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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 779 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Delegations will find attached document COM(2023) 779 final.

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2023/0453 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)

{SWD(2023) 855 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Chemicals are everywhere in our daily lives and they play a fundamental role in most of our activities. They form part of virtually every product we use for our well-being, the products we use to protect our health and security, and the innovative solutions to meet new challenges. However, some chemicals can also cause harm to human health and the environment. Certain chemicals can cause cancers, affect the immune, respiratory, endocrine, reproductive and cardiovascular systems, and increase our vulnerability to disease. Exposure to these harmful chemicals is therefore a threat to human health. In addition, chemical pollution of the environment is one of the key drivers putting the earth at risk[1], affecting and amplifying planetary crises such as climate change, degradation of ecosystems and loss of biodiversity. Examples of these effects are the negative effects chemicals have on pollinators, insects, aquatic ecosystems, and on the bird population.

The European Union has developed a comprehensive regulatory framework for chemicals. The aim is to provide a high level of protection of human health and the environment from the adverse effects of harmful chemicals and to support the efficient functioning of the internal market for chemicals while promoting the competitiveness and innovation of EU industry. A fitness check of the most relevant chemicals legislation (excluding REACH)[2] assessed over 40 pieces of legislation. It concluded that overall, the EU chemicals regulatory framework delivers results as intended and is fit for purpose. However, it found a number of significant weaknesses that prevent the framework from achieving its full potential. If not rapidly addressed, the framework will struggle to cope effectively with the risks posed by existing and new chemicals.

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

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

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

[2] Fitness Check of the most relevant chemical legislation (excluding REACH) (europa.eu).

It is essential to assess the environmental impacts generated by chemicals along their entire life cycle in order to conserve our natural resources, protect ecosystems and people, and to live within the limits of our planet. To evaluate several categories of impact, such as climate change and resource use, we need access to robust and high-quality information. Armed with this information, we can guide the design, development and production of chemicals and the products for which they are used that provide a desirable function or service while being safe and sustainable. Moreover, making available information on the sustainability of chemicals could trigger demand for chemicals with lower environmental impacts, which would have a direct benefit for health and the environment.

Building on the findings of the fitness check, the Commission committed in the European Green Deal[3] to present a chemicals strategy for sustainability[4] ('the strategy'). As part of this work, it committed to start using the 'one substance, one assessment' approach to improve the efficiency, effectiveness, coherence and transparency of issuing safety assessments of chemicals across different pieces of EU legislation.

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

– *Initiation of chemicals safety assessments.* This means synchronising and coordinating the initiation or triggering of assessments and assessing groups of substances instead of assessing substances individually, to the extent possible.

– *Attribution of tasks.* This involves a clear allocation of responsibilities to bodies performing assessments, making good use of available expertise and resources, as well as ensuring the good cooperation between the parties involved.

– *Information.* Ensuring that information on chemicals is easily findable, accessible, interoperable, secure, of high quality, and can be shared and reused to ensure that assessors have access to all available data without technical or administrative burden.

– *Methodologies.* The methods used for the assessments are coherent and, to the extent possible, harmonised.

– *Transparency.* Ensuring a high level of transparency in performing assessments, as well as in the underlying scientific data and information on chemicals.

To enable the design, production and use of chemicals that are safe and sustainable by design, and throughout their life cycle, the strategy announced that the Commission would develop criteria for chemicals that are 'safe and sustainable by design'[5]. To that end, a comprehensive assessment of both safety and sustainability throughout the whole life cycle of chemicals is required.

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

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

5 Commission Recommendation of 8.12.2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and material, C(2022) 8854 final.

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

The EU action plan entitled *Towards Zero Pollution for Air, Water and Soil*[6] ('the EU Zero Pollution action plan') contributed to the strategy's objectives by committing to developing an integrated zero pollution monitoring and outlook framework. It also consolidated the roles of the European Environment Agency and the Commission's Joint Research Centre in close collaboration with the European Chemicals Agency, the European Food Safety Authority, the European Maritime Safety Agency and other agencies as the EU's knowledge centres of excellence in the zero pollution monitoring and outlook framework.

In addition, the EU action plan and the proposal for a regulation on establishing a framework for setting ecodesign requirements for sustainable products[7] emphasise the commitment to ensure that chemicals and materials are as safe and sustainable as possible by design and during their life cycle, so that material cycles are non-toxic.

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

– develop a common data platform bringing together chemicals data from multiple sources, including environmental sustainability-related data;

– ensure that information contained in the common data platform is secure, of high quality, findable, accessible, interoperable and re-usable;

– enable the commissioning of testing and monitoring of substances as part of the regulatory framework when further information is considered necessary;

– keep records of studies commissioned or carried out by businesses in a chemicals regulatory context and set up an early warning system for emerging chemical risks.

– establish a monitoring and outlook framework for chemicals

- **Consistency with existing policy provisions in the policy area**

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6 Communications from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil'. COM (2021) 400 final.

7 The EU Action Plan and the Proposal for a Regulation on establishing a framework for setting ecodesign requirements for sustainable products. COM (2022) 142 final.

The proposal complements the body of EU law governing chemicals. In addition, it complements or is consistent with several specific legal provisions under specific chemicals-related legislations.

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

The proposed provisions related to the service under the common data platform on regulatory information will integrate existing practices on disseminating regulatory process information by the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA), notably the Public Activities Coordination Tool[8] and Open EFSA[9]. The provisions are consistent with the proposals made to revise Regulation (EC) No 1272/2008[10] on classification, labelling and packaging of substances and mixtures and the proposal for a directive amending Directive 2000/60/EC[11] establishing a framework for Community action in the field of water policy, Directive 2006/118/EC[12] on the protection of groundwater against pollution and deterioration and Directive 2013/39/EU[13] as regards priority substances in the field of water policy, which oblige authorities to inform the European Chemicals Agency on regulatory processes they intend to start or have started.

