**EUROPEAN UNION**

**THE EUROPEAN PARLIAMENT** **THE COUNCIL**

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# 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

**REGULATION (EU) 2025/…**
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 26 November 2025**

# 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

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

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1 OJ C, C/2024/3381, 31.5.2024, ELI: http://data.europa.eu/eli/C/2024/3381/oj.

2 Position of the European Parliament of 21 October 2025 (not yet published in the Official Journal) and decision of the Council of 13 November 2025.

Whereas:

(1) The communication of the Commission of 11 December 2019 on the European Green Deal sets high ambitions for enabling the transition towards a toxic-free environment and zero pollution. The strategy set out in the communication of the Commission of 14 October 2020 entitled ‘Chemicals Strategy for Sustainability Towards a Toxic-Free Environment’ (the ‘Strategy’) is a crucial step towards achieving zero-pollution and introduces the ‘one substance, one assessment’ approach, which aims to improve the efficiency, effectiveness, coherence and transparency of safety assessments of chemicals across Union legal acts. According to the Strategy, ‘safe and sustainable by design’ criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also states that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals and groups of chemicals, to ensure that Union policies address emerging chemical risks as soon as they are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of Union law on chemicals. This Regulation aims to implement those objectives.

(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform on chemicals (the 'common data platform'), to be managed by the European Chemicals Agency (the 'ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals *acquis*. This Regulation should also establish dedicated services within the common data platform and lay down rules on the transparency, accessibility and usability of the data contained in the platform. This Regulation aims to create a common knowledge base on chemicals, which would be available to risk assessors to enable better, complete, consistent and robust scientific assessments of chemicals and their impact and to ensure the best use of existing information for the purpose of the implementation and the development of Union legal acts and thereby contribute to the replacement and reduction of animal testing wherever possible. This Regulation aims to improve the integration of information from different sources and establish a cost-effective digital infrastructure, providing a one-stop-shop for chemicals data and information in the Union that is accessible to the public. This will increase the predictability and transparency of regulatory processes on chemicals and strengthen public trust in the robustness of scientific decision-making. By collecting and making available all data on chemicals in the Union, the data platform will also foster innovation and support the development of advanced tools, methods and models for chemicals assessments.

(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[3], harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data, where possible, and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of those technologies and ensuring that the data and information are transparent, authentic, interoperable and publicly accessible is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of the Union's environmental policy and specifically of its chemicals policy.

[3] Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p. 22, ELI: http://data.europa.eu/eli/dec/2022/591/oj).

(4) In its communication of 19 February 2020 on a European strategy for data, the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation therefore aims to build a data space for chemicals by establishing the common data platform, which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including accessibility, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation therefore aims to increase the availability of data on chemicals by requiring the Commission and the relevant Union agencies, namely the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency (the 'EEA'), the European Food Safety Authority (the 'EFSA'), and the European Medicines Agency (the 'EMA') (together the 'Agencies'), to make data available for incorporation in the common data platform, to promote interoperability of those data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities enabling them to effectively carry out their regulatory and policy development tasks.

(5) This Regulation also aims to implement the principles laid out in the proposal for an Interoperable Europe Act in the chemicals sector by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increasing cross-border data flows for truly European digital services and will broaden the access to publicly available chemicals data for utilisation in other sectors' applications.

(6) Business operators and competent authorities of the Member States are required by various Union legal acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions as well as in different formats. Such fragmentation prevents public authorities, as well as the public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union legal acts on chemicals, and of damaging the public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals are easily findable, accessible, interoperable and reusable, the ECHA should establish the common data platform. The common data platform should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of consistent hazard and risk assessments of chemicals across various Union legal acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution. Authorities should take the necessary measures to protect the confidentiality of data, including, where relevant, by means of physical and cybersecurity measures.

(7) Unless this Regulation specifies otherwise, the common data platform should contain, but not be limited to, all chemicals-related data and information held by the Agencies or the Commission and generated or submitted to them as part of the implementation of Union legal acts listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the Agencies, but also chemicals data on the occurrence of chemicals submitted by Member States to the Agencies or the Commission as well as chemicals data resulting from Member States' implementation activities, in compliance with their reporting obligations. The common data platform should also include chemicals data and information generated as part of Union, national or international programmes or from research activities related to chemicals, where those data and that information are held by the Commission or one of the Agencies. In addition, the common data platform should allow for the incorporation of chemicals data provided on a voluntary basis by Member States and other parties, including national agencies and research institutes, as well as chemicals data resulting from international collaboration with third-country organisations and held by the Commission or one of the Agencies.

(8) While some medicinal products are also chemicals and are relevant to the objectives of this Regulation, the application and use of hazard and risk assessments performed on chemicals under Union law on medicinal products is different from the application and use of hazard and risk assessments performed under the main Union legal acts on chemicals. It is thus appropriate to adopt a stepwise approach and to include, as a first step and taking due account of the administrative burden for the EMA, only the chemicals data which have the highest added value. Under that first step, the data with the highest assessed added value are data on relevant active substances, which are considered to be active substances covered by Union legal acts on medicinal products listed in Annex I, Part 2, and also subject to regulatory processes under other Union legal acts listed in Annex I, Part 1, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment. The specific chemicals data to be included for those relevant active substances should include chemicals data related to environmental risk assessments carried out under Union law on medicinal products for human and veterinary use, non-clinical studies carried out under Union law on medicinal products for human use and maximum residue limit values and the chemicals data underlying their derivation that the EMA holds, as well as specific reference values.

(9) Taking due account of the administrative work for the EMA from the adaptation of such data to an appropriate format for incorporation in the common data platform, it is appropriate to adopt a stepwise approach and to include during the first stage only chemicals data for active substances which are submitted to the EMA in the context of the relevant procedures that are finalised after the entry into force of this Regulation. No later than six years after the entry into force of this Regulation, the EMA should also start incorporating chemicals data on active substances resulting from procedures concluded before the entry into force of this Regulation.

(10) Other chemicals data submitted or generated under Union legal acts on medicinal products could also be of relevance to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data and data related to other substances contained in medicinal products besides active substances. Moreover, a relevant part of the medicinal data is held by the competent authorities of the Member States. No later than 6 years after the entry into force of this Regulation, the Commission should therefore assess, in consultation with Member States and the Agencies, whether such additional data should be included in the common data platform. That assessment should also take into account the relevance, the anticipated added value and the cost-benefit balance of incorporating the additional data.

(11) In order to add data to be made available by the EMA through the common data platform where relevant to support the achievement of the objectives of this Regulation, such as to ensure consistency and the efficient delivery of hazard and risk assessments of chemicals, or if, in view of scientific progress, there is new knowledge about the hazards or risks to the environment or human health, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of amending Article 3(3) of this Regulation.

(12) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council[4], that information should not be included in the common data platform. Likewise, due to the commercial sensitivity of data and information on final cosmetic products, the information related to cosmetic products notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council[5] should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.

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4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

5 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, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

(13) To safeguard the ability of the European Commission, of the Agencies and of the competent authorities of the Member States to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should, in principle, not be included in the common data platform.

(14) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework granting access to the chemicals data contained in the common data platform. That framework should, as a general principle, grant the widest possible access to that chemicals data. It should also specify, where appropriate, who is entitled to access and use that chemicals data, under which conditions, on what basis, and for what purposes. The Authorities entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to fulfil their regulatory duties and tasks effectively, in order to improve the effectiveness, efficiency and consistency of chemicals-related assessments as well as the development of Union chemicals policies. Access to personal data should be limited to what is necessary for the purposes for which those data are processed by the Authorities.

(15) Chemicals data and information generated as a result of obligations laid down by Union legal acts on chemicals could contain commercially sensitive information or be protected under those Union legal acts by confidentiality claims on confidential business information. The public dissemination of such data could affect the commercial interests of private parties. To ensure legal certainty and predictability for duty holders and to protect their legitimate expectations, as well as to ensure the industry's competitiveness on the internal market, the ECHA, as a manager of the common data platform, should grant differentiated access rights to the data and information contained in the common data platform. To that end, the Authorities should have full access to all chemicals data and information contained in the common data platform, also in machine-readable formats, including access to all confidential information and information that is not made available to the public. In contrast, other parties should not have access via the common data platform to confidential data or to data that are not made available to the public under the originating Union act as they could contain commercially sensitive information and the confidentiality of those data has not been assessed. Nevertheless, all parties should maintain the right to request access to any data contained in the common data platform in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council[6].

[6] 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 (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

(16) When using data contained in the common data platform, the Authorities should respect the originator principle. Under that principle, the confidentiality marking of chemicals data as carried out by the originator and as correspondingly indicated by the relevant agency when it provides those data to the common data platform should be respected by the Authorities using those data to perform their regulatory functions or fulfil their tasks. The common data platform should also include terms and conditions of use of the data, including regarding intellectual property rights.

(17) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union legal acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in those Union legal acts should apply only to the disclosure of the data and information submitted or generated in compliance with those legal acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[7], where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the EFSA can disclose information previously considered confidential under that Regulation and the EFSA is required to make public information which was previously considered confidential where that information forms part of the conclusions of scientific outputs of the EFSA which relate to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[8] provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.

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[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

[8] Regulation (EC) No 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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(18) When processing or disclosing personal data contained in the common data platform, the Agencies and the Commission should comply with Regulation (EU) 2018/1725 of the European Parliament and of the Council[9], and the competent authorities of the Member States should comply with Regulation (EU) 2016/679 of the European Parliament and of the Council[10].

(19) Given that the Agencies would be required to store scientific data which includes confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of information system security and that access to confidential data is auditable.

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9 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

10 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

(20) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be provided for by this Regulation. As such, the common data platform should, in addition to providing access to chemicals-related data made available by the Agencies and the Commission, provide access to the chemicals data and information made available through its dedicated services. Those dedicated services should be integrated into the common data platform and consist of the existing Information Platform for Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies, a database of environmental sustainability-related data, a database on chemicals in articles or products, a database on alternatives to substances of concern and a dashboard of indicators on chemicals.

(21) The Commission should adopt an implementation plan identifying datasets of chemicals data to be made accessible via the common data platform and the timeline for their incorporation, informed by the preparatory work of the Commission and the Agencies. The Commission should set up a governance scheme to support and steer the operation and evolution of the data platform, covering the organisation of work structures and coordination between the ECHA and data providers, required rules, formats and vocabularies for data incorporation, and, through an implementation plan, ensuring progress in identifying and incorporating new datasets of chemicals data and services for the common data platform. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from the Agencies and the Commission. The Commission should ensure that all fields of work within the scope of this Regulation are considered by the steering committee. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.

