TÜRKİYE ODALAR VE BORSALAR BİRLİĞİ

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**Sayı** : E-34221550-045.99-8435 **Tarih**: 24.07.2025
**Konu** : AB Kimyasal Tek Madde Tek Değerlendirme Paketi (OSOA)

**TÜM ODA VE BORSALARA**
**(Genel Sekreterlik)**

Ticaret Bakanlığı Uluslararası Anlaşmalar ve Avrupa Birliği Genel Müdürlüğü tarafından Birliğimize iletilen yazıda, Tek Madde Tek Değerlendirme Paketi (OSOA-one substance one assessment) kapsamında uzlaşıya varıldığı bildirilmektedir.

Yazıda devamla bahse konu paket kapsamında bir tüzük ve üç düzenleme önerilmekte olunduğu ve düzenlemelerin 25 Haziran 2025 tarihli AB Konseyi Daimi Temsilciler Komitesi toplantısında kabul edildiği belirtilmektedir.

Bu kapsamda ilgili yazı ve yazının ekinde bulunan mevzuat tekliflerine ilişkin metinler, ekte takdim edilmektedir.

Bilgilerinizi rica ederim.

Saygılarımla,

*e-imza*
Cengiz DELİBAŞ
Genel Sekreter Yardımcısı

EK:
1- Üst Yazı - AB Kimyasal Tek Madde Tek Değerlendirme Paketi (OSOA) Düzenlemeleri (1 sayfa)
2- Kimyasallar Paketi_Ek_ST-10883-2025-ADD-1_en (146 sayfa)
3- Kimyasallar Paketi_Ek_ST-10883-2025-ADD-2_en (18 sayfa)
4- Kimyasallar Paketi_Ek_ST-10883-2025-ADD-3_en (27 sayfa)

**T.C.**
**TİCARET BAKANLIĞI**
**Uluslararası Anlaşmalar ve Avrupa Birliği Genel Müdürlüğü**

2025 AİLE YILI

Sayı : E-79668890-749-00111318532
Konu : AB Kimyasal Tek Madde Tek Değerlendirme Paketi (OSOA) Düzenlemeleri

**DAĞITIM YERLERİNE**

İlgi : 24.06.2025 tarihli ve E-79668890-749-00110643718 sayılı yazımız.

İlgi'de kayıtlı yazımız ile AB Konseyi ve Avrupa Parlamentosunun (AP), kimyasalların değerlendirilmesine ve kimyasal risklere karşı erken önlem alınmasına yönelik olarak hazırlanan Tek İçerik Tek Değerlendirme Paketi (OSOA-one substance one assessment) üzerinde, 12 Haziran 2025 tarihinde geçici uzlaşıya vardığı bildirilmişti.

Bahse konu paket kapsamında, bilimsel ve teknik görevlerin yeniden atanmasına ilişkin bir direktif, kimyasallar alanında Birlik ajansları arasında işbirliğini artırmayı amaçlayan bir tüzük ve kimyasallar hakkında ortak bir veri platformu kurulmasına yönelik bir tüzük olmak üzere 3 düzenleme önerilmekte olup, anılan düzenlemeler 25 Haziran 2025 tarihli AB Konseyi Daimi Temsilciler Komitesi toplantısında kabul edilmiştir.

Söz konusu mevzuat tekliflerine ilişkin nihai konsolide metinler yazımız ekinde iletilmektedir.

Bilgilerini rica ederim.

**Fatma Canan NİLÜFER DORA**
**Bakan a.**
**Genel Müdür Yardımcısı**

Ek:
1- Kimyasallar Paketi_Ek_ST-10883-2025-ADD-1_en
2- Kimyasallar Paketi_Ek_ST-10883-2025-ADD-2_en
3- Kimyasallar Paketi_Ek_ST-10883-2025-ADD-3_en

Dağıtım:
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Council of the European Union

Brussels, 26 June 2025
(OR. en)

10883/25
ADD 1

**Interinstitutional File:**
**2023/0453 (COD)**

ENV 600
COMPET 625
CHIMIE 62
MI 478
ENT 117
IND 232
FOOD 56
RECH 307
CODEC 910

**OUTCOME OF PROCEEDINGS**

| | |
|---|---|
| From: | General Secretariat of the Council |
| To: | Delegations |
| 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 in the Annex the final consolidated text of the abovementioned proposal endorsed by the Permanent Representatives Committee meeting on 25 June 2025.