The proposed provisions on using standard formats and controlled vocabularies by EU agencies are consistent with and complementary to provisions under:

– Regulation (EC) No 1907/2006[14] concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (Articles 77 and 111);

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8 PACT - Public Activities Coordination Tool - ECHA (europa.eu)

9 Open EFSA (europa.eu)

10 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

11 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ L 327, 22.12.2000, 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 Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy Text with EEA relevance. OJ L 226, 24.8.2013, p. 1

14 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.

– Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products (Articles 76 and 79);

– Commission Implementing Regulation (EU) 2021/428[15] adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009[16] (Articles 1 and 2);

– Regulation (EC) No 178/2002[17] laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Articles 39f) and

– Council Regulation (EEC) No 1210/90[18] on the establishment of the European Environment Agency and the European Environment Information and Observation Network (Annex A).

The proposed provisions on the use by authorities of information contained in the common data platform complement existing reuse provisions. They aim to align with EU policies on data and therefore give consistent and transparent expectations on the reuse of data compiled under different pieces of legislation.

The proposed provisions on the notification of studies commissioned or carried out by business operators are consistent with a similar notification obligation stipulated in Article 32b of Regulation (EC) No 178/2002 for studies commissioned or carried out by business operators to support an application or notification in food-related areas.

The proposed provisions on creating a data generation mechanism build upon Article 32 of Regulation (EC) No 178/2002, which states that the European Food Safety Authority shall commission scientific studies necessary for the performance of its mission.

The proposed provisions on creating a database on environmental sustainability-related information is complementary to Article 19a of Directive (EU) 2022/2464[19] setting the

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15 Commission Implementing Regulation (EU) 2021/428 of 10 March 2021 adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council. OJ L 84 11.3.2021, p. 25 – 26.

16 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.

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

18 Council Regulation (EEC) No 1210/90 of 7 May 1990 on the establishment of the European Environment Agency and the European environment information and observation network. OJ L 120 11.5.1990, p. 1.

reporting requirements needed to understand an undertaking's impacts on sustainability matters, and the information needed to understand how sustainability matters affect the undertakings' development, performance and market position and are relevant to the proposed Ecodesign Regulation[20]. The aim of the Ecodesign Regulation is, among others, to create harmonised reporting obligations for environmental sustainability information along the value chain.

This proposal is closely linked to, and part of the same 'one substance, one assessment' legislative package, as the proposal as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals. That proposed regulation makes targeted amendments to the allocation of tasks under Directive 2011/65/EU[21] on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Regulation (EU) 2019/1021[22] on persistent organic pollutants and Regulation (EU) 2017/745[23] on medical devices. The proposal also amends Regulation (EC) No 401/2009[24] establishing the European Environmental Agency and Regulation (EC) No 178/2002 laying down the general principles and requirements of general food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. The aim is to ensure good cooperation between EU agencies on all aspects affecting coherence and efficiency of assessment of chemicals (such as methodology development, data exchange and solving divergences in scientific output).

This proposal also relates to the proposal for a regulation on the European Chemicals Agency. This may include provisions on methodologies and cooperation between EU agencies.

- **Consistency with other Union policies**

The regulation aims to consolidate the data on chemicals in a central IT infrastructure and to ensure that that information is secure, of high quality, findable, accessible, interoperable and re-usable to the extent possible. Data considered publicly available under related specific Union acts and contained in the infrastructure will be accessible by the public. Member State competent authorities, EU agencies and the European Commission will have access to all data

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19 The Directive (EU) 2022/2464 - Corporate Sustainability Reporting Directive ("CSRD"). OJ L 322, 16.12.2022, p. 15–80.

20 Commission proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC (Ecodesign Regulation). COM (2022) 142 final

21 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 (recast). OJ L 174, 1.7.2011, p. 88

22 Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast). OJ L 169, 25.6.2019, p. 45

23 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

24 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

contained in the infrastructure. This availability of data will ensure the detection of early warning signals on emerging chemical risks and facilitate the generation of further scientific chemicals data when necessary. This should help build up a broad knowledge base and enable more coherent assessments across different pieces of EU legislation to underpin evidence-based, transparent and inclusive policy making. This proposal is therefore consistent with the objective of Better Regulation.

The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and machine readability of the chemicals information collected under EU law on chemicals under the scope of this Regulation, of environmental sustainability-related data for chemicals - including data on resources, emissions and relevant by-products - and of information on early warning signals for emerging chemical risks. It builds on existing legal instruments on data governance, such as the Data Act[16] and Data Governance Act[17]. It lays down specific rules governing data on chemicals and setting conditions for accessing and reusing this data to better protect human health and the environment.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

This proposal has its legal basis in Article 114 of the Treaty on the Functioning of the European Union. The measures laid out in this proposal pursue a better-informed, more robust scientific decision-making in the EU that would allow to achieve a high level of protection of human health and the environment. The common data platform on chemicals will give broader access to and encourage the use by public authorities in the performance of regulatory functions and fulfilment of their missions of data on chemicals in the environment and on the presence and risk of chemicals in humans. In addition, the proposal will improve the functioning and effectiveness of the governance of the internal market for chemicals as the common data platform will provide information on planned, ongoing and completed regulatory processes on chemicals as well as information on legal obligations under Union acts on chemicals. This information will increase predictability for business operators.