(22) When exercising implementing powers, and in the cases in which Regulation (EU) No 182/2011 of the European Parliament and of the Council[11] does not apply, the Commission should, as part of its preparatory work, take into account the views of Member States.

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[11] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(23) The common data platform should serve the widest possible community and should have the ability to address new use cases, incorporate new relevant datasets of chemicals data, develop new functionalities, and respond to developing tools and applications.

(24) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and the Agencies should act as data providers and make available any such relevant data they have or hold to the ECHA for incorporation in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping of the common data platform's structure, and respect rules on standard formats and controlled vocabularies, where available. The quality control of data and completeness checks of data submissions should be carried out by the originator in accordance with the originating Union act under which the data was submitted or generated.

(25) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available to the public, via the common data platform, chemicals data generated as part of Union, national or international programmes or from research activities other than the data already flowing to the Agencies pursuant to the obligations under the Union legal acts listed in Annex I or to other obligations laid down in this Regulation. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. Member States or other parties, including national agencies, research institutes and third country organisations should be able to offer chemicals data to the Agencies or the Commission using the appropriate standard format, where available. In such cases, it should be for the Agencies or the Commission, as appropriate, to decide whether to host and maintain the data.

(26) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity with regard to the responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host and maintain specific data types and provide those data types to the common data platform. To this end, the EEA should host data on indoor air quality and environmental monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine (‘human biomonitoring data’), and provide those data to the common data platform, and the ECHA should host workplace monitoring data, including occupational human biomonitoring data, and provide those data to the common data platform.

(27) To improve the uptake of academic data and to expand the knowledge base for safety assessments of chemicals and for environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes or, as relevant, national programmes should, in line with the 'as open as possible, as closed as necessary' principle, make available any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and should make available any environmental sustainability-related data on chemicals or materials they collect or generate to the ECHA. For human biomonitoring data constituting personal data, the EEA should specify which type of data should be made available to it, that is to say whether they are anonymised, pseudonymised or identifiable data.

(28) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting human biomonitoring data. It should also host and maintain such human biomonitoring data, with the exception of occupational human biomonitoring data, which should be hosted and maintained by the ECHA.

(29) The Agencies and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring data constituting personal data are a special category of personal data, namely, health data, the Agencies and the Commission should process such data only where the processing is necessary for reasons of substantial public interest, as laid down in Article 10(2)(g) of Regulation (EU) 2018/1725, or for scientific research as laid down in Article 10(2)(j) of that Regulation. This Regulation should lay down the cases in which there is such substantial public interest in processing human biomonitoring data constituting personal data.

(30) Human biomonitoring data collected prior to the entry into force of this Regulation should be included in the common data platform to ensure the completeness and relevance of the human biomonitoring datasets for the purposes of this Regulation. Therefore, the Agencies and the Commission should be able to process any such data gathered prior to the entry into force of this Regulation.

(31) The Agencies and the Commission should be able to process human biomonitoring data constituting personal data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to assess the need for regulatory action and prioritise such action, to monitor the impact of regulatory action, and to support policy making and the development of legislation, including by carrying out scientific research for those purposes. In addition, taking into account their mission and activities, the EEA, the ECHA, the EFSA, EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data to develop health risk and impact indicators, the ECHA, the EFSA and the EMA should be able to process such data to perform regulatory risk assessments and support regulatory risk management, and the EEA, the ECHA, the EFSA and the Commission should be able to process such data in the context of studies under the data generation mechanism established through this Regulation. The EEA and EU-OSHA should also be able to process human biomonitoring data constituting personal data to support regulatory risk assessment and management and the Commission should be able to process such data to perform regulatory risk assessment and management. When processing human biomonitoring data constituting personal data, the Agencies and the Commission should pay particular attention to the need to comply with Article 13 of Regulation (EU) 2018/1725.

(32) In order to ensure that appropriate safeguards are in place to secure the protection of human biomonitoring data constituting personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for incorporation in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans and products. In order to take advantage of the incorporation of various information systems and to ensure that occurrence data on chemicals are made available for use together with the other chemicals data, the ECHA should take over the operation of IPCHEM from the Commission and incorporate IPCHEM in the common data platform as one of its main dedicated services.

(33) In order to prevent any disruption to the current operation and functioning of IPCHEM, the ECHA should incorporate IPCHEM in the common data platform together with the data present in IPCHEM at the time of incorporation. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over the operation of IPCHEM from the Commission and incorporates it into the common data platform, takes over the initial datasets and sets up adequate data flows, it is necessary to allow the ECHA sufficient time to carry out those actions, namely up to 3 years from the date of entry into force of this Regulation.

(34) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union legal acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values that are established or adopted under the Union legal acts listed in Annexes I and II. The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union legal acts for reference values adopted under them. To facilitate easy access of the public to up-to-date reference values, the ECHA should incorporate the repository of reference values in the common data platform as a dedicated service and include in that repository all reference values it has received or retrieved, together with the relevant context data. The ECHA should ensure that those values and those context data are machine readable. The ECHA should also include in the repository of reference values any other reference values it considers relevant and that are generated as part of Union, national or international programmes or from research activities and made available to the ECHA in a standard format where such format is available. For a reference value for the carcinogenic effect of a chemical for which no maximum exposure level can be specified below which no harmful effects on human health are to be expected, the statistical cancer risk associated with that reference value should also be specified, if known.

(35) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operators themselves or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union legal acts listed in Annex I, Part 1. The ECHA should establish and manage a database of study notifications, separate from the common data platform. That database should be used to store information related to those studies and that information should be kept confidential. Authorities and national enforcement authorities should have access to the database while ensuring safe transmission of data contained in it. In order to allow business operators and laboratories sufficient time to prepare study notifications, the obligation to notify studies should start to apply only 22 months after the date of entry into force of this Regulation.

(36) Under Regulation (EC) No 178/2002, business operators and laboratories are obliged to notify to the database of study notifications established and managed by the EFSA the studies they commission to support an application or notification in relation to which Union law contains provisions for the EFSA to provide a scientific output. To avoid overburdening business operators and laboratories, they should therefore not be required to also notify those studies to the database of study notifications established and managed by the ECHA under this Regulation.

(37) To ensure consistency between those two study notification mechanisms, as well as to ensure certainty for business operators that are required to notify studies, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution. In order to respect the confidentiality of relevant elements of study notifications when they are incorporated in the common data platform, where the Commission or one of the Agencies makes the corresponding registration, application, notification or other relevant regulatory dossier available to the ECHA, it should also indicate which elements of the study notification are to be confidential when it is included in the common data platform. Only those elements should be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant regulatory dossier in accordance with the provisions on confidentiality under the originating Union act. In order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases. To avoid uncertainty for business operators resulting from the existence of two databases of study notifications, one managed by the ECHA and one by the EFSA, the ECHA should lay down, in close cooperation with the EFSA and in consultation with stakeholders, practical arrangements to facilitate the implementation of the notification obligation, including details as regards the type of studies requiring notification.

(38) While the obligation to notify studies under this Regulation should apply in the context of all the Union legal acts on chemicals listed in Annex I, Part 1, the various relevant data collection and safety assessment processes under those acts can vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, so as to make it possible to have a centralised and complete overview of the studies being performed to support an application, notification or regulatory dossier intended to be notified or submitted to an Authority, as well as any studies on chemicals on their own or in products, that business operators commission as part of a risk or safety assessment, to ensure compliance under the Union legal acts listed in Annex I. Given that objective and considering the fact that assessment processes under Union legal acts on chemicals listed in Annex I can vary widely, it would be beyond the scope and aims of this Regulation to amend those processes set out under the Union legal acts listed in Annex I by imposing additional conditions for those processes leading to potential consequences on market access not envisaged in those Union legal acts. Consequently, it is not appropriate, in this Regulation, to provide for consequences associated with non-compliance with the obligation to notify studies as those provided for in Article 32b of Regulation (EC) No 178/2002 for non-compliance with the obligation to notify studies under that Regulation.

(39) Nevertheless, to ensure compliance with the obligation to notify studies under this Regulation, and to cater for the specificities of individual assessment processes, if any, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate and dissuasive, since non-compliance with this Regulation could result in less robust risk assessments of chemicals, creating potential risks and consequently adverse effects on human health and the environment.

(40) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to the ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities to help them to check compliance with the obligations laid down in this Regulation.

(41) While Regulation (EC) No 178/2002 also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would impose a disproportionate administrative burden on the ECHA, given the wide scope of the studies that are to be notified under this Regulation.

(42) Under the mechanism for study notifications established by Regulation (EC) No 1907/2006, where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they are first to submit a testing proposal to the ECHA. The ECHA then issues a decision requiring them to perform a study. Such decisions can also be issued as an outcome of a compliance check or substance evaluation under that Regulation. In order to increase the transparency and traceability and to facilitate effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.

(43) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the national agencies, the Commission, the ECHA, the EEA, the EFSA and EU-OSHA and committees referred to in the Union legal acts listed in Annex III to this Regulation and incorporate that database into the common data platform for access by the Authorities. The information on such regulatory processes or activities should include at least the chemical identity and the identification, status and the outcome of the regulatory process or activity, if any. That information should also be made available without delay and kept updated through the assessment process. Once the process or activity has formally started, that information should also be shared publicly on the common data platform.

(44) The use of articles or products containing chemicals could lead to exposure to those chemicals. Knowledge about the presence of chemicals in articles or products is therefore essential to understand the potential risk arising from the use of such articles or products, to steer innovation towards substitution in applications with the highest risk, as well as to provide information as to whether and how such articles and products can be recycled safely. Currently, there are data gaps on the occurrence of hazardous and other harmful chemicals in articles and products on the Union market. In order to enhance the visibility of the available data, the ECHA should establish and manage a database containing data on chemicals in articles or products that have been generated or submitted under Union legal acts listed in Annex V and incorporate it into the common data platform as a dedicated service.

(45) In order to support and promote research and development as regards alternatives to substances of concern, and to promote the uptake of such alternatives, the ECHA should establish and manage a repository with data on alternatives to potential substances of concern, collect data that are made available by the Commission, Agencies and, as the case may be, competent authorities of the Member States, and incorporate that database into the common data platform as a dedicated service. The ECHA should also facilitate the voluntary submission by interested parties of information on alternatives to substances of concern, including information on alternative technologies or on materials not requiring such substances.