**ANNEX**

**PE-CONS No /YY - 2023/0453(COD)**

# REGULATION (EU) 2025/...
# OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**of...**

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

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN ***UNION***,

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

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability[2] 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 ***and groups of chemicals*** to ensure that Union policies 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.

[1] 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)0640).

[2] 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)0667).

(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from ▌ chemicals, as well as to facilitate the functioning of the internal market for chemicals. ▌ For that purpose, this Regulation should establish a common data platform 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 ***transparency,*** 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 ***and thereby contribute to the replacement and reduction of the animal testing wherever possible. Improving the integration of information from different sources, and establishing a cost-effective digital infrastructure will also improve the predictability and transparency of regulatory processes and result in a reduction of the administrative burden and overlaps***. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the ▌ 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. ***By collecting and making available all data on chemicals that exist in the Union, the database will also foster innovation and support the development of advanced tools, methods and models for chemicals assessments.***

(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[1], 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.

[1] 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).

(4) In its communication of 19 February 2020 on a European strategy for data[1], 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, 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 ***Commission and 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.

[1] 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)0066).

(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act[1] 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.

[1] 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)0720).

(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 ▌ 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 ▌ 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. ***Authorities should take the necessary measures to protect the confidentiality of data, including, where relevant, by means of physical and cybersecurity measures.***

(7) The common data platform should contain***, but not be limited to, all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted ***to them*** as part of the implementation of Union chemicals legislation listed in Annex I***, unless this Regulation specifies otherwise***. 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 ***as well as chemicals data resulting from Member States' implementation activities,*** in compliance with their reporting obligations. The common data platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies. ***In addition, the common data platform should allow for the integration of chemicals data provided on a voluntary basis by Member States and other parties, including national agencies and research institutes, as well as chemicals data resulting from international collaboration with third countries' organisation, and held by the Commission or one of the relevant agencies.***

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

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

***(9a) Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data and data related to other substances contained in medicinal products besides active substances . Moreover, a relevant part of the medicinal data is held by the National Competent Authorities. At a later stage and no later than 6 years after the entry into force of this Regulation, the Commission should therefore assess, in consultation with Member States and the Agencies, whether such additional data should be included in the common data platform. This assessment should take also into account the relevancy, the anticipated added value as well as the cost-benefit balance of incorporating the additional data.***

***(9c) In order to add, where relevant, data to be made available by the EMA through the common data platform to support the achievement of the objectives of this Regulation, especially to ensure coherence and the efficient delivery of hazard and risk assessments of chemicals, or to adapt if, in view of developed scientific knowledge, there is new knowledge on the hazards or risks to the environment or human health;, the power to adopt acts in accordance with Article 290 of the Treaty of the Functioning of the European Union should be delegated to the Commission in respect of amending Article 3, paragraph 2a.***

(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[1], 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[2] 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.

[1] 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).

[2] 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).

(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***, granting, as a general principle, the widest possible access to chemicals data and, where appropriate,*** specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and 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. ***Access to personal data should be limited to what is necessary in relation to the purposes for which those data are processed by the Authorities.***

(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may ***contain commercially sensitive information or*** be protected by confidentiality claims on confidential business information ***under those Union acts***. The public dissemination of such data may affect the commercial ***interests*** of private parties. To ensure legal certainty ***and predictability*** for duty holders and to protect their legitimate expectations, as well as to ensure 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 ***in human and machine-readable formats***, including access to ***all*** confidential information ▌ and information ***that is not made available to the public. In contrast, other parties should not have*** access ***via the common data platform*** to confidential ***data, or data that is not made available to the public under the originating Union act as it may contain commercially sensitive*** information ***and its confidentiality has not been assessed***. ***Nevertheless, all parties should maintain the right to request access to any data contained in the platform in accordance with Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.***

(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. ***The common data platform should also include terms and conditions of use, including regarding intellectual property rights.***

(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[1], 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[2] provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.

[1] 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).

[2] 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).