• Subsidiarity (for non-exclusive competence)

The aim of providing a high level of protection of human health and the environment and of contributing to coherent safety assessments to that end applies to all EU Member States, though the extent of chemicals risks may vary between countries and regions. The environmental impacts of harmful substances have no boundaries.

In order to address the problem of chemicals data being scattered among different EU agencies, Commission departments and at Member State level the availability of information at EU level needs to be improved. The ultimate objective regarding information availability

and information sharing is to collate all data on chemicals centrally in an accessible location, which by definition requires action at EU level. The same logic applies to the other objectives relating to incomplete knowledge bases: to improve the uptake of peer-reviewed published scientific information, to create a data generation mechanism for the European Chemicals Agency and to create an early warning system for chemical risks.

- **Proportionality**

This initiative does not go beyond what is necessary to achieve the set objectives.

The accompanying staff working document[25] assesses the impacts of the proposed provisions. A more detailed estimate of the impacts of creating the common data platform on chemicals and related actions (such as setting standard formats and controlled vocabularies) in particular is given in the staff working document[26] accompanying the proposal for a regulation as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of on chemicals to the EU agencies.

The proposal does not create any new data requirements. Economic operators and laboratories will experience some administrative burden linked to the requirement to submit a notification when a study is intended to be commissioned or carried out. It has been estimated that it will only take 30 minutes to submit one notification. The information requirements under existing EU chemicals legislation continue to apply. This proposal streamlines information flows and centralises the data collected under current EU legislation. This will make it easier for assessment authorities to find and access information and broaden the evidence base for their existing tasks. In the longer term, this will improve coherence between scientific assessments at EU level and will enable better, more informed and more efficient policy choices. This will have a knock-on benefit for citizens, industry and the environment.

The proposal aims to strike a balance between giving public authorities access to data and allowing them to use that data for the purpose of human health and environmental protection, while preserving business incentives to innovate, and preserve their competitiveness on the internal market by providing operators with comprehensive information and data relevant to fulfilling their obligations and allowing them to monitor developments in chemicals production and use.

- **Choice of the instrument**

The proposed instrument is a legislative proposal for a regulation of the European Parliament and the Council. This regulation will set direct requirements for all operators, EU agencies

[25] SWD (2023) 855
[26] SWD (2023) 850

and bodies within the scope of this Regulation, thus providing the legal certainty and scope needed to enforce a fully integrated market across the EU. A regulation also ensures that the obligations are implemented at the same time and in the same way in all 27 Member States.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

• Ex-post evaluations/fitness checks of existing legislation

The Commission carried out a fitness check of the most relevant pieces of legislation governing chemicals, assessing over 40 pieces of legislation in 2019[27]. It concluded that, overall, the legislation was delivering the results intended and is fit for purpose, but a number of significant weaknesses prevent the legislation from achieving its full potential. It identified shortcomings across pieces of legislation in terms of the coherence of safety assessments, efficiency of the underlying technical and scientific work and the coherence of transparency rules. These shortcomings can lead to inconsistency and incoherence in safety assessments, slow procedures, inefficient use of resources, unnecessary burden, (perceived) lack of transparency and occasional quality issues of scientific advice. It also showed significant potential for streamlining the technical and scientific work through EU agencies that would improve the efficiency of chemicals legislation. It would also improve the quality of assessments and give stakeholders and the general public greater predictability.

This proposal directly tackles the problems and opportunities identified in the fitness check.

• Stakeholder consultations

The Commission published a call for evidence for this initiative on the website 'Have your say'[28] on 19 July 2022. The public and stakeholders were invited to provide feedback by 16 August 2022. In total, the Commission received 68 submissions from the following categories of respondents:

– business associations (35%),

– NGOs (16%),

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

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

– individual companies (15%),

– EU citizens (12%),

– public authorities (9%),

– others (4%),

– non-EU citizens (3%),

– academic/research institutions (3%), and

– trade unions (3%).

The Commission held an extensive discussion with representatives of Member States and EU Agencies at three meetings of the Expert Group on One Substance, One Assessment[29]. The meetings were held on 29 September 2021, 2-3 June 2022 and 30 March 2023.

The Commission also informed and consulted stakeholders during the online information session on One Substance, One Assessment held on 1 June 2022. Around 800 participants attended.

The proposal was underpinned by a study[30], which used a combination of tools and methods to collect views and data from different stakeholder groups. It involved:

– an online questionnaire targeting Member States yielding 15 responses;
– an online questionnaire targeting academia, industry and NGOs, yielding 65 responses;
– 14 interviews conducted with Commission departments and EU agencies;
– three online workshops for all stakeholders on 15 November 2022, 19 January 2023 and 27 February 2023, attended by 44, 72 and 61 participants, respectively.

Feedback on the establishment of a common data platform on chemicals

Generally, the consultation process revealed broad support for creating a common data platform on chemicals. Several public authorities stated that national authorities and EU agencies should make more data available and claimed that public authorities should have unrestricted access to all data in the platform. Industry emphasised the importance of maintaining the confidentiality of information shared and used. NGOs advocated for the general public to have full transparency of data on chemicals. Some NGOs stated that

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29 Register of Commission expert groups and other similar entities (europa.eu)

30 Study on streamlining chemicals data flows, increasing data interoperability, dissemination, re-use, and the use of all available data, and on the establishment of a data generation mechanism for the purpose of safety assessments in the context of the European chemicals regulatory framework (to be published).

obstacles related to intellectual property rights and confidentiality should be removed to enable broader access to and reuse of information.