(46) The existing project ‘The EU Chemicals Legislation Finder’, managed by the ECHA, makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the support function of the project for business operators, it should be established on a permanent basis and more Union legal acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union legal acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.

(47) In order to ensure that chemicals data are easily findable in the common data platform and that all relevant data on a specific chemical or material are linked, each chemical or material should be identified by a unique technical identifier and, where possible and available, a chemical notation specifying the molecular structure, taking into account any applicable confidentiality requirements. In order to ensure that chemicals data are interoperable and comparable, and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in appropriate, consistent and interoperable formats and use consistent and interoperable controlled vocabularies. Some Union legal acts listed in Annex I set procedures to establish or make data formats available to the public, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union legal acts listed in Annex I, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using formats established by the Organisation for Economic Cooperation and Development ('OECD') or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission procedures. When specifying such formats and controlled vocabularies, the Agencies and Commission should, where relevant, take into account input and contributions from Member States and stakeholders.

(48) The Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, incorporate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. Whenever the Agencies or the Commission establish formats or controlled vocabularies, they should cooperate with each other to ensure their consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.

(49) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository, and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the public.

(50) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the OECD. The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data are being submitted to the ECHA in IUCLID under Union legal acts such as Regulation (EC) No 1907/2006, and Regulations (EC) No 1107/2009[12] and (EU) No 528/2012[13] of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID and IUCLID implements the standard formats agreed at OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union legal acts listed in Annex I when they make the data contained in those dossiers available to the ECHA.

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[12] 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, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).

[13] 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, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

(51) In order to support the uptake of peer-reviewed published research data in regulatory assessments of chemicals and the implementation of the obligation to consider all available data in such assessments, the Commission and the Agencies should promote the development and use of tools and practices facilitating such uptake, including the development and use of reporting standards for such data and tools to search, screen and extract relevant peer-reviewed published research data. Where the Commission or one of the Agencies engages in the development of such tools and practices they should closely cooperate and provide assistance as appropriate. In addition, the Commission should assess whether to collaborate with scientific and academic publishers and operators of databases containing contents of peer-reviewed journals on harmonised reporting and on the use of tools to search, screen and extract peer-reviewed published research data relevant for assessments of chemicals from databases containing contents of peer-reviewed journals. For the purposes of its assessment, the Commission should take into account the work done by the OECD on the generation, reporting and use of peer-reviewed published research data for regulatory assessments.

(52) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for incorporation into the common data platform. Once the Commission has identified the relevant existing datasets of chemicals data on environmental sustainability-related data and has designed the relevant related database functionalities, the ECHA should establish a database of environmental sustainability-related data, collect any data made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, as well as by other parties, if any, and incorporate that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.

(53) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly, in collaboration with the EFSA, the EMA, EU-OSHA and the Commission, develop and regularly update, at least every two years, a framework of indicators and present it in the form of a dashboard. The framework of indicators should, where meaningful and to the extent possible, include an aggregated territory-based risk indicator at appropriate geographical levels to monitor time and spatial trends in the exposure of populations to chemicals, and health risks associated with such exposure. The EFSA, the EMA, EU-OSHA and the Commission should regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should incorporate the dashboard of indicators into the common data platform.

(54) This Regulation should establish an early warning and action system to identify emerging chemical risks and enable early regulatory follow-up to such risks. To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals, draw up an annual summary report and present it to the Authorities. In its work, the EEA should include its own sources and targeted literature searches, and should make use of information from national early warning systems as well as relevant datasets from the EU dataset catalogue established by Regulation (EU) 2025/327 of the European Parliament and of the Council[14]. It should also include relevant information resulting from the related work of the ECHA, the EFSA, EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation (EC) No 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access to the data and the report, and the use thereof, for further action on existing and emerging risks concerning chemicals, groups of chemicals, and cumulative exposure to chemicals. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should deliver the first report only six months after the end of the first calendar year after the entry into force of this Regulation. Based on the risks and warning signals identified in the report, the Authorities should consider taking regulatory, policy or enforcement action and should provide a justification if they decide not to act. Emerging chemical risks identified in the early warning and action system should also be considered a valuable source of information when setting priorities for the strategic planning of Horizon Europe – the Framework Programme for Research and Innovation established by Regulation (EU) 2021/695 of the European Parliament and of the Council[15].

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14 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj).

15 Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj).

(55) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the Union market.

(56) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals and groups of chemicals with the potential to contribute to emerging chemical risks (the 'observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their novelty and disruptive potential that could contribute to an emerging chemical risk. Another criterion for selection should be any higher degree of uncertainty surrounding the chemicals and, due to less regulatory experience regarding them, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of such chemicals by collecting, generating and disseminating reliable information on the properties, uses and market presence of selected chemicals to the public.

(57) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.

(58) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member State or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals and groups of chemicals within its mandate, while maintaining the principle that the burden of proof of compliance with Union chemicals legislation remains on the duty holder, and seeking to avoid duplication with Member State or Union research or implementation programmes. Furthermore, the ECHA should commission such studies on its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union legal acts on chemicals within its mandate and contributing to the development of a Union chemicals policy. Where obtaining a sample of a substance or mixture is a precondition for conducting the scientific studies, the ECHA should be given the necessary sample, including the substance or mixture characterisation where relevant, by the business operator free of charge and upon request. Where the business operator submits a justified confidentiality claim regarding the information it provides on the sample, the ECHA should respect that confidentiality. Where relevant and whenever possible, when commissioning a study, the ECHA should give priority to the use of validated non-animal test methods, using tests on vertebrate animals only as a last resort.

(59) To gather information on the exposure of European citizens to chemicals, to support the effective implementation and evaluation of Union legal acts on chemicals and to contribute to the development of a comprehensive Union chemicals policy, the ECHA and the EFSA, in cooperation with the EEA, should commission a Union-wide human biomonitoring study. The Member States should cooperate with the ECHA, the EFSA and the EEA in the planning and organisation of that study, and should provide the necessary technical assistance and administrative support to the parties contracted by the ECHA or the EFSA to carry out the sampling in order to enable sampling in their territories and to ensure that the samples are sufficiently representative. The human biomonitoring study should adhere to ethical and confidentiality standards. Taking into account the experience gained through that human biomonitoring study, the Commission should assess the appropriateness of requiring regular human biomonitoring studies, as well as the resources necessary for such studies and modalities for involving Member States in such studies. Depending on the outcome of that assessment, the Commission should consider presenting a legislative proposal.

(60) In order to ensure the optimal functioning of this Regulation and to stay abreast of technological and legislative developments, the Commission should carry out a general review of this Regulation and present a report to the European Parliament and the Council, accompanied, if appropriate, by a legislative proposal. The report should assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has achieved its objectives, in particular to allow a better reuse of data across the Union legal acts listed in Annex I, and the appropriateness of resource allocation amongst the Agencies and the Commission.

(61) In order to adjust the content of Annex I, which should list all Union legal acts pursuant to which chemicals data are generated or submitted to the Agencies or the Commission, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annex I by adding new Union legal acts pursuant to which relevant chemicals data and information are generated or submitted, as soon as such Union legal acts enter into force or are revised, unless otherwise provided.

(62) In order to adjust the content of Annex II, which should list relevant reference values resulting from the implementation of Union legal acts listed in Annex I, Part 2, and held by the EMA, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annex II where, taking into account the digitalisation and interoperability of the reference values held by the EMA as well as the values' usefulness for other policy areas and for the implementation of the Union *acquis*, there is a need to list additional reference values.

(63) In order to adjust the content of Annex III, which should list all Union legal acts pursuant to which regulatory processes on chemicals or groups of chemicals are undertaken by competent authorities of the Member States, the Agencies or the Commission, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annex III by adding new Union legal acts pursuant to which relevant regulatory processes on chemicals or groups of chemicals are undertaken by competent authorities of the Member States, the Agencies or the Commission, as soon as such Union legal acts enter into force or are revised, unless otherwise provided.

(64) In order to adjust the content of Annex V, which should list Union legal acts pursuant to which data on chemicals in articles or products are generated or submitted to the Agencies or the Commission, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annex V by adding any new Union legal act pursuant to which data on chemicals in articles or products are generated or submitted, as soon as it enters into force, unless such act contains a provision adding that act to Annex V, any existing Union legal act listed in Annex I which is amended in such a way that data on chemicals in articles or products are generated or submitted, as soon as the respective amending act enters into force, unless the amending act contains a provision adding that act to Annex V, or any existing Union legal act listed in Annex I for which it has become apparent from further verification that data on chemicals in articles or products are generated or submitted pursuant to it.

(65) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[16]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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16 OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

(66) Since the objectives of this Regulation, namely to ensure the efficient delivery of consistent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, in order to achieve a high level of protection of human health and the environment, enable the development and use of safe and sustainable chemicals, ensure the proper functioning of the single market for chemicals, improve the Union's citizens' knowledge about, and trust in, the scientific basis for decisions taken under Union legal acts on chemicals, and to contribute to the replacement and reduction of animal testing wherever possible, cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union-wide common data platform, but can rather, by reason of chemicals data and information being held at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(67) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on 29 January 2024,

HAVE ADOPTED THIS REGULATION:

# Chapter I

# Subject matter, scope and definitions

*Article 1*

*Subject matter and scope*

1. This Regulation aims to ensure the efficient delivery of consistent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, in order to achieve a high level of protection of human health and the environment, enable the development and use of safe and sustainable chemicals, ensure the proper functioning of the single market for chemicals, improve the Union's citizens' knowledge about, and trust in, the scientific basis for the decisions taken under Union legal acts on chemicals, and to contribute to the replacement and reduction of animal testing wherever possible.

2. To achieve the objectives referred to in paragraph 1, this Regulation lays down measures to:

   (a) bring together chemicals data and ensure that such data are easily findable accessible, interoperable and reusable;

   (b) keep records of studies commissioned by business operators in the context of fulfilling their obligations under Union law on chemicals;

(c) establish the widest possible scientific basis for the implementation and development of Union law and policy related to chemicals;

(d) establish an early warning and action system for emerging chemical risks.