***(15a) When processing or disclosing personal data contained in the common data platform, the Agencies and the Commission should comply with Regulation (EU) 2018/1725 of the European Parliament and of the Council[1], and the Member State competent authorities should comply with Regulation (EU) 2016/679 of the European Parliament and of the Council[2].***

(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, ***a database on chemicals in articles or products, a database on alternatives to substances of concern,*** as well as a dashboard of indicators on chemicals.

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1 ***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 – 98).***

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

(18) The Commission should adopt an implementation plan identifying ▌ datasets ***of chemicals data*** to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies[1]. 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 ***of chemicals data*** 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. ***The Commission should ensure that all work areas in the scope of the present regulation are considered by the steering committee.*** In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.

***(18a) When exercising implementing powers, and in the cases in which Regulation (EU) No. 182/2011 does not apply, the Commission should, as part of its preparatory work, take into account views of Member States.***

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

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

(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. ***The quality control of data and completeness checks of data submissions should be carried out by the originator in accordance with the originating Union act under which the data was submitted or generated.***

(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, ***chemicals*** 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 ***or other obligations laid down in this Regulation***. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. ***Member States or other parties, including national agencies, research institutes and third countries' organisations should be able to offer chemicals data to the Agencies or the Commission using the appropriate standard format, where available. In such case, it should be for the Agencies or the Commission, as the case may be, to decide whether to host and maintain the data.***

(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, ***including occupational human biomonitoring 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, or, as relevant, national*** 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. ***For human biomonitoring data constituting personal data, the EEA should specify which type of data should be made available to it (i.e. anonymised, pseudonymised, or identifiable data).***

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

***(24a) The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitute a special category of personal data, namely, health data, the EEA, the Commission, the ECHA, the EFSA, the EU-OSHA and the EMA should process those data only where the processing is necessary for reasons of substantial public interest, as laid down in Article 10(2)(g) and for scientific research as laid down in Article 10(2)(j) of Regulation (EU) No 2018/1725. The present Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data constituting personal data.***

***(24b) Human biomonitoring data lawfully collected prior to the entry into force of this Regulation in the common data platform should be included in the platform to ensure the completeness and relevance of the human biomonitoring datasets for the purposes of this Regulation. Therefore, any such data gathered prior to the coming into force of this Regulation should be able to be processed by the EEA, the ECHA, the EFSA, the EMA and the Commission when this Regulation comes into force.***

***(24c) The EEA, ECHA, EFSA, EMA, EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitutes a special category of personal data, namely, health data, the EEA, ECHA, EFSA, EMA, EU-OSHA and the Commission should process that data only where the processing is necessary for reasons of substantial public interest, as laid out in Article 10(2)(g) and for scientific research as laid out in Article 10(2)(j) of Regulation (EU) No 2018/1725. The present Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data constituting personal data.***

***(24d) The EEA, ECHA, EFSA, EMA, EU-OSHA and the Commission should be allowed to process that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to assess the need for regulatory action and prioritise such action, to monitor the impact of regulatory intervention, and to support policy making and legislation, including performing scientific research to that effect. In addition, taking into account their mission and activities, the EEA, ECHA, EFSA, EU-OSHA and Commission should be allowed to process human biomonitoring data constituting personal data to develop health risk and impact indicators, the ECHA, EFSA and EMA to perform regulatory risk assessments and support regulatory risk management and the EEA, ECHA, EFSA and Commission in the context of studies under the data generation mechanism established through this Regulation. The EEA and EU-OSHA should also be allowed to process human biomonitoring data constituting personal data to support regulatory risk assessment and management and the Commission to perform regulatory risk assessment and management. When processing human biomonitoring data constituting personal data, the EEA, ECHA, EFSA, EMA, EU-OSHA and the Commission should pay particular attention to compliance with Article 13 of Regulation (EU) No 2018/1725.***

(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 ***easy*** access of the ▌ 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. ***The ECHA should also include in the repository of reference values any reference value it considers relevant and that is generated as part of Union, national or international programmes or research activities and made available to the ECHA in a standard format where that is available. For a reference value for the carcinogenic effect of a chemical for which no maximum exposure level can be specified below which no harmful effects on human health are to be expected, the statistical cancer risk associated with that reference value should also be specified, if available.***