Feedback on options related to data formats

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

Feedback on controlled vocabularies

The majority of the feedback received related to examples of different pieces of legislation using different terms for the same concept. To remedy this, EU agencies agreed on the benefit of using a controlled vocabulary. Industry associations indicated that stakeholders should be involved in developing controlled vocabularies and they should build on existing initiatives. EU agencies, industry and Member States agreed that it was not possible to harmonise substance identifiers. EU agencies raised the idea to work towards a common set of identifiers, which can be used for all chemicals data sets. Sector-specific identifiers could be used in addition. Data sets should also be linked to the regulatory context in which they were generated, so that regulators could identify the specific substance definition. Several Member States indicated that in addition to substance identifiers, information on the purity of a substance is similarly important. They considered it necessary to find common definitions for 'substance', 'constituent', 'component', 'impurity', 'substance identity', 'intrinsic property' to ensure that different datasets generated under different regulatory frameworks are interoperable. They strongly recommended involving the OECD in this work.

Feedback on transparency and reuse

Academics indicated that it may not be necessary to disseminate more data than is currently made available to the general public. But scientific experts from academia need to have access to more data in order to ensure that the public is protected sufficiently from any harm caused by chemicals. They noted that currently, the main legal obstacles to accessing information are confidential business information and lack of access to full industry study reports. They supported the suggestion to harmonise transparency rules across the chemicals regulatory framework. NGOs called for better data access to enable them to perform analyses and find potentially harmful and under-regulated substances. They suggested limiting confidentiality claims to a minimum and applying fees to prevent default claims.

One NGO highlighted that the system that eventually will be set up must enable independent scientists to scrutinise industry studies, to ensure that adverse effects or indicators of adverse

effects are not overlooked. Today, only summaries of the studies are available. In cases of controversy, it is in the public interest and important to provide access to the raw data for independent parties, on a confidential basis. Industry representatives welcomed the dissemination of assessment reports but highlighted the danger of disclosing proprietary and confidential business information that could undermine competitiveness and innovation. They suggested limiting transparency to chemicals already on the market and ensuring fair sharing of costs involved in generating test data. One industry sector expressed concerns that undifferentiated dissemination of data could facilitate counterfeiting and pose a risk to human health. Industry also suggested using a disclaimer prior to providing access to data in order to clarify the legal situation and ownership and protect against misuse. One company expressed support for the originator principle.

On the subject of the use of information, some data providers expressed concern about how their data will be interpreted or used. While industry generally accepted the need for authorities to use data for legal purposes, they highlighted the obstacles of fair cost-sharing mechanisms, unfair competition, inappropriate use of data, and compromised data generation and sharing. There was a certain perceived risk that data could be used inappropriately, as tests are designed for specific purposes and specific chemicals. One industry association welcomed the suggestion that data reuse should not be used to fill data gaps in regulatory files.

Stakeholder feedback on creating a data generation mechanism

On this aspect, several Member States, business associations, companies, NGOs, and one university voiced different opinions on the scope of a data generation mechanism. The views ranged from using the mechanism 'only in exceptional cases', to 'solve doubts or unclarities in specific dossiers', for 'targeted and specific data requests', to 'broad scope' and 'all testing of chemicals'. The university, several business associations and an individual expert also emphasised the need to avoid overlap with existing systems. Existing data should be evaluated before new data are generated. One EU agency and a Member State emphasised that data generation should be relevant for several Member States. One EU agency, one university and a Member State also stressed the importance of following existing principles and obligations, such as the precautionary principle, the polluter pays principle or specific obligations for companies (such as to monitor the real-life fate and effects of their substances).

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

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

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

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

For the most part, respondents agreed that a study notification requirement would greatly limit the scope to hide study results relevant to a given regulatory process. Industry stakeholders were generally against the proposal to extend the notification mechanism that already exists under general food legislation to the rest of the chemicals sector while NGO and academia respondents were generally in favour.

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

- **Impact assessment**

The fitness check of all chemical legislation (excluding REACH) already assessed and concluded on most of the challenges and risks addressed through this initiative. Moreover, for most of the proposed provisions in this initiative the options were of a more technical or legal implementation nature rather than policy options. While the Commission therefore did not carry out a formal impact assessment for this proposal, the study supporting the initiative did assess impacts - quantitatively or qualitatively - where relevant and possible.

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

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

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

- Trough the extended utility of shared information in the common data platform, this proposal will help minimise potential duplication of efforts and optimise data generation strategies. With an increased volume and transparency of data on chemical properties and supported by adequate context data that enables the responsible use of that chemicals data, compliance with and enforcement of existing obligations should be facilitated.

- Building on integrated access and services the common data platform is expected to provide additional insight into effective risk management measures and to facilitate the search for safe and sustainable alternatives, leading to improvements in the protection of human health and the environment.

- Bringing together chemicals data and being allowed to use it will increase the knowledge base for scientific assessments and opinions, thus improving their robustness. This will in turn increase the acceptance by society of conclusions and regulatory decisions. Knowing through the notification of studies that all studies have been considered in an assessment further strengthens the trust of citizens in regulatory decisions.

- A dedicated service in the common data platform related to information on regulatory processes planned or ongoing by the Commission, EU agencies and Member States will improve the coordination of activities, which in turn will allow better planning for the authorities and agencies involved, thus increasing efficiency. That information will also allow better predictability and planning for industry, facilitating receipt of comprehensive but also consistent input to the activities, where required. It will be easier for industry but also other stakeholders to know when and how to contribute to regulatory processes.

- A dedicated service in the common data platform related to obligations under EU legal acts on chemicals will be very valuable for industry, and in particular for SMEs and microenterprises, to easily get an overview of their legal obligations, which will give them certainty on what exactly their duties are. Acting with such full knowledge in turn supports compliance and correspondingly reduces burden on national authorities.