3. This Regulation applies to chemicals data as referred to in Article 3(2) and (3).

*Article 2*

*Definitions*

For the purpose of this Regulation, the following definitions apply:

(1) 'Agencies' means the European Chemicals Agency (the 'ECHA'), the European Environment Agency (the 'EEA'), the European Food Safety Authority (the 'EFSA'), the European Medicines Agency (the 'EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');

(2) 'Authorities' means the Commission, the competent authorities of the Member States as referred to in any of the Union legal acts listed in Annexes I or III, and the Agencies, excluding their management boards;

(3) 'duty holder' means a natural or legal person responsible for meeting obligations under the Union legal acts listed in Annex I;

(4) 'business operator' means a duty holder which is a private or public undertaking;

(5) ‘human biomonitoring data’ means data on concentrations of chemicals measured in human matrices such as blood or urine;

(6) ‘reference value’ means an estimate of a maximum exposure level or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to adverse effects of that chemical on human health or the environment are considered acceptable or tolerable;

(7) ‘originator’ means the Commission or the agency or competent authority of a Member State responsible for confidentiality assessments under any Union legal act listed in Annex I;

(8) ‘originating Union act’ means the Union legal act pursuant to which chemicals data and information were generated or submitted;

(9) ‘controlled vocabularies’ means standardised and organised arrangements of words and phrases presented as lists of terms or as a thesaurus, and taxonomies with a hierarchical structure of broader and narrower terms;

(10) ‘chemicals data’ means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physicochemical properties, hazard properties, use, exposure, risk, occurrence, emissions, fate and manufacturing process of chemicals, as well as environmental sustainability-related information on chemicals, including climate change-related information, regulatory process-related information on chemicals, data on alternatives to substances of concern, standard formats, controlled vocabularies, or any information on applicable legal obligations relating to chemicals;

(11) ‘environmental sustainability-related data’ means any data relevant for the environmental sustainability assessment of a chemical or material throughout its entire life cycle, including:

(a) data on resources, including raw materials, water, energy, fossil fuels and land;

(b) data on emissions, including of greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and

(c) data on by-products originating during the chemical’s life cycle that can be used as resources for other production processes, including hydrogen and carbon monoxide;

(12) ‘peer-reviewed published research data’ means any chemicals data derived from scientific studies that are published in peer-reviewed publications and that are not carried out specifically for the purposes of regulatory assessments;

(13) ‘personal data’ means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 and as defined in Article 3, point (1), of Regulation (EU) 2018/1725;

(14) ‘processing’ means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 and as defined in Article 3, point (3), of Regulation (EU) 2018/1725;

(15) ‘data controller’ means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of Regulation (EU) 2018/1725;

(16) ‘data processor’ means a processor as defined in Article 4, point (8), of Regulation (EU) 2016/679, and as defined in Article 3, point (12), of Regulation (EU) 2018/1725;

(17) ‘interoperability’ means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions;

(18) ‘the public’ means one or more natural or legal persons, and associations, organisations or groups of such persons.

# Chapter II

# Information systems and platforms

*Article 3*

*Common data platform on chemicals*

1. The ECHA shall establish and manage a common data platform on chemicals (the 'common data platform').

2. The common data platform shall provide access to all chemicals data:

   (a) generated or submitted as part of the implementation of the Union legal acts listed in Annex I and held by the Agencies or the Commission;

   (b) generated as part of Union, national or international programmes or from research activities in the field of chemicals and held by the ECHA, the EEA, the EFSA, EU-OSHA or the Commission;

   (c) provided on a voluntary basis by Member States or other parties, including national agencies, research institutes and third-country organisations, and held or accepted by the ECHA, the EEA, the EFSA, EU-OSHA or the Commission.

3. By way of derogation from paragraph 2, the common data platform shall provide access to chemicals data related to human and veterinary medicinal products as part of the implementation of the Union legal acts listed in Annex I, Part 2, only if such data:

(a) are held by the EMA; and

(b) relate to active substances:

(i) that are subject to regulatory processes under other Union legal acts listed in Annex I, Part 1; or

(ii) that have particular persistent, bio-accumulative and toxic properties; or

(iii) for which a high level of residues has been identified in the environment; and

(c) fall into at least one of the following categories:

(i) non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council[17] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[18]; or

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[17] 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, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

[18] 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, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

(ii) data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council[19]; or

(iii) maximum residue levels and the data from which they were derived, compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council[20].

4. The Commission is empowered to adopt delegated acts in accordance with Article 28 to amend:

(a) paragraph 3, point (b), of this Article, by adding chemicals data relating to substances contained in medicinal products other than active substances or relating to active substances contained in medicinal products with properties other than those referred to in paragraph 3, point (b) (i) and (ii), of this Article, where relevant to the objectives of this Regulation or if, in view of scientific progress, there is new knowledge about the hazards or risks to the environment or human health;

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[19] 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, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

[20] 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, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

(b) paragraph 3, point (c), of this Article, by adding new categories of data types relevant to the objectives of this Regulation or, if, in view of scientific progress, there are new data on the hazard or risk to the environment or human health.

5. The following information shall not be included in the common data platform:

(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008;

(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009.

6. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required to be included pursuant to Article 10.

7. The ECHA shall ensure that each chemical or material for which chemicals data are hosted on the common data platform is identified by a unique technical identifier that links all chemicals data on that chemical or material, and, where possible and available, by specifying its molecular structure by means of a chemical notation, without prejudice to any confidentiality requirements in the originating Union act.

8. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:

(a) the Information Platform for Chemical Monitoring ('IPCHEM'), referred to in Article 7;

(b) the repository of reference values, referred to in Article 8;

(c) the Database of Study Notifications, referred to in Article 9;

(d) the database containing information on regulatory processes, referred to in Article 10;

(e) the database containing data on chemicals in articles or products, referred to in Article 11;

(f) the database containing data on alternatives to substances of concern, referred to in Article 12;

(g) the database containing information on obligations under Union law on chemicals, referred to in Article 13;

(h) the repository of standard formats and controlled vocabularies, referred to in Article 14;

(i) the database of environmental sustainability-related data, referred to in Article 15.

The common data platform shall contain appropriate background and explanatory information in order to make it easier for the Authorities and the public to use those data in an informed manner.

9. The Authorities and the public shall, in accordance with Article 19, have easy access, free of charge, to the data contained in the common data platform, as well as to any related context data as referred to in Article 4(5), point (c). Where the data were generated by the Authorities, the context data shall include an indication to that effect.

10. Article 20 shall apply to the use of the data contained in the common data platform by the Authorities.

11. The data contained in the common data platform shall be made available in standard format, and through controlled vocabularies, where available.

12. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks arising from the storage of chemicals data in the common data platform. The relevant Agencies shall take measures in cooperation with the ECHA to ensure that chemicals data are transmitted securely to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.

13. The Commission or Agencies under whose authority chemicals data are included in the common data platform shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001.

14. The common data platform and its dedicated services shall be established by … [three years from the date of entry into force of this Regulation], unless specified otherwise.

By … [three years from the date of entry into force of this Regulation] the common data platform shall contain at least the datasets as set out in Annex IV.

Other relevant datasets, including chemicals data generated or submitted before … [date of entry into force of this Regulation], shall be incorporated progressively into the common data platform by … [ten years from the date of entry into force of this Regulation] in accordance with the implementation plan referred to in Article 4(1). Chemicals data related to human and veterinary medicinal products, as specified in paragraph 3, points (a), (b) and (c), of this Article, resulting from procedures that were concluded before … [date of entry into force of this Regulation], shall be incorporated progressively into the common data platform from … [six years from the date of entry into force of this Regulation].

When the ECHA receives chemicals data in accordance with Article 5 belonging to a dataset which has already been incorporated, it shall make those data available through the common data platform within 90 days of receipt.

*Article 4*

*Implementation plan and governance of the common data platform*

1. By … [six months from the date of entry into force of this Regulation] the Commission shall by means of an implementing act adopt an implementation plan identifying datasets of chemicals data for inclusion in the common data platform together with a timeline for their inclusion. Subsequent implementation plans shall be adopted in line with the governance scheme adopted pursuant to paragraph 4.

2. The Commission shall, by means of an implementing act, establish and manage a platform steering committee, which shall include at least one representative from each of the Agencies and as many representatives from the Commission as from all of the Agencies combined.

3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme referred to in paragraph 4.

4. The Commission shall adopt and publish the governance scheme for the common data platform and any revision thereof by means of implementing acts.

   In preparing the governance scheme, the Commission shall take into account the different levels of responsibility of the Commission and the Agencies in the management and operation of the common data platform.

5. The governance scheme for the common data platform shall describe:

(a) the organisation of the main work structures supporting the development and implementation of the common data platform;

(b) the preparation and adoption of implementation plans for the common data platform;

(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;

(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the common data platform;

(e) any other rules or requirements necessary for the operation of the common data platform and the use of the data contained in it, such as the policy regarding data updating, archiving and deletion and the terms and conditions of use;

(f) the operation and transparency obligations of the steering committee itself.

*Article 5*

*Data flows for the purpose of the common data platform*

1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international law, programmes or from research activities corresponding to their mandate and to the type of data they already hold. In addition, Agencies may, in accordance with their mandate, host and maintain chemicals data submitted to them by Member States or other parties, including national agencies, research institutes and third-country organisations.

2. Where the Commission or one of the Agencies holds data or information as referred to in Article 3(2) or (3), it shall make those data available to the ECHA, which shall incorporate them into the common data platform. The Commission and the Agencies shall provide the data or information to the ECHA in a standard format, where available, together with the relevant context data as referred to in Article 4(5), point (c). Where those data are or that information is not made available to the public under the originating Union act, the Commission and the Agencies shall so indicate.

3. The ECHA shall host and maintain occurrence data related to workplace monitoring, including occupational human biomonitoring data.

4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.

5. From … [date of entry into force of this Regulation], researchers or research consortia funded by Union framework programmes or national programmes shall make all human biomonitoring data they collect or generate available to the EEA. The EEA shall host that data. For human biomonitoring data constituting personal data, the EEA shall specify which type of data are to be made available to it.

6. From … [date of entry into force of this Regulation], researchers or research consortia funded by Union framework programmes shall make all environmental sustainability-related data they collect or generate available to the ECHA. The ECHA shall host that data.

7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the chemicals data provided in accordance with paragraph 2 to be incorporated into and published through the common data platform. The ECHA shall provide support to the Authorities and national agencies to facilitate the incorporation of the chemicals data provided in accordance with paragraph 2.

8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data that they have collected or received available to the ECHA without delay once they have performed validity and confidentiality assessments of the data in accordance with applicable rules and once they have incorporated the corresponding dataset into the common data platform.

9. The Authorities and national agencies shall ensure, when making data available to the ECHA, that such data are downloadable, machine readable and interoperable. They shall curate and validate the data in an appropriate manner before providing them to the ECHA.