(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 ▌ ***, Part 1.*** The ECHA should establish and manage a database of study notifications ▌ to store the information related to those studies. ***That database should be a separate database in which notification information is kept confidential to which Authorities and national enforcement authorities have access while ensuring safe transmission of data contained in it.*** 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 ***22 months*** 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***. In order to respect*** the confidentiality of ***relevant elements of study notifications when they are integrated in the common data platform, where the Commission or an Agency makes available to the ECHA the corresponding registration, application, notification or other relevant regulatory dossier, it should also indicate which elements of the study notification are to be confidential when they will be included in the common data platform. Only those elements should be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant*** regulatory dossier ***in accordance with the provisions on confidentiality under the originating*** Union ***act***. ▌ In order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases. ***To avoid uncertainty for business operators resulting from the existence of two databases of study notifications, managed by ECHA and EFSA, respectively, ECHA should lay down, in close cooperation with the EFSA and in consultation with stakeholders, practical arrangements to facilitate the implementation of the notification obligation, including details as regards the type of studies requiring notification.***

(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***, Part 1***, 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 ***an application, notification or*** regulatory ***dossier intended to be notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, to ensure*** compliance under ***the*** Union acts ▌ 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 ***with*** 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 ***to help them to verify*** 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 ***are*** 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 ***chemical*** 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.

***(36a) The use of articles or products containing chemicals may lead to exposure to those chemicals. Knowledge on the presence of chemicals in articles or products is essential to understand the potential risk from the use of such articles or products, to steer innovation towards substitution in applications with the highest risk as well as to inform whether and how articles and products can be recycled safely. Currently, there are data gaps on the occurrence of hazardous and other harmful chemicals in articles and products on the Union market. In order to enhance visibility of the available data the ECHA should establish and manage a database with data on chemicals in articles or products generated or submitted under Union acts listed in Annex IIIb to this Regulation and integrate it into the common data platform as a dedicated service.***

***(36b) In order to support and promote research and development as regards alternatives to substances of concern, as well as the promotion and uptake of such alternatives, the ECHA should establish and manage a repository with data on alternatives to potential substances of concern, collect the data as made available by the Commission, the Agencies and possibly Member State competent authorities, and integrate the content of that database into the common data platform as a dedicated service. The ECHA should also facilitate the voluntary submission by interested parties of information on alternatives to substances of concern, including information on alternative technologies to substances of concern, or of materials not requiring such substances.***

(37) The existing ‘The EU Chemicals Legislation Finder’[1] 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.

[1] 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 that chemicals data is easily findable in the common data platform and that all relevant data is linked together on a specific chemical or material, each chemical or material should be identified by a unique technical identifier and, where possible and available, a chemical notation specifying the molecular structure, taking into account any applicable confidentiality requirements.*** In order to ensure 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 ▌ 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 ▌ , 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. ***When specifying such formats and controlled vocabularies, the Agencies and Commission should, where relevant, take into account input and contributions from Member States and stakeholders.***

(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 ▌ 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[1] and (EU) No 528/2012[2] 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 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 .

[1] 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).

[2] 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).

***(41a) In order to support the uptake of peer-reviewed published research data in regulatory chemicals assessments and the implementation of the obligation to consider all available data in such assessments, the Commission and the Agencies should promote the development and use of tools and practices facilitating such uptake, including the development and use of reporting standards for such data and tools to search, screen and extract relevant peer-reviewed published research data. Where the Commission or one of the Agencies engages in the development of such tools and practices they should closely cooperate and provide assistance as appropriate. In addition, the Commission should assess whether to initiate collaboration with scientific and academic publishers and operators of databases containing contents of peer-reviewed journals on harmonized reporting and on the use of tools to search, screen and extract peer-reviewed published research data relevant for chemicals assessments from databases containing contents of peer-reviewed journals. For the purposes of this assessment, the Commission should take into account the work done by the Organisation for Economic Co-operation and Development on the generation, reporting and use of peer-reviewed published research data for regulatory assessments.***