- The establishment of a monitoring and outlook framework including an early warning and action system for emerging chemical risks will allow to shorten the reaction time between early signals of risks and regulatory measures to reduce those risks, and as such will lead to an improved protection of human health and the environment.

- The establishment of a data generation mechanism allows the commissioning of studies when there are no legal provisions to obtain them. This will contribute to the creation of a complete knowledge base.

The establishment and operation of the platform will not impose any costs on industry. Economic operators will continue to be bound by their existing legal obligations. Economic operators and laboratories will experience some administrative burden linked to the requirement to submit a notification when a study is intended to be commissioned or carried out. Quantified costs associated with the notification obligation are set out in the staff working document[31] accompanying this proposal.

The establishment of the platform will be associated with significant costs for the EU agencies, but they should principally be seen as investment in technical progress within the data economy, enhancing the value of existing and future data. The task requires the adaptation and expansion of existing data structures and IT systems as well as the development of new ones, principally on the ECHA's side, but also on the side of other EU agencies as data source owners who are to prepare datasets for integration in the platform. These costs have been quantified and assessed in detail in cooperation with the agencies concerned. They are set out in the staff working document[32] accompanying the proposal for a regulation as regards the (re-)attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals.

- **Regulatory fitness and simplification**

The proposed centralisation of chemicals data and widening of the knowledge base on chemicals will improve the coherence, efficiency and effectiveness of the legal framework as a whole, and especially of chemical safety assessments.

The proposal will generate added value in terms of improving scientific consistency between different pieces of legislation and the scientific quality and robustness of safety assessments. It will significantly improve transparency and the inclusiveness of the processes to regulate chemicals. Setting standard data formats and controlled vocabularies will also facilitate digitalisation and the interoperability of data and will ensure that data are machine readable.

The initiative is expected to have only a limited impact on small, medium and micro enterprises. The only new requirement for business operators that this initiative proposes to bring in is the obligation to notify when a study is commissioned or carried out. It is estimated that it will take around 30 minutes to submit one notification.

- **Fundamental rights**

The proposal has no implications on the protection of fundamental rights.

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31 SWD (2023) 855
32 SWD (2023) 850

4. BUDGETARY IMPLICATIONS

The budgetary implications of this proposal are covered by the wider assessment of budgetary needs for the one substance, one assessment package. This includes the current proposal and the proposal for a regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, EU 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals. The Commission drew up a financial statement when preparing the second proposal showing the budgetary implications and the human and administrative resources required. The overall package will have budgetary implications for the Commission, the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA) and the European Medicine Agency (EMA) in terms of the human and administrative resources required.

The table below gives an overview of the additional resource needs for the activities covered by the current proposal.

	Full time equivalent staff per year						**Operational costs (in EUR 1 000)**		
	Y1		**Y2**		**Y3**		**Y1**	**Y2**	**Y3**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
ECHA	7	8	9	10	9	10	0	5 076	7 023
EEA	3	2	3	2	3	2	0	766	684
EFSA	0	5	0	5	0	5	670	670	670
EMA	0	3	0	3	0	3	100	100	100
EU OSHA	0	0	0	0	0	0	0	0	0
JRC	0	0	0	0	0	0	180	180	180
SUM	**10**	**18**	**12**	**20**	**12**	**20**	**950**	**6 792**	**8 657**

Y = year; TA = temporary agent; CA = contract agent

5. OTHER ELEMENTS

An implementation and monitoring plan for creating a common data platform is documented in the project initiation document (used also to underpin the assessment of impacts in the accompanying staff working document). It outlines the steps involved, the governance setup and population of the platform by the different data providers with datasets identified for a minimum viable product. The Commission will closely monitor progress through interim outputs until the go-live version of the platform within 36 months after the regulation enters into force. The platform governance envisions regular reporting on its operations including the effectiveness of work on interoperability i.e. integrating individual chemical datasets.

The common data platform itself will enable users to monitor associated activities such as the early warning system and the application of a data generation mechanism. The same applies to chemical indicators, expected to contribute to the 8th environmental action plan monitoring framework[33]. The standing expert group on one substance-one assessment is expected to continuously monitor progress on interoperability, on the reuse of data and on the utility of the common data platform and its products.

- **Detailed explanation of the specific provisions of the proposal**

Chapter I, General Issues, lays out the scope and definitions applicable to this Regulation. The core aim of this Regulation is to increase the effectiveness, efficiency and coherence of chemicals assessments, thus contributing to the protection of human health and the environment. The Regulation targets key actors broadly referred to as authorities. These include the European Commission, the European Agency for Safety and Health at Work ('EU-OSHA'), the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA'), the European Medicines Agency ('EMA'), and Member State authorities.

Chapter II, Information System and Platforms, comprises 11 provisions that provide for the setup by the ECHA of a common data platform on chemicals providing access to chemicals-related data. Such chemicals-related data comprises:

- physico-chemical, hazard, use, exposure safety, risk, occurrence, emissions and manufacturing process-related data and information on chemical substances, on their own, or in mixtures or articles, generated or submitted under EU chemicals legislation;
- Environmental sustainability related data and information, including climate change related information;
- information on legal obligations, academic studies and chemicals-related data not generated in an EU regulatory context but as part of EU, national or international programmes or research activities;
- data and information on reference values;
- data and information from study notifications;
- information related to regulatory processes under the Union acts listed in Annex III to this Regulation, as well as any data on applicable legal obligations under the EU legislation listed in Annex I; and
- data and information supporting the implementation of this Regulation such as standard formats and controlled vocabularies.