10. Without prejudice to Article 6(11), the Commission and the Agencies shall act as data controller for any personal data they provide to the ECHA for incorporation into the common data platform.

*Article 6*

*Human biomonitoring data*

1. The EEA shall collect human biomonitoring data generated within the territory of the EEA's member and cooperating countries. In the case of occupational human biomonitoring data, the EEA shall cooperate with the ECHA.

2. By … [three years from the date of entry into force of this Regulation], the Commission shall transfer any human biomonitoring data it holds to the EEA.

3. The EEA shall process human biomonitoring data constituting personal data for the following purposes only:

   (a) assessing the impact of chemicals on human health and the environment;

   (b) monitoring time and spatial trends in exposure;

   (c) developing health risk and impact indicators;

   (d) monitoring the impact of regulatory intervention;

   (e) supporting regulatory risk assessments and regulatory risk management;

(f) supporting policy making and the development of legislation;

(g) facilitating the processing of human biomonitoring data by the Commission, the ECHA, the EFSA, the EMA, and EU-OSHA in accordance with paragraphs 4 to 8.

4. The Commission shall process human biomonitoring data constituting personal data for the following purposes only:

(a) assessing the impact of chemicals on human health and the environment;

(b) monitoring time and spatial trends in exposure;

(c) developing health risk and impact indicators;

(d) monitoring the impact of regulatory intervention;

(e) assessing the need for regulatory action and prioritising such action;

(f) performing regulatory risk assessment and regulatory risk management;

(g) supporting policy making and the development of legislation, including by carrying out scientific research to that effect;

(h) in the context of studies under the data generation mechanism referred to in Article 24 and the human biomonitoring study referred to in Article 25.

5. The ECHA shall process human biomonitoring data constituting personal data for the following purposes only:

(a) assessing the impact of chemicals on human health and the environment;

(b) monitoring time and spatial trends in exposure;

(c) developing health risk and impact indicators;

(d) monitoring the impact of regulatory intervention;

(e) performing regulatory risk assessment and regulatory risk management;

(f) in the context of studies under the data generation mechanism referred to in Article 24 and the human biomonitoring study referred to in Article 25;

(g) assessing the need for regulatory action and prioritising such action;

(h) supporting policy making and the development of legislation, including by carrying out scientific research to that effect;

(i) facilitating the processing of human biomonitoring data by the Commission, the EEA, the EFSA, the EMA, and EU-OSHA in accordance with paragraphs 3, 4, 6 and 7.

6. The EFSA shall process human biomonitoring data constituting personal data for the following purposes only:

(a) assessing the impact of chemicals on human health and the environment;

(b) monitoring time and spatial trends in exposure;

(c) developing health risk and impact indicators;

(d) in the context of studies under the data generation mechanism referred to in Article 24 and the human biomonitoring study referred to in Article 25;

(e) performing regulatory risk assessment and supporting regulatory risk management;

(f) assessing the need for regulatory action and prioritising such action;

(g) monitoring the impact of regulatory intervention;

(h) supporting policy making and the development of legislation, including by carrying out scientific research to that effect.

7. The EMA shall process human biomonitoring data constituting personal data for the following purposes only:

(a) assessing the impact of chemicals on human health and the environment;

(b) monitoring time and spatial trends in exposure;

(c) performing regulatory risk assessment and supporting regulatory risk management;

(d) assessing the need for regulatory action and prioritising such action;

(e) monitoring the impact of regulatory intervention;

(f) supporting policy making and the development of legislation, including by carrying out scientific research to that effect.

8. EU-OSHA shall process human biomonitoring data constituting personal data for the following purposes only:

(a) assessing the impact of chemicals on human health and the environment;

(b) monitoring time and spatial trends in exposure;

(c) monitoring the impact of regulatory intervention;

(d) assessing the need for regulatory action and prioritising such action;

(e) supporting regulatory risk assessment and regulatory risk management;

(f) supporting policy making and the development of legislation, including by carrying out scientific research to that effect;

(g) developing health risk and impact indicators.

9. Any processing of human biomonitoring data constituting personal data by the Agencies or the Commission for the purposes referred to in paragraphs 3 to 8 of this Article shall not entail the sharing of such data with third parties other than those within the meaning of Article 4, point (10) of Regulation (EU) 2016/679 and Article 3, point (14) of Regulation (EU) 2018/1725.

10. The EEA and the ECHA shall make human biomonitoring data they hold or host publicly available in anonymised form through the IPCHEM.

11. The Agencies and the Commission shall act as data controller for the human biomonitoring data constituting personal data they hold, host or process for the purposes referred to in paragraphs 3 to 8.

12. The EEA and the ECHA shall determine the storage period for the human biomonitoring data constituting personal data that they hold as well as the criteria used for that purpose, and shall review that period and those criteria.

13. For the purposes of this Article, human biomonitoring data include personal data collected before the entry into force of this Regulation in accordance with relevant data protection rules.

*Article 7*

*Information Platform for Chemical Monitoring*

1. The ECHA shall operate and maintain the IPCHEM containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans and products as part of the common data platform.

2. By … [three years from the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the IPCHEM to the ECHA for incorporation in the common data platform.

3. By … [three years from the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the IPCHEM to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agency's mandate and in accordance with Article 5.

4. After the completion of the transfer referred to in paragraph 3, where the Commission or one of the Agencies hosts or holds occurrence data on chemicals and related chemicals data, it shall make those data available to the ECHA without delay for incorporation in the IPCHEM.

5. The Commission and the Agencies shall cooperate at technical level with the ECHA to enable occurrence data on chemicals and related chemicals data they host or hold to be incorporated into and published on the common data platform.

6. The ECHA shall ensure that the data contained in the IPCHEM are machine readable and downloadable.

*Article 8*

*Repository of reference values*

1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.

2. Without delay, the ECHA shall include any reference value adopted under Union legal acts listed in Annex I in the repository of reference values.

3. For reference values not adopted under Union legal acts listed in Annex I, the Agencies holding or establishing reference values as part of their activities under Union legal acts listed in Annex I, Part 1, or the reference values referred to in Annex II shall make those reference values available to the ECHA without delay, in the standard formats provided for in Article 17, where available, and for incorporation in the repository of reference values.

4. For the purposes of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with the ECHA without delay once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.

5. Without delay, the ECHA shall include in the repository of reference values any reference value it considers relevant that is generated as part of Union, national or international programmes or from research activities and made available to the ECHA in the standard formats as referred to in Article 17, where such a standard format has been developed.

6. The ECHA shall ensure that the data contained in the repository of reference values are machine readable.

*Article 9*

*Database of Study Notifications*

1. By … [22 months from the date of entry into force of this Regulation], the ECHA shall establish a Database of Study Notifications, which it shall manage.

2. The ECHA shall store the chemicals data notified to it in accordance with Article 26 in the Database of Study Notifications.

3. Data contained in the Database of Study Notifications shall be considered confidential and shall not be made public.

4. Without prejudice to paragraph 7 of this Article, where the Commission or any of the Agencies makes available to the ECHA, in accordance with Article 5(2), a registration, application, notification or other relevant regulatory dossier in the context of which a notification was submitted under Article 26, they shall indicate which elements of the study notifications are confidential when incorporated into the common data platform. Only the elements indicated as confidential in the corresponding application, notification or other relevant regulatory dossier, in accordance with the provisions on confidentiality under the originating Union act, shall be indicated as confidential in the study notification when incorporated into the common data platform.

5. Upon receipt by the ECHA, in accordance with Article 5(2), of a registration, application, notification or other relevant regulatory dossier in the context of which a notification was submitted under Article 26, the ECHA shall make the related notification information available to the public through the common data platform, and shall respect the confidentiality of the elements indicated confidential in accordance with paragraph 4 of this Article.

6. Authorities and national enforcement authorities shall have access to the data contained in the Database of Study Notifications before those data are incorporated into the common data platform.

7. When the EFSA receives an application under Regulation (EC) No 178/2002 and has decided on the disclosure of the studies accompanying that application in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002, it shall make the data that are contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 and that correspond to that application available to the ECHA for incorporation in the common data platform.

8. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 26 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively, and shall facilitate the traceability of the studies notified to their respective databases.

*Article 10*

*Information on regulatory processes on chemicals*

1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes and activities on individual chemicals or groups of chemicals that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States, the national agencies or the Union institutions, the ECHA, the EEA, the EFSA, EU-OSHA or committees referred to in the Union legal acts listed in Annex III.

2. Where competent authorities of the Member States as referred to in any of the Union legal acts listed in Annex III hold information as referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union legal act listed in Annex III without delay. For each regulatory process or activity, at least the following information shall be included:

(a) the chemical identity;

(b) the Union legal act and the regulatory process in the context of which the activity takes place;

(c) the person or body responsible for the regulatory process or activity;

(d) the status of the regulatory process or activity;

(e) the outcome of the regulatory process or activity, including, where applicable, any reports or opinions adopted;

(f) where applicable, the intended start date of the regulatory process or activity, and the date of completion and latest progress update.

3. Where the ECHA, the EEA, the EFSA, EU-OSHA or the Commission hold information as referred to in paragraph 1, they shall make that information available to the ECHA for incorporation in the common data platform in the standard formats provided for in Article 17 without delay and, where relevant, once the agency responsible or the Commission has carried out a validity assessment. When making that information available, at least the following information shall be included for each regulatory process or activity:

(a) the chemical identity;

(b) the Union legal act and the regulatory process in the context of which the activity takes place;

(c) the person or body responsible for the regulatory process or activity;

(d) the status of the regulatory process or activity;

(e) the outcome of the regulatory process or activity, including, where applicable, any reports or opinions adopted;

(f) where applicable, the intended start date of the regulatory process or activity, and the date of completion and latest progress update.

4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or activity shall be made available to the public once that process or activity has formally started.

*Article 11*

*Data on chemicals in articles or products*

1. The ECHA shall establish and manage, as part of the common data platform, a database containing data on chemicals in articles or products generated or submitted as part of the implementation of Union legal acts listed in Annex V. The Commission shall design relevant related database functionalities.

2. Where the Commission or one of the Agencies holds the data referred to in paragraph 1 of this Article, it shall make those data available to the ECHA for incorporation in the common data platform in the standard formats as referred to in Article 17, where available, without delay and, where relevant, once the agency responsible or the Commission has performed the validity assessment.