(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 ***of chemicals data*** 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 ***as well as possibly other parties***, 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***, in collaboration with the EFSA, the EMA, the EU-OSHA and the Commission,*** develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard***. The framework of indicators should, where meaningful and to the extent possible, include an aggregated territory-based risk indicator at appropriate geographical levels to monitor time and spatial trends in exposure of populations to chemicals and health risks associated with such exposure***. 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) ***This Regulation should establish an early warning and action system to identify emerging chemical risks and enable early regulatory follow-up to such risks.*** To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals***,*** draw up an annual summary report ***and present it to Authorities***. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems ***as well as relevant datasets from the EU dataset catalogue established by Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space***. 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 ***concerning chemicals, groups of chemicals, and cumulative exposure to chemicals***. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after ***the*** entry into force of this Regulation. ***Based on the risks and warning signals identified in the report, the Authorities should consider undertaking regulatory, policy or enforcement action or provide a justification when they decide not to proceed with any action. Emerging chemical risks identified in the early warning and action system should also be considered a valuable source of information when setting priorities*** for the ***strategic planning of Horizon Europe***.

(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[1] ('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 and groups of*** 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 ▌ public.

[1] 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)0138.

(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 ***and groups of chemicals*** within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder ***and seeking to avoid duplication with Member State or Union research or implementation programmes***. Furthermore, the ECHA should commission such studies 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. ***When obtaining a sample of a substance or mixture is a precondition for conducting the scientific studies, ECHA should be given the necessary sample, including substance or mixture characterisation where relevant, by the business operator free of charge and upon request. Where the business operator submits a justified confidentiality claim on the information it provides on the sample, the ECHA should respect that confidentiality. Where relevant and whenever possible, when commissioning a study, ECHA should give priority to the use of validated non-animal methods, using tests on vertebrate animals only as a last resort.***

***(48a) To gather information on the exposure of European citizens to chemicals, to support the effective implementation and evaluation of Union acts on chemicals and to contribute to the development of a comprehensive Union chemicals policy the ECHA and EFSA, in cooperation with the EEA, should commission a Union-wide human biomonitoring study. The Member States should cooperate with the relevant agencies in the planning and organisation of the human biomonitoring study and provide the necessary technical assistance and administrative support to the parties contracted by the ECHA or EFSA and performing the sampling in order to enable sampling in their territories and to ensure adequate representativeness of the samples. The human biomonitoring study should adhere to ethical and confidentiality standards. Taking into account the experience gained through this human biomonitoring study, the Commission should assess the appropriateness of requiring regular human biomonitoring studies, as well as the resource needs for and modalities to involve Member States in such studies. Depending on the outcome of that assessment, the Commission should consider presenting a legislative proposal.***

***(48b) In order to ensure an optimal functioning of this Regulation and to stay abreast of technological and legislative developments, the Commission should carry out a general review of this Regulation, and present a report to the European Parliament and the Council, accompanied, if appropriate, by a legislative proposal. The report should assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has contributed sufficiently to achieve its objectives, in particular to allow a better reuse of data across the Union acts referred to in Annex I, and the appropriateness of resource allocation to the Agencies and the Commission.***

(49) In order to adjust the ***content of Annex I, which should list all*** Union acts under which ▌chemicals data▌ is generated or submitted ***to the Agencies or the Commission, it is appropriate to empower the Commission*** to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union ***to amend Annex I by adding new Union acts under which relevant chemicals data and information is generated or submitted, as soon as these Union acts enter into force or are revised, unless otherwise provided***.

***(49a) In order to adjust the content of Annex II, which should list relevant reference values resulting from the implementation of Union acts listed in Annex I, Part 2, and held by the EMA, 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 to amend Annex II when, taking into account the digitalisation and interoperability of the reference values held by the EMA as well as the values' usefulness for other policy areas and for the implementation of the Union acquis, there is a need to list additional reference values.***

***(49b) In order to adjust the content of Annex III, which should list all Union acts under which regulatory processes on chemicals or groups of chemicals are undertaken by Member States' competent authorities, the Agencies or the Commission it is appropriate to empower the Commission to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend Annex III by adding new Union acts under which relevant regulatory processes on chemicals or groups of chemicals are undertaken by Member States' competent authorities, the Agencies or the Commission , as soon as these Union acts enter into force or are revised, unless otherwise provided.***

***(49c) In order to adjust the content of Annex IIIb, which should list Union acts under which data on chemicals in articles or products is generated or submitted to the Agencies or the Commission, it is appropriate to empower the Commission to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend Annex IIIb by adding any new Union act under which data on chemicals in articles or products is generated or submitted, as soon as it enters into force, unless it contains a provision adding that act to Annex IIIb, any existing Union act listed in Annex I which is amended in such a way that data on chemicals in articles or products is generated or submitted, as soon as the respective amending act enters into force, unless the amending act contains a provision adding that act to Annex IIIb, or any existing Union act listed in Annex I for which it has become apparent from further verification that data on chemicals in articles or products is generated or submitted under it.***

***(49d) 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[1]. 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.***

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

(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 ***29 January 2024***.