[33] 8th Environmental Action Plan (EAP) monitoring framework. COM (2022) 357 final.

The proposal creates an obligation to ensure that chemicals-related data of the type explained above held by these agencies or the Commission is included in the common data platform. Documents relating to authorities' internal work or decision-making processes need not be included in the common data platform, unless explicitly required so.

For medicinal active substances, only data on relevant substances needs to be included. Relevant active substances are substances that are not only covered by medicines legislation, but also have a relevance for other chemicals legislation, or environmental or health policies. These include dual-use active substances 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.

This Chapter provides for a platform steering committee to be set up and for the Commission to decide on a governance scheme for the common data platform to support and steer the platform's operation and evolution. It also defines the data flows that will feed into the common data platform, to enable the ECHA to collect and make data available through the platform. It proposes to streamline monitoring and hazard data on chemicals to ensure that the relevant EU agency hosts the right monitoring and hazard data in line with their field of expertise and mandate. As the collection of human biomonitoring data can mean processing personal data, the proposal includes a provision to authorise the lawful processing of that data by the EEA. The existing IPCHEM will be integrated into the common data platform gradually to prevent any service disruptions.

Seven building blocks making up dedicated services are set up as part of the common data platform. They include an information platform on chemical monitoring, 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 and a database on environmental sustainability-related information, including climate change relevant data. Individual provisions cover each service, including specific obligations applicable to the bodies involved in providing the service.

Chapter III, Data Formats and Controlled Vocabularies, comprises two provisions. These provisions aim to enable users to find the data (discoverability), and for chemicals-related information to be interoperable and accessible. It places obligations on the Commission and EU agencies to specify formats and controlled vocabularies and make them available free of charge on the common data platform on chemicals. It also sets an obligation to resolve any divergence on standard formats or controlled vocabularies between the establishing parties.

Chapter IV, Data use and Confidentiality, comprises two provisions laying down rights for access to information in the common data platform and use rights for authorities to use data in the common data platform. It differentiates access rights to distinguish between rights for authorities and the general public to access information. Authorities may use the data contained in the common data platform. Conditions apply to the use of the data, including the need to respect the confidentiality regime of the originating legislation under which the data was submitted.

Chapter V, Monitoring and Outlook Framework for Chemicals, comprises three independent, yet closely related provisions creating a monitoring framework for chemicals and chemical risks. It places obligations on Union agencies to set up a dashboard of indicators to monitor the impacts of chemical pollution and measure the effectiveness of chemicals legislation. It also places obligations on agencies to help set up and operate an early warning and action

system for emerging chemical risks. It establishes an observatory function compiling and publicly disseminating information on the properties, uses and market presence of selected chemicals, with an initial focus on nanomaterials, covering the previously established European Observatory for Nanomaterials (EUON). It places obligations on the Commission to select relevant chemicals or groups of chemicals and gives the possibility to the ECHA to then use the data in the common data platform and generate new data, as appropriate, including by using the data generation mechanism. The aim of this Chapter is to set out a comprehensive and useful monitoring and outlook framework on chemicals to feed into and underpin actions and policymaking on chemicals.

Chapter VI establishes the 'Data generation mechanism', enabling the ECHA to commission studies in the form of testing or monitoring. The objective is to support the implementation and evaluation of EU chemicals legislation within its mandate and to help support and develop EU chemicals policy. It sets conditions for and qualifiers to the provision to commission scientific studies, including ensuring that they do not duplicate existing studies, maintaining the burden of proof on duty holders under the respective EU legislations, and making it mandatory for the ECHA and the EFSA to cooperate on the planning and commissioning of studies under the current proposal and under Article 32 of Regulation (EC) No 178/2002. The mechanism could feed into regulatory processes where data are lacking, to verify the effectiveness of legal measures and to generate additional data to provide evidence in exceptional cases of serious controversy on a specific substance or file. This will contribute to a more effective and robust knowledge base on chemicals and to building public trust in scientific assessments.

Chapter VII, Notification of Studies, lays out obligations for business operators to notify information on studies to the database of study notifications, part of the common data platform, when they commission studies to fulfil the obligations under legislation listed in Annex I to this Regulation. The obligation is placed both on industry and on the laboratories and testing facilities commissioning or intending to carry out such studies. The ECHA has the task of managing the database of study notifications. Study notification information is only transferred to the common data platform once a corresponding regulatory dossier is submitted where applicable, and once relevant confidentiality assessments have been completed. The aim of this Chapter is to strengthen transparency in the chemicals sector and to ensure that all available data are included in a dossier supporting a regulatory process. As a result, the Authorities can be informed when a study is planned in the context of a regulatory processes under the legislation governing the chemicals industry.

Chapter VIII, Delegated Powers, empowers the Commission to amend the annexes to this Regulation to update the provisions to any new EU legislation of relevance.

Chapter IX, Enforcement, sets out provisions for enforcing the obligations on private parties and lays down provisions for the Member States on reporting and setting penalties.

2023/0453 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN,

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,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Green Deal[34] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability[35] is a crucial delivery of this zero-pollution ambition 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 legislation. According to that 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 sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies

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[34] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM (2019) 640 final.

[35] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM (2020) 667 final,

address emerging chemical risks as soon as these 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 chemicals legislation. This Regulation aims to implement these 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 hazardous 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 data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('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 accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.

(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[36], 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 these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and implementation of a Union environmental policy, and specifically of a chemicals policy.

(4) In its communication of 19 February 2020 on a European strategy for data[37], 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 aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('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 data availability, data infrastructures and governance,

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36 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).

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

interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.

(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act[38] 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 increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications.

