recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;* *(i) safety data sheets;* *(j) methods of analysis referred to in Article 19(1)(c);* *(k) methods of disposal of the product and of its packaging;* *(l) procedures to be followed and measures to be taken in the case of spillage or leakage;* *(m) first aid and medical advice to be given in the case of injury to persons.* 4. Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.

	commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information: *(a) study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation; and* *(b) the assessment report.*	
Regulation (EU) No 517/2014 on fluorinated greenhouse gases	Article 6 <u>Record keeping</u> 1. Operators of equipment which is required to be checked for leaks pursuant to Article 4(1), shall establish and maintain records for each piece of such equipment specifying the following information: *(a) the quantity and type of fluorinated greenhouse gases installed;* *(b) the quantities of fluorinated greenhouse gases added during installation, maintenance or servicing or due to leakage;* *(c) whether the quantities of installed fluorinated greenhouse gases have been recycled or reclaimed, including the name and address of the recycling or reclamation facility and, where applicable, the certificate number;* *(d) the quantity of fluorinated greenhouse gases recovered;* *(e) the identity of the undertaking which installed, serviced, maintained and where applicable repaired or decommissioned the equipment, including, where applicable, the number of its certificate;* *(f) the dates and results of the checks carried out under Article 4(1) to (3);*	Article 19 <u>Reporting on production, import, export, feedstock use and destruction of the substances listed in Annexes I or II</u> 1. By 31 March 2015 and every year thereafter, each producer, importer and exporter that produced, imported or exported one metric tonne or 100 tonnes of CO2 equivalent or more of fluorinated greenhouse gases and gases listed in Annex II during the preceding calendar year shall report to the Commission the data specified in Annex VII on each of those substances for that calendar year. This paragraph shall also apply to undertakings receiving quotas pursuant to Article 18(1). 2. By 31 March 2015 and every year thereafter, each undertaking that destroyed 1 metric tonne or 1 000 tonnes of CO2 equivalent or more of fluorinated greenhouse gases and gases listed in Annex II during the preceding calendar year shall report to the Commission the data specified in Annex VII on each of those substances for that calendar year. 3. By 31 March 2015 and every year thereafter, each undertaking that used 1 000 tonnes of CO2 equivalent or more of fluorinated greenhouse gases as feedstock during the preceding calendar year shall report to the Commission the data specified in Annex VII on each of those substances for that calendar year. 4. By 31 March 2015 and every year thereafter, each undertaking that placed 500 tonnes of CO2 equivalent or more of fluorinated greenhouse gases and gases listed in Annex II contained in products or equipment on the market during the preceding calendar year shall report to the Commission the data specified in Annex VII on each of those substances for that calendar year.

	(g) if the equipment was decommissioned, the measures taken to recover and dispose of the fluorinated greenhouse gases. 2. Unless the records referred to in paragraph 1 are stored in a database set up by the competent authorities of the Member States the following rules apply: *(a) the operators referred to in paragraph 1 shall keep the records referred to in that paragraph for at least five years;* *(b) undertakings carrying out the activities referred to in point (e) of paragraph 1 for operators shall keep copies of the records referred to in paragraph 1 for at least five years.* The records referred to in paragraph 1 shall be made available, on request, to the competent authority of the Member State concerned or to the Commission. To the extent that such records contain environmental information, Directive 2003/4/EC of the European Parliament and of the Council (1) or Regulation (EC) No 1367/2006 of the European Parliament and of the Council (2) shall apply as appropriate. **(Aarhus convention)** 3. For the purpose of Article 11(4), undertakings supplying fluorinated greenhouse gases shall establish records of relevant information on the purchasers of fluorinated greenhouse gases including the following details: *(a) the numbers of certificates of the purchasers; and* *(b) the respective quantities of fluorinated greenhouse gases purchased. The undertakings supplying fluorinated greenhouse gases shall maintain those records for at least five years.*	5. Each importer of equipment that places on the market pre-charged equipment where hydrofluorocarbons contained in this equipment have not been placed on the market prior to the charging of the equipment shall submit to the Commission a verification document issued pursuant to Article 14(2). 6. By 30 June 2015 and every year thereafter, each undertaking which under paragraph 1 reports on the placing on the market 10 000 tonnes of CO2 equivalent or more of hydrofluorocarbons during the preceding calendar year shall, in addition, ensure that the accuracy of the data is verified by an independent auditor. The auditor shall be either: *(a) accredited pursuant to Directive 2003/87/EC; or* *(b) accredited to verify financial statements in accordance with the legislation of the Member State concerned.* The undertaking shall keep the verification report for at least five years. The verification report shall be made available, on request, to the competent authority of the Member State concerned and to the Commission. 7. The Commission may, by means of implementing acts, determine the format and means of submitting the reports referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24. **8. The Commission shall take appropriate measures to protect the confidentiality of the information submitted to it in accordance with this Article.**