3. Where competent authorities of the Member States hold the data referred to in paragraph 1 of this Article, they may make those data available in the standard formats as referred to in Article 17, where available, to the agency responsible under the relevant Union legal act listed in Annex V, or to the ECHA in the absence of such agency, which may host the data.

4. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable data on chemicals in articles or products to be incorporated into the database referred to in paragraph 1.

*Article 12*

*Data on alternatives to substances of concern*

1. The ECHA shall establish and manage, as part of the common data platform, a database containing data on alternatives to substances of concern as defined in Article 2, point 27 of Regulation (EU) 2024/1781 of the European Parliament and of the Council[21] and to substances that meet the criteria for classification in hazard classes referred to in Article 2, point (27)(b), of that Regulation. Those data shall include data on alternative technologies or materials that do not require such substances.

2. Where the Commission or one of the Agencies holds data as referred to in paragraph 1, it shall make those data available to the ECHA for incorporation in the common data platform.

3. Where competent authorities of the Member States hold data as referred to in paragraph 1 of this Article, they may make those data available in the standard formats as referred to in Article 17, where available, to the agency responsible under the relevant Union legal act listed in Annex I or, in the absence of such agency, to the ECHA, which may host the data.

4. The ECHA shall facilitate the voluntary submission by interested parties of data as referred to in paragraph 1.

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[21] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1781/oj).

*Article 13*

*Information on the obligations under Union legal acts on chemicals*

1. The ECHA shall establish and manage, as part of the common data platform, a database containing information on the provisions and legal obligations applicable to chemicals under the Union legal acts listed in Annex I, Part 1.

2. The ECHA shall update the information in the database referred to in paragraph 1 of this Article on a regular basis at least annually, and in accordance with the governance scheme referred to in Article 4(3).

*Article 14*

*Repository of standard formats and controlled vocabularies*

1. The ECHA shall establish and manage, as part of the common data platform, a repository of standard formats and controlled vocabularies.

2. Where standard data formats are established under the Union legal acts listed in Annex I, the ECHA shall include them in the common data platform.

3. Where the Commission or one of the Agencies specifies a standard format or controlled vocabulary in accordance with Articles 17 or 18, it shall make it available to the ECHA without delay for incorporation in the common data platform.

*Article 15*

*Database of environmental sustainability-related data*

1. By … [six years from the date of entry into force of this Regulation], the ECHA shall establish, as part of the common data platform, a database that contains environmental sustainability-related data and that has functionalities designed in accordance with paragraph 4, which it shall manage.

2. Where the Commission or one of the Agencies hosts or holds environmental sustainability-related data, it shall make those data available to the ECHA without delay for incorporation in the database of environmental sustainability-related data once the Commission or the agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. In addition, Member States or other parties, including national agencies, research institutes and third country organisations may submit environmental sustainability-related data to the ECHA. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable such data to be incorporated into the database of environmental sustainability-related data. The ECHA shall provide the necessary support to the Commission and the Agencies to facilitate the incorporation of such data.

3. Where, pursuant to Article 5(6), researchers or research consortia funded by Union framework programmes make any environmental sustainability-related data on chemicals or materials they collect or generate available to the ECHA, the ECHA shall incorporate those data into the database of environmental sustainability-related data.

4. By … [three years from the date of entry into force of this Regulation], the Commission shall, in consultation with the Member States, design database functionalities and identify existing datasets of chemicals data on environmental sustainability-related data other than data as referred to in paragraph 2. Such data shall be hosted and maintained by the ECHA.

*Article 16*

*Uptake of peer-reviewed published research data*

1. The Commission and the Agencies shall promote the development and use of tools and practices facilitating the uptake of peer-reviewed published research data in regulatory chemicals assessments, including practices to develop and use reporting standards for such data, and tools to search, screen and extract relevant peer-reviewed published research data.

2. Where the Commission or one of the Agencies engages in the development of the tools and practices referred to in paragraph 1, the Commission and the Agencies shall cooperate closely and provide assistance as appropriate.

# Chapter III

# Standard formats and controlled vocabularies

*Article 17*

*Standard formats*

1. Without prejudice to Union provisions on the development or making available of data formats, the Commission and the Agencies shall, where relevant, establish standard formats and software packages for the data referred to in Article 3(2) and (3) falling within their mandate and make them available free of charge through the common data platform.

2. The standard formats shall, to the extent possible:

   (a) avoid the use of proprietary standards;

   (b) re-use existing data formats or parts thereof;

   (c) use OECD or other internationally agreed formats;

   (d) ensure consistency with other relevant data formats;

   (e) ensure interoperability with existing data submission procedures.

3. The standard formats shall be interoperable with the common data platform and be user-friendly.

4. The Authorities or national agencies shall exchange data contained in the common data platform in the relevant standard format.

5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making the relevant parts of dossiers under the following Union legal acts available to the ECHA for incorporation in the common data platform:

(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[22];

(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[23];

(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[24];

(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[25];

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22 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, ELI: http://data.europa.eu/eli/reg/2003/1831/oj).

23 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, ELI: http://data.europa.eu/eli/reg/2004/1935/oj).

24 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, ELI: http://data.europa.eu/eli/reg/2008/1331/oj).

25 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, ELI: http://data.europa.eu/eli/reg/2008/1332/oj).

(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[26];

(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[27];

(g) Regulation (EC) No 1223/2009;

(h) Commission Regulation (EU) No 234/2011[28];

(i) Directive 2009/48/EC of the European Parliament and of the Council;[29]

(j) Regulation (EC) No 1107/2009;

(k) Regulation (EC) No 396/2005 of the European Parliament and of the Council[30].

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26 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, ELI: http://data.europa.eu/eli/reg/2008/1333/oj).

27 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, ELI: http://data.europa.eu/eli/reg/2008/1334/oj).

28 Commission Regulation (EU) No 234/2011 of 10 March 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 64, 11.3.2011, p. 15, ELI: http://data.europa.eu/eli/reg_impl/2011/234/oj).

29 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, ELI: http://data.europa.eu/eli/dir/2009/48/oj).

30 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, ELI: http://data.europa.eu/eli/reg/2005/396/oj).

6. The Commission and the Agencies shall cooperate when establishing standard formats to ensure they are consistent with other relevant formats and are interoperable with the common data platform and existing data submission procedures.

7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence between data formats is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve the divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to resolve the divergence.

8. The Commission shall adopt an implementing act to resolve the divergence referred to in paragraph 7.

*Article 18*

*Controlled vocabularies*

1. The Commission and the Agencies shall establish and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2) and (3), where relevant.

2. The Commission and the Agencies shall prioritise establishing controlled vocabularies for the identification of chemicals and the characterisation of their forms.

3. In establishing controlled vocabularies the Commission and the Agencies shall:

(a) avoid the use of proprietary controlled vocabularies to the extent possible;

(b) re-use existing substance identifiers and controlled vocabularies or parts thereof to the extent possible;

(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;

(d) ensure consistency with other relevant controlled vocabularies including by preparing alignment tables.

4. The controlled vocabularies shall be interoperable with the common data platform.

5. Where controlled vocabularies are established, the Commission and the Agencies shall:

(a) make them available free of charge through the common data platform as open datasets, supporting their re-use;

(b) incorporate them in any submission software or template to be used by duty holders under the Union legal acts listed in Annex I, Part 1 and referred to in Article 3(2); and

(c) use them when exchanging data through the common data platform.

6. The Commission and the Agencies shall cooperate with each other in establishing controlled vocabularies.

7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify, at an early stage, any potential divergence between controlled vocabularies. If a divergence between controlled vocabularies is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve the divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to resolve the divergence.

8. The Commission shall adopt an implementing act to resolve the divergence.

# Chapter IV
# Chemicals data confidentiality and use

*Article 19*

*Access rights and transparency*

1. Without prejudice to Regulation (EC) No 1049/2001, the public shall have access to all the chemicals data contained in the common data platform, except data which are indicated in accordance with Article 5(2) of this Regulation as not being made available to the public under the originating Union act.

2. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which are indicated in accordance with Article 5(2) as not being made available to the public under the originating Union act.

3. The Authorities shall take the necessary measures, including security measures, to ensure that information contained in the common data platform indicated in accordance with Article 5(2) as not being made available to the public under the originating Union act are not made available to the public.

*Article 20*

*Use of chemicals data contained in the common data platform*

1. The Authorities may use the chemicals data contained in the common data platform or in the Database of Study Notifications referred to in Article 9 in the performance of any of their activities, where those activities support the development, implementation or enforcement of Union law and policy.

2. Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders except for the assessment of the completeness of chemicals data submitted by duty holders or where existing provisions provide for the sharing and use of chemicals data under the Union legal acts listed in Annex I.

3. When using chemicals data contained in the common data platform that are indicated in accordance with Article 5(2) as not being made available to the public, the Authorities shall respect that indication and shall not make those data available to the public without the consent of the originator.

# Chapter V

# Monitoring and outlook framework for chemicals

*Article 21*

*Framework of indicators*

1. The EEA and the ECHA shall, in collaboration with the EFSA, the EMA, EU-OSHA and the Commission, and in consultation with the Member States, establish, manage and update as appropriate a framework of indicators to:

(a) monitor chemical pollution throughout a chemical's lifecycle, including emissions, occurrence and fate;

(b) monitor the drivers and impacts of exposure to chemicals; and

(c) measure the effectiveness of Union law on chemicals and the transition towards the production of safe and sustainable chemicals.

2. The framework of indicators shall, where meaningful and to the extent possible, include an aggregated territory-based risk indicator to monitor, as regards the exposure of populations to individual and multiple chemicals:

(a) time and spatial trends in such exposure;

(b) health risks associated with such exposure.

3. The framework of indicators shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available to the public through the common data platform.

*Article 22*

*Early warning and action system for emerging chemical risks*

1. By … [one year from the date of entry into force of this Regulation], the EEA shall establish a Union early warning system for emerging chemical risks, which it shall manage.

2. For the purpose of paragraph 1, the EEA shall compile data on early warning signals, which shall include at least signals from:

(a) the EFSA's emerging risks exchange network;

(b) national early warning systems;

(c) data that the EEA holds, including human biomonitoring data, and data from the framework of indicators as referred to in Article 21;

(d) targeted literature searches performed by the EEA;

(e) data made available by the ECHA, the EFSA, EU-OSHA and the EMA in accordance with paragraph 3;

(f) relevant datasets from the EU dataset catalogue established pursuant to Article 79 of Regulation (EU) 2025/327;

(g) relevant information resulting from the implementation of Union law.