(6) Business operators and Members States' competent authorities are required by various Union 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 and in different formats. Such fragmentation prevents public authorities, as well as the general 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 acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.

(7) The common data platform should contain chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission 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 research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.

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

(8) Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform. For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by other Union legislation identified in this Regulation, 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.

(9) These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.

(10) 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[39], that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness 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[40] of the European Parliament and of the Council 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.

(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), 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.

(12) 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 specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and

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[39] 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).

[40] 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).

for which purposes. The Authorities that are 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 effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies.

(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may be protected by confidentiality claims on confidential business information. The public dissemination of such data may affect the commercial interest of private parties. To ensure legal certainty for duty holders and to protect their legitimate expectations, as well as to ensure 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 this end, the Authorities should have full access to all chemicals data and information contained in the common data platform, including access to confidential information, while business operators and the general public should have restricted access to that data and information, which does not include access to confidential information.

(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.

(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union 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 the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[41], where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates 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[42] provides for the possibility for the ECHA to disclose

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41 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 (General Food Law) (OJ L 031 1.2.2002, p. 1).

42 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),

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.

(16) Taking into account 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 security of information systems and that access to confidential data is auditable.

(17) While the ECHA should identify and develop the technical functionalities of the common data platform in stages, certain dedicated services should be defined 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. These 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 on environmental sustainability related data, as well as a dashboard of indicators on chemicals.

(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies[43]. The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. 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 Union agencies and the Commission. 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.

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

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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).

[43] European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023.

(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration 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 to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.

(21) 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, via the common data platform, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.

(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').

(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.

(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council[44]. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health

[44] 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).

and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.

(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration 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 integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.

(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. 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 from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.

(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union 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 acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.

(28) 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 operator itself 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 acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.

(29) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council, 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.

(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, 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 and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, 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.

(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may 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, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, 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 chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.

(33) 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 ECHA should, where relevant,

cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.

(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council 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 lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.

(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and 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 of the European Parliament and of the Council, 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.

(36) 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 Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.

(37) The existing 'The EU Chemicals Legislation Finder'[45] project 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 supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.

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[45] EU Chemicals Legislation Finder - ECHA (europa.eu), database managed by ECHA and funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME).

(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, 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 OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches.

(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate 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 set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, 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.

(40) 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 general public.

(41) 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 Organisation for Economic Cooperation and Development ('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 is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/2009[46] and (EU) No 528/2012[47] 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 the OECD level, it is appropriate and necessary to require the Commission and the

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[46] 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).

[47] 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).

Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .

(42) 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 integration into the common data platform. Once the Commission has identified the relevant existing datasets on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. 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.

(43) 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 develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall 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 integrate this dashboard of indicators into the common data platform.

(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. 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 only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. this Regulation sets a deadline for the first report and associated data.

(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[48] ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.

(46) The ECHA should continue operating the EUON and transform it into an observatory for specific chemicals with potential contribution 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 may contribute to an emerging chemical risk. Another criterion for that selection should be the higher degree of uncertainty surrounding them and, due to less regulatory experience regarding those chemicals, the resulting need for additional scrutiny and transparency. The observatory should facilitate regulatory implementation and responsible use of these chemicals by collecting, generating, and disseminating reliable information on selected chemicals' properties, uses and market presence to the general public.

(47) 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.

(48) 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 States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.

(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and,

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48 Commission Staff Working Document – Impact assessment accompanying the document: Commission implementing decision on a delegation agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME program. SWD (2017) 138 final.

where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. 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 through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[49]. 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.

(50) Since the objectives of this Regulation 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 hosted 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.

(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [*OP: Please insert the date of the opinion of the EDPS*].

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 coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the

[49] OJ L 123, 12.5.2016, p. 1.

single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.

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

   (a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;

   (b) keep records of studies commissioned or carried out by business operators in the context of fulfilling their obligations set under Union chemicals legislation;

   (c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;

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

3. The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).

Article 2

Definitions

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

1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');
2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;
3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;
4. 'business operators' means duty holders which are private or public undertakings;
5. 'human biomonitoring data' means concentrations of chemicals measured in human matrices such as blood or urine;
6. 'reference value' means an estimate of a maximum exposure to 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 the adverse effects on human health or the environment are considered acceptable or tolerable;
7. 'originator' means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;
8. 'originating Union act' means the Union act under 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 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 physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and

manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related 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 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. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (16), of Regulation (EU) 2018/175 of the European Parliament and of the Council;
13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of Regulation (EU) 2018/175 of the European Parliament and of the Council;
14. '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) 2018/175 of the European Parliament and of the Council;
15. '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.

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 acts listed in Annex I to this Regulation and held by the Agencies or the Commission;

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

    (c) listed in Annex II and held by the EMA;

3. 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[50];

   (b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[51] of the European Parliament and of the Council.

4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.
5. 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) information on regulatory processes referred to in Article 10;

   (e) information on obligations under Union chemicals legislation referred to in Article 11;

   (f) the repository of standard formats and controlled vocabularies referred to in Article 12;

   (g) the database on environmental sustainability-related data referred to in Article 13.

6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.
7. The data contained in the common data platform may be used in accordance with Article 17.
8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.
9. 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 at stake for the storage of chemicals data in and transmission of chemicals data 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.

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[50] 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).

[51] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).

10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001[52].
11. The common data platform and its dedicated services shall be established by [*OP: please insert date: three years after the date of entry into force of this Regulation*], unless specified otherwise. The relevant datasets shall be integrated progressively into the common data platform by [*OP please insert date: ten years from the date of entry into force of this Regulation*] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.