	The undertakings supplying fluorinated greenhouse gases shall make such records available, on request, to the competent authority of the Member State concerned or to the Commission. To the extent that the records contain environmental information, Directive 2003/4/EC or Regulation (EC) No 1367/2006 shall apply as appropriate. 4. The Commission may, by means of an implementing act, determine the format of the records referred to in paragraphs 1 and 3 of this Article and specify how they should be established and maintained. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24	
		Article 27 <u>Reporting by undertakings</u> 1. Each year by 31 March, each undertaking shall communicate to the Commission, sending a copy to the competent authority of the Member State concerned, the data listed in paragraphs 2 to 6 for each controlled substance and each new substance listed in Annex II for the previous calendar year. 2. Each producer shall communicate the following data: *(a) its total production of each substance referred to in paragraph 1;* *(b) any production placed on the market or used for the producer's own account within the Community, separately identifying production for feedstock, process agent and other uses;* *(c) any production to meet the essential laboratory and analytical uses in the Community, licensed in accordance with Article 10(6);* *(d) any production authorised under Article 10(8) to satisfy essential laboratory and analytical uses of Parties;* *(e) any increase in production authorised under Article 14(2), (3) and (4) in connection with industrial rationalisation;* *(f) any quantity recycled, reclaimed or destroyed and the technology used for the destruction, including amounts produced and destroyed as by-product as referred to in Article 3(14);* *(g) any stocks;*

		(h) any purchases from and sales to other producers in the Community. 3. Each importer shall communicate for each substance referred to in paragraph 1 the following data: *(a) any quantities released for free circulation in the Community, separately identifying imports for feedstock and process agent uses, for essential laboratory and analytical uses licensed in accordance with Article 10(6), for use in quarantine and preshipment applications and for destruction. Importers which imported controlled substances for destruction shall also communicate the actual final destination or destinations of each of the substances, providing separately for each destination the quantity of each of the substances and the name and address of destruction facility where the substance was delivered;* *(b) any quantities imported under other customs procedures, separately identifying the customs procedure and the designated uses;* *(c) any quantities of used substances referred to in paragraph 1 imported for recycling or reclamation;* *(d) any stocks;* *(e) any purchases from and sales to other undertakings in the Community;* *(f) the exporting country.* 4. Each exporter shall communicate for each substances referred to in paragraph 1 the following data: *(a) any quantities of such substances exported, separately identifying quantities exported to each country of destination and quantities exported for feedstock and process agent uses, essential laboratory and analytical uses, critical uses and for quarantine and preshipment applications;* *(b) any stocks;* *(c) any purchases from and sales to other undertakings in the Community;* *(d) the country of destination.* 5. Each undertaking destroying controlled substances referred to in paragraph 1 and not covered by paragraph 2 shall communicate the following data:

		(a) any quantities of such substances destroyed, including quantities contained in products or equipment; *(b) any stocks of such substances waiting to be destroyed, including quantities contained in products or equipment; (c) technology used for the destruction.* 6. Each undertaking using controlled substances as feedstock or process agents shall communicate the following data: *(a) any quantities of such substances used as feedstock or process agents;* *(b) any stocks of such substances;* *(c) the processes and emissions involved.* 7. Each year before 31 March, each producer or importer which holds a licence under Article 10(6) shall, for each substance for which an authorisation has been received, report to the Commission, sending a copy to the competent authority of the Member State concerned, the nature of the use, the quantities used during the previous year, the quantities held in stock, any quantities recycled, reclaimed or destroyed, and the quantity of products and equipment containing or relying on those substances placed on the Community market and/or exported. **8. The Commission shall take appropriate steps to protect the confidentiality of the information submitted to it.** 9. The format of the reports referred to in paragraphs 1 to 7 shall be established in accordance with the management procedure referred to in Article 25(2). 10. The Commission may amend the reporting requirements laid down in paragraphs 1 to 7. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).
Directive 2009/48/EC	Article 49	Article 49

on the safety of toys	Transparency and confidentiality When the competent authorities of the Member States and the Commission adopt measures under this Directive, the requirements of transparency and confidentiality provided for in Article 16 of Directive 2001/95/EC shall apply.	Transparency and confidentiality When the competent authorities of the Member States and the Commission adopt measures under this Directive, the requirements of transparency and confidentiality provided for in Article 16 of Directive 2001/95/EC shall apply.
Regulation (EC) No 1223/2009 on cosmetic products	Article 21 Access to information for the public Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means. The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.	