The early warning signals compiled by the EEA pursuant to the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.

3. The ECHA, the EFSA, EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the fields falling within their respective mandates and provide those data to the EEA, including data obtained pursuant to this Regulation.

4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. The first report shall be prepared by … [six months from the end of the first calendar year after the date of entry into force of this Regulation]. The EEA shall present that report to the Authorities. Within nine months of the presentation of each annual report, the Authorities shall consider undertaking regulatory, policy or enforcement actions accordingly, and provide a justification if they decide not to proceed with any action.

5. The EEA shall make all data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for incorporation in the common data platform.

*Article 23*

*Observatory for specific chemicals with the potential to contribute to emerging chemical risks*

1. The ECHA shall establish and manage an observatory for specific chemicals or groups of chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on properties, safety aspects, uses and market presence of those chemicals.

2. The Commission shall select the chemicals for the purposes of the observatory referred to in paragraph 1on the basis of scientific and technical progress and using the signals of the early warning system referred to in Article 22. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.

3. By … [six months from the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the chemicals selected pursuant to paragraph 2 by means of an implementing act. The Commission shall review the list regularly and adopt any revision thereof by the same means. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 29.

4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:

(a) make use of relevant chemicals data incorporated in the common data platform and compile, analyse and curate further available data on selected chemicals or classes of chemicals;

(b) commission studies and, where relevant, use the data generation mechanism established under Article 24 to address knowledge gaps or significant uncertainties;

(c) make compiled data available to the public through the common data platform or other communication and outreach tools, as appropriate, to facilitate the identification of potential further research needs or risk management measures, and to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update those data.

# Chapter VI
# Data generation mechanism

*Article 24*

*Data generation mechanism*

1. Using the best independent resources available, the ECHA may commission scientific studies to:

(a) support the implementation of Union legal acts on chemicals or groups of chemicals listed in Annex I, Part 1, within its mandate;

(b) contribute to supporting, evaluating and developing Union chemicals policy;

(c) investigate further emerging chemical risks identified in the report referred to in Article 22(4).

2. Without prejudice to the obligations on duty holders under the Union legal acts listed in Annex I, Part 1, the Commission, in exceptional circumstances of serious controversy or conflicting results, may request the ECHA to commission scientific studies with the objective of verifying evidence used in its chemicals assessment process. Those studies may have a wider scope than the evidence subject to verification.

3. Upon request by the Commission, the ECHA shall commission scientific studies as referred to in paragraphs 1 and 2.

4. The ECHA shall only commission scientific studies where results cannot be obtained through existing legal provisions or processes under Union legal acts listed in Annex I, Part 1. It shall give priority to the use of validated non-animal methods, with animal testing on vertebrate animals to be used only as a last resort. It shall not commission studies with a predominant research objective.

5. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.

6. The ECHA shall commission scientific studies pursuant to this Article in an open and transparent manner, and only after it has consulted the Member States.

7. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraphs 1, 2 and 3 of this Article and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.

8. The ECHA may request a sample of a substance or mixture necessary for performing the scientific studies referred to in paragraphs 1, 2 and3 from a business operator manufacturing, importing, formulating or placing such substance or mixture on the market. In order to request a sample, the ECHA shall send a draft request to the business operator, explaining the request and specifying the quantity and form of the sample as well as the date by which the sample is to be provided. The ECHA may also ask the business operator to provide substance or mixture characterisation. The ECHA shall inform the business operator of its right to comment within 30 days of receipt of the request. Any such comment received shall be taken into account by the ECHA, which shall confirm or amend the request.

Where the ECHA confirms or amends the request, the business operator shall provide the requested sample free of charge to the ECHA or to any natural or legal person commissioned by the ECHA to perform the scientific study within the deadline set by the ECHA. The business operator may request the ECHA not to disclose certain characterisation information relating to the provided sample if the business operator demonstrates that the disclosure would undermine the protection of its commercial interests.

If the ECHA deems the request to be justified, the information concerned shall be considered confidential and shall not be made available to the public.

9. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.

*Article 25*

*Human biomonitoring study*

1. By … [four years from the date of entry into force of this Regulation], the ECHA and the EFSA, in cooperation with the EEA, shall, in the context of the data generation mechanism referred to in Article 24, commission a Union-wide human biomonitoring study covering all Member States.

2. Member States shall cooperate with the ECHA, the EFSA and the EEA in the planning and organisation of the human biomonitoring study and provide the necessary technical assistance and administrative support to the parties contracted by the ECHA or the EFSA to perform the sampling in order to enable sampling in their territories and to ensure that the samples are sufficiently representative. The human biomonitoring study shall comply with ethical and confidentiality standards.

# Chapter VII
# Notification of studies

*Article 26*

*Notification of studies*

1. Business operators shall notify to the Database of Study Notifications referred to in Article 9 of this Regulation, without delay, any studies that generate chemicals data and that they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that business operators commission as part of a risk or safety assessment under the Union legal acts listed in Annex I, Part 1, to this Regulation. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 of this Regulation studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 of this Regulation the identity of the chemicals concerned, title and scope of the study, the laboratory or testing facility carrying out the study, the intended starting and planned completion dates, and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.

At the time a study is commissioned, business operators shall inform the laboratory or testing facility in which the study is carried out whether the study is subject to the notification obligation under this Article.

3. Laboratories and testing facilities shall, without delay, notify to the Database of Study Notifications referred to in Article 9 of this Regulation any information as referred to in paragraph 2 of this Article related to studies commissioned by business operators to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that they commission as part of a risk or safety assessment under the Union legal acts listed in Annex I, Part 1, to this Regulation. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 of this Regulation studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

4. For the purposes of paragraph 3 of this Article, for each study, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the identity of the chemicals concerned, the title and scope of the study, the intended start and completion date and the name of the business operator that commissioned the study.

5. Paragraphs 3 and 4 shall apply, *mutatis mutandis*, to laboratories and testing facilities located in third countries, insofar as set out in relevant agreements with those third countries.

6. The obligations laid down in paragraphs 1 to 5 shall apply from … [22 months from the date of entry into force of this Regulation].

7. Member States may provide for exemptions from the obligations laid down in paragraphs 1 to 5 of for studies conducted in the interests of defence.

Where a Union legal act listed in Annex I, Part 1, provides that Member States may provide for exemptions from the obligations of that legal act in the interests of national security, Member States may provide for exemptions from the obligations laid down in paragraphs 1 to 5.

8. The ECHA, in close cooperation with the EFSA and in consultation with stakeholders, shall lay down the practical arrangements for implementing this Article.

# Chapter VIII

# Delegated powers and committee procedure

*Article 27*

*Amendment of Annexes I, II, III and V*

1. In order to ensure that Annex I lists all relevant Union legal acts pursuant to which chemicals data are generated or submitted to the Agencies or to the Commission, and in order to keep the common data platform up to date, as soon as new Union legal acts pursuant to which chemicals data are generated or submitted enter into force, or an existing Union legal act is amended to introduce provisions on the generation or submission of data, the Commission shall adopt delegated acts in accordance with Article 28 to amend Annex I by adding those Union legal acts to that Annex, where the Union legal act concerned did not amend Annex I accordingly.

2. The Commission is empowered to adopt delegated acts in accordance with Article 28 to amend Annex II to this Regulation by adding new reference values derived under Union law on medicinal products, taking into account advances in digitalisation and interoperability as well as the values' relevance for other chemicals policy and regulatory areas.

3. In order to ensure that Annex III lists all Union legal acts pursuant to which regulatory processes on chemicals or groups of chemicals are undertaken by competent authorities of the Member States, the ECHA, the EEA, the EFSA, EU-OSHA or the Commission, and in order to keep the common data platform up to date, as soon as new Union legal acts pursuant to which new regulatory processes are established enter into force, or an existing Union legal act is amended to establish new regulatory processes, the Commission shall adopt delegated acts in accordance with Article 28 to amend Annex III by adding those Union legal acts to that Annex, where the Union legal act concerned did not amend Annex III accordingly.

4. The Commission shall adopt delegated acts in accordance with Article 28, where necessary to keep Annex V as complete as possible, and to keep the common data platform up to date, to amend Annex V by adding

   (a) any new Union legal act pursuant to which data on chemicals in articles or products are generated or submitted, as soon as it enters into force, unless it contains a provision adding that act to Annex V;

(b) any existing Union legal act listed in Annex I which is amended in such a way that data on chemicals in articles or products are generated or submitted pursuant to it, as soon as the respective amending act enters into force, unless the amending act contains a provision adding that act to Annex V; or

(c) any existing Union legal act listed in Annex I for which it has become apparent from further verification that data on chemicals in articles or products are generated or submitted pursuant to it.

*Article 28*

*Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 3(4) and Article 27 shall be conferred on the Commission for a period of five years from … [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.

3. The delegation of power referred to in Article 3(4) and Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 3(4) or Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

*Article 29*

*Committee procedure*

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

# Chapter IX
# Enforcement and penalties

*Article 30*

*Cooperation on compliance*

The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance by business operators and laboratories with the obligation to notify studies in accordance with Article 26.

*Article 31*

*Penalties for non-compliance*

1. Member States shall introduce penalties for non-compliance by business operators and laboratories with the obligations laid down in Article 26, and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

2. Member States shall notify the Commission of those rules and of those measures by … [22 months from the date of entry into force of this Regulation], and shall notify the Commission without delay of any subsequent amendment thereto.

# Chapter X

# Review and entry into force

*Article 32*

*Reports and review*

1. No later than … [six years from the date of entry into force of this Regulation], the Commission shall assess and adopt a report on the appropriateness and cost-benefit ratio of including in the common data platform the following chemicals data relating to medicinal products pursuant to Article 3(3):

   (a) new categories of data types;

(b) chemicals data on substances other than active substances;

(c) chemicals data on active substances that do not meet the criteria referred to in Article 3(3), point (b);

(d) chemicals data collected and submitted under Union legal acts listed in Annex I, Part 2, and held by competent authorities of the Member States and not by the Agencies.

2. No later than … [four years from the date of entry into force of this Regulation], and taking into account the work done by the OECD on the generation, reporting and use of peer-reviewed published research data for regulatory assessments, the Commission shall assess whether to collaborate with scientific and academic publishers and operators of databases containing contents of peer-reviewed journals on:

(a) harmonised reporting of peer-reviewed published research data to scientific peer-reviewed journals; and

(b) the use of tools to search, screen and extract peer-reviewed published research data relevant for chemicals assessments from databases containing content from peer-reviewed journals.