Article 4

Implementation plan and governance of the common data platform

1. By [*OP please insert date: 6 months after the date of entry into force of this Regulation*] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.
2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.
3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.
4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing decision
5. That governance scheme 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 rolling 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;

[52] 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).

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

(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;

(f) the operation 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 legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold.
2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as referred to in Article 4(4), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.
3. The ECHA shall host and maintain occurrence data related to workplace monitoring.
4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.
5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [*OP please insert: date of the entry into force of this Regulation*].
6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [*OP please insert: date of the entry into force of this Regulation*].
7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.
8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.
9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.

Article 6

Human biomonitoring data

1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.
2. At the latest by [*OP please insert date: 3 years after entry into force of this Regulation*] the Commission shall transfer any human biomonitoring data it holds to the EEA.
3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.
4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:

   (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.

5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.
6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2.

Article 7

Information Platform for Chemical Monitoring

1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring 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. At the latest by [*OP please insert date: 3 years after the date of entry into force of this Regulation*], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.
3. At the latest by [*OP please insert date: 3 years after entry into force of this Regulation*], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5.
4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.

5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.
6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is 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. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.
3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.
4. For the purpose 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 ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.
5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.

Article 9

Database of Study Notifications

1. The ECHA shall establish and operate a Database of Study Notifications by [O*P please insert date: two years after the date of entry into force of this Regulation*].
2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.
3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.
4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided

on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.

5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and 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 on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.
2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.
3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:

   (a) substance identity;

   (b) the Union act and the regulatory process under which the activity takes place;

   (c) submitter or actor responsible for the regulatory process or activity;

   (d) status of the regulatory process or activity;

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

   (f) where applicable, date of intention to start the regulatory process or activity, completion and latest 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

Information on the obligations under Union acts on chemicals

1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.
2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).

Article 12

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 acts listed in Annexes I and II, the ECHA shall include them in the common data platform.
3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.

Article 13

Database on environmental sustainability related data

1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.
2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.
3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.
4. By [*OP* please *insert date: three years after the date of entry into force of this Regulation*], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.

Chapter III

DATA FORMATS AND CONTROLLED VOCABULARIES

Article 14

Standard formats

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

   (a) avoid the use of proprietary standards;

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

   (c) use OECD or other internationally agreed formats;

   (d) be coherent with other existing data formats;

   (e) ensure interoperability with existing data submission approaches.

3. Those standard formats shall be interoperable with the common data platform and be user-friendly.
4. The Commission and the 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 available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:

   (a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[53];

   (b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[54];

   (c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[55];

   (d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[56];

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53 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 18.20.2003, p. 29).

54 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).

55 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).

(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[57];

(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[58];

(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [59];

(h) Commission Regulation (EU) No 234/2011[60];

(i) Directive 2009/48/EC of the European Parliament and of the Council.[61]

6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.
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 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 that 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 remedy the divergence.
8. The Commission shall adopt an implementing decision to remedy the divergence.

Article 15

Controlled vocabularies

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56 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).

57 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).

58 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).

59 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).

60 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 064 11.3.2011, p. 15).

61 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).

1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.
2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.
3. Those controlled vocabularies shall:

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

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

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

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

4. Those controlled vocabularies shall be interoperable with the common data platform.
5. Where controlled vocabularies are specified, the Commission and the Agencies shall:

   (a) make them available free of charge through the common data platform and as open datasets;

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

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

6. The Commission and the Agencies shall cooperate with each other in setting the 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 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 that 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 remedy the divergence.
8. The Commission shall adopt an implementing decision to remedy the divergence.

Chapter IV

CHEMICALS DATA CONFIDENTIALITY AND USE

Article 16

Access rights and transparency

1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.
2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.
3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.

Article 17

Use of chemicals data contained in the common data platform

1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.
2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.
3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.

Chapter V

MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS

Article 18

Framework of indicators

1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.
2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.

Article 19

Early warning and action system for emerging chemical risks

1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [*OP please insert date: one year after the date of entry into force of this Regulation*].
2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:

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

   (b) existing national early warning systems;

   (c) data that the EEA holds;

   (d) targeted literature searches performed by the EEA;

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

   The early warning signals compiled by the EEA under 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, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.
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 [*OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation*]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals.
5. The EEA shall make all relevant 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 integration in the common data platform.

Article 20

Observatory for specific chemicals with potential contribution to emerging chemical risks

1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.
2. By [*OP please insert date: 6 months after the date of entry into force of this Regulation*] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.

3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. 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.
4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:

   (a) make use of relevant datasets integrated 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 21 to address knowledge gaps or significant uncertainties;

   (c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.

Chapter VI

DATA GENERATION MECHANISM

Article 21

Data generation mechanism

1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.
2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.
3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.
4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.
5. The ECHA shall commission these scientific studies in an open and transparent manner.
6. 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 paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.
7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.

Chapter VII

NOTIFICATION OF STUDIES

Article 22

Notification of studies

1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals 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 they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 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 the title, scope, 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.
3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.
4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.
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 set under this article shall apply from [*OP please insert date: 24 months after the date of entry into force of this Regulation*].
7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.

Chapter VIII

DELEGATED POWERS

Article 23

Amendment of Annexes I, II and III

1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.
2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.
3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.

Article 24

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 23 shall be conferred on the Commission for a period of five years from [*OP please insert: the date of the 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 23 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 23 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.

Chapter IX

ENFORCEMENT AND PENALTIES

Article 25

Enforcement

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 22.

Article 26

Penalties for non-compliance

1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 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 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.

Article 27

Entry into force and application in time

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 Brussels,

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