3. Within two years of completing the human biomonitoring study referred to in Article 25, the Commission shall assess the appropriateness of requiring the ECHA and the EFSA, in cooperation with the EEA, to commission regular human biomonitoring studies, as well as the resources necessary for such studies and the practical arrangements for involving Member States in such studies.

On the basis of that assessment the Commission may present a legislative proposal.

4. By … [six years from the date of entry into force of this Regulation], the Commission shall carry out a general review of this Regulation and present a report to the European Parliament and to the Council, accompanied, if appropriate, by a legislative proposal. The report shall assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has achieved its objectives, in particular to make it easier to reuse data across the Union legal acts listed in Annex I, and the appropriateness of resource allocation to the Agencies and the Commission.

*Article 33*

*Entry into force*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *The President* |

# ANNEX I

Part 1

Union legal acts referred to in Articles 2, 3, 8, 12, 13, 14, 18, 20, 24, 26 and 27

Each reference to the Union legal acts listed in this Part shall be understood also as a reference to all implementing and delegated acts adopted under the Union legal act concerned, where relevant.

1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater 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 37, 13.2.1993, p. 1)

4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10)

5. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety 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)

6. 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, mutagens or reprotoxic substances 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)

7. 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)

8. 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)

9. 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)

10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1)

11. 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)

12. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)

13. 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)

14. 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)

15. 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)

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 23, 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 70, 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 33, 4.2.2006, p. 1)

23. 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)

24. Regulation (EC) No 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)

25. 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)

26. 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)

27. 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)

28. 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)

29. 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)

30. 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)

31. 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)

32. 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)

33. 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)

34. 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)

35. 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)

36. 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)

37. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10)

38. 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)

39. 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)

40. 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)

41. 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)

42. 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)

43. 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)

44. 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)

45. 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)

46. 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)

47. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial and livestock rearing emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)

48. Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 27, 30.1.2010, p. 1)

49. 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)

50. 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)

51. 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)

52. 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)

53. 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)

54. 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)

55. 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)

56. 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)

57. 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)

58. 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)

59. 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)

60. 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 95, 7.4.2017, p. 1)

61. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)

62. 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)

63. 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).

64. 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)

65. 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)

66. 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)

67. Regulation (EU) 2024/1991 of the European Parliament and of the Council of 24 June 2024 on nature restoration and amending Regulation (EU) 2022/869 (OJ L, 2024/1991, 29.7.2024, p. 1)

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

69. Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (OJ L, 2024/573, 20.2.2024)

70. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)

Part 2

Union legal acts referred to in Article 3(3)

Each reference to the Union legal acts listed in this Part shall be understood also as a reference to all implementing and delegated acts adopted under the Union legal act concerned, where relevant.

1. 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)

2. 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)

3. 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)

4. 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)

# ANNEX II

Reference values referred to in Articles 8 and 27

Reference values to be included in the repository of reference values referred to in Article 8(3)

1. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC, Regulation (EC) No 726/2004 and Regulation (EU) 2019/6.

Those reference values shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.

# ANNEX III

Union legal acts referred to in Articles 10 and 27

Each reference to the Union legal acts listed in this Annex shall be understood also as a reference to all implementing and delegated acts adopted under the Union legal act concerned, where relevant.

1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1)

2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10)

3. 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)

4. 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)

5. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1)

6. 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)

7. 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)

8. 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, mutagens or reprotoxic substances 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)

9. 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)

10. 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 23, 26.1.2005, p. 3)

11. 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)

12. 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)

13. Regulation (EC) No 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)

14. 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)

15. 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)

16. 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)

17. 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)

18. 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)

19. 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)

20. 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)

21. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10)

22. 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)

23. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)

24. 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)

25. 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)

26. 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)

27. 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)

28. 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)

29. 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)

30. 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)

31. 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)

32. 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)

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

34. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)

# ANNEX IV

Datasets to be included at the date of establishment of the common data platform

All chemicals data of the datasets specified in the table below shall be included in the common data platform, within three years of … [the date of entry into force of this Regulation]. This includes data generated or submitted before … [the date of entry into force of this Regulation], unless specified otherwise, as well as data indicated in accordance with Article 5(2) as not being made available to the public under the originating Union act.

| Dataset | Description | Data provider |
|---|---|---|
| Datasets behind dedicated services | Chemicals data covered by: | |
| | IPCHEM (Article 7)<br>This includes all chemicals data contained in the IPCHEM operated by the Commission before transfer of the operation to the ECHA. | Commission |
| | Repository of reference values (Article 8)<br>This includes the following data:<br>(a) regulatory reference values formally adopted under Union legal acts listed in Annex I;<br>(b) scientific reference values available in formal opinions delivered under Union legal acts listed in Annex I, Part 1; and<br>(c) scientific reference values specified in Annex II resulting from relevant procedures that are concluded after the entry into force of this Regulation. | Agencies |
| | Information on regulatory processes on chemicals (Article 10):<br>This includes the following information:<br>(a) information contained in the existing Activities Coordination Tool of the ECHA;<br>(b) information on regulatory processes on chemicals available via the existing Open EFSA of the EFSA; and<br>(c) other information as provided to the ECHA in accordance with Article 10. | Authorities |
| | Information on the obligations under Union legal acts on chemicals (Article 13)<br>This includes information on the obligations under Union legal acts listed in Annex I, including information available through the existing European Union Legislation Finder of the ECHA. | ECHA |
| | Repository of standard formats and controlled vocabularies (Article 14)<br>This includes standard formats and controlled vocabularies available in accordance with Article 14. | Agencies, Commission |

| Dataset | Description | Data provider |
|---|---|---|
| REACH registrations | Registration dossiers submitted under Title II of Regulation (EC) No 1907/2006. | ECHA |
| CLP classification and labelling inventory | – Classification and labelling information submitted in registration dossiers under Title II of Regulation (EC) No 1907/2006 and notified under Title V of Regulation (EC) No 1272/2008; and<br>– Harmonised classification and labelling entries from Annex VI of Regulation (EC) No 1272/2008. | ECHA |
| BPR applications for approval and renewal of active substances and summaries of biocidal product characteristics | – Applications for approval or renewal of approval of biocidal active substances under Chapter II and III of Regulation (EU) No 528/2012 and available in IUCLID; and<br>– Summaries of biocidal product characteristics submitted by applicants for Union authorisation under Chapter VIII of Regulation (EU) No 528/2012 and by applicants under Regulation (EU) No 414/2013 and available in IUCLID. | ECHA |
| DWD applications for inclusion of substances in the European positive lists | Applications to add new entries, and to amend or remove existing entries from the European positive lists of substances in contact with drinking water, submitted by economic operators or relevant authorities under Article 13 of Directive (EU) 2020/2184. | ECHA |

| Dataset | Description | Data provider |
|---|---|---|
| Study notifications | Study notification information once a corresponding registration, application or other relevant regulatory dossier has been submitted and any confidentiality claims assessed:<br>– from the ECHA Database of Study Notifications referred to in Article 9 of this Regulation; and<br>– from the EFSA database referred to in Article 32b of Regulation (EC) No 178/2002 as made available to the ECHA in accordance with Article 9(4) of this Regulation. | ECHA, EFSA |
| Open Food Tox | The EFSA's chemicals hazard database that compiles, in a structured format, EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs. | EFSA |
| Chemical monitoring data | EFSA chemical monitoring data[1] covering multiple regulations under the EFSA's remit and including<br>– chemical monitoring data for pesticides and veterinary medicinal product residues and contaminants data;<br>– the individual measurements of chemicals in food/feed and other materials sampled as part of official controls and enforcement activities;<br>– measurements of chemicals in food and feed received from industry; and<br>– other sources in response to a call for data. | EFSA |

[1] Data collection: chemical monitoring EFSA.

| Dataset | Description | Data provider |
|---|---|---|
| Food chain | Food chain application dossiers containing chemicals data submitted through the E-submission Food Chain Platform by applicants under different regulated product areas under Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004, Regulation (EC) No 1924/2006 and Regulation (EU) 2015/2283 and available in structured formats. | EFSA |
| Applications under PPPR | Dossiers submitted by applicants under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, including the active substance, maximum residue levels and basic substance submission types and available in IUCLID. | EFSA |
| Air quality | Air quality data from a range of sources including<br>– time series of measurements from Europe's air quality monitoring network; and<br>– statistics for air pollutants calculated from officially verified country data as compiled under Directive (EU) 2024/2881<br>but not including EEA-held near-real time information on air quality and associated data products e.g. Air Quality Index. | EEA |
| Waterbase water quality | Time series of concentrations of nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters as reported in accordance with the Watch List for chemicals in surface waters under Directive 2000/60/EC (also identified as WISE-6). | EEA |
| Waterbase Emissions | Time series of emissions of nutrients and hazardous substances to water, reported on yearly riverine input loads to transitional, coastal and marine waters under Directive 2000/60/EC (also identified as WISE-1). | EEA |

| Dataset | Description | Data provider |
|---|---|---|
| Industrial emissions | Chemicals data on releases, transfers and emissions of regulated pollutants as reported by Member States into the European Pollutant Release and Transfer Register under Regulation (EC) No 166/2006 and Directive 2010/75/EU. | EEA |
| NEC emissions inventory | Data on emissions of air pollutants as reported by Member states under Directive (EU) 2016/2284 and contained in the emission inventory. | EEA |
| Human medicinal products data on environmental risk assessment and non-clinical safety data | Environmental risk assessment and non-clinical safety data from marketing authorisation applications for medicinal products for human use under Directive 2001/83/EC and Regulation (EC) No 726/2004. This includes only data on relevant active substances submitted to the EMA in the context of the relevant procedures that are concluded after the entry into force of this Regulation. | EMA |
| Veterinary medicinal products data on environmental risk assessment and on maximum residue limits | Environmental risk assessment data, maximum residue limits (MRLs) values and MRL assessment data from marketing authorisation applications for medicinal products for veterinary use under Regulation (EU) 2019/6 and Regulation (EC) No 470/2009. This includes only data on relevant active substances submitted to the EMA in the context of the relevant procedures that are concluded after the entry into force of this Regulation. | EMA |

# ANNEX V

Union legal acts referred to in Articles 11 and 27

Each reference to the Union legal acts listed in this Annex shall be understood also as a reference to the data on chemicals in articles or products generated or submitted as part of the implementation of the Union legal act concerned.

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)

2. 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)

3. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for setting ecodesign requirements for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)