HAVE ADOPTED THIS REGULATION:

Chapter I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation aims to ensure the efficient delivery of 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 ***safe and*** sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' ***knowledge of, and*** trust in***,*** the scientific base for the decisions taken under Union legal acts on chemicals***, and to contribute to the replacement and reduction of animal testing wherever possible***.

2. To achieve the objectives referred to in paragraph 1, this Regulation 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 ▌ 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, paragraphs 2 and 2a.***

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 ***or*** III, and the Agencies, excluding their management boards;

3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I ***;***

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 ▌;

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***, fate*** 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, ***data on alternatives to substances of concern,*** 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.

***(11a) 'peer-reviewed published research data' means any chemicals data derived from scientific studies published in peer-reviewed literature that are not carried out specifically to inform regulatory assessments;***

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

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

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/ 1725***;

***14a. ‘data processor’ means a processor as defined in Article 4, point (8), of Regulation (EU) 2016/679 of the European Parliament and of the Council, and as defined in the Article 3, point 12, of the regulation 2018/1725;***

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.

***16. ‘the public’ means one or more natural or legal persons, and associations, organisations or groups of such persons.***

Chapter II

INFORMATION SYSTEMS AND PLATFORMS

Article 3

Common Data Platform on Chemicals

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

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

(a) generated or submitted as part of the implementation of the Union 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;

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

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

*(a) it is held by the EMA and*

*(b) it relates to active substances:*

*(i) subject to regulatory procedures under other Union acts listed in Annex I, Part 1, to this Regulation; or*

*(ii) with particular persistent, bio-accumulative and toxic properties; or*

*(iii) with a known high level of residues in the environment; and*

*(c) it falls into at least one of the following categories:*

– *non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the Council*[1] *and Regulation (EC) No 726/2004 of the European Parliament and of the Council*[2]*; or*

[1] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).*

[2] *Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).*

– ***data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council[1]; or***

– ***maximum residue levels and the data used to derive them, compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council[2]***

***2b. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend:***

– ***point b of Article 3(2a), by including, chemicals data related to substances contained in medicinal products besides active substances or active substances with other properties than those referred to in points (i) and (ii) of paragraph 2a, point b, when presenting an interest for the objectives of this Regulation or if, in view of developed scientific knowledge, there is new knowledge on the hazards or risks to the environment or human health;***

1 ***Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).***

2 ***Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).***

– ***point c of Article 3(2a), by adding new categories of data types presenting an interest for the objectives of this Regulation or, if, in view of developed scientific knowledge, there is new data on the hazard or risk to the environment or human health.***

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[1];

(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[2] 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.

***4a. The ECHA shall ensure that each chemical or material for which chemicals data is hosted on the common data platform is identified by a unique technical identifier used to link together all chemicals data on that chemical or material, and, where possible and available, a chemical notation specifying its molecular structure, without prejudice to any confidentiality requirements in the originating Union act.***

[1] 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).

[2] 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).

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;

***(da) data on chemicals in articles or products referred to in Article 10a;***

***(db) data on alternatives to substances of concern referred to in Article 10b;***

(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.

***The common data platform shall contain appropriate background and explanatory information in order to facilitate informed use of the data by the Authorities and the public.***

6. The Authorities and the general public shall have ***easy*** access ***free of charge, in accordance with Article 16,*** to the data contained in the common data platform***, as well as any related context data as referred to in paragraph 5, point (c) of*** Article ***4, including, where relevant, an indication whether the data was generated by Authorities***.

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 ***the common data platform. The relevant Agencies shall take measures in cooperation with the ECHA to ensure secure*** 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.

10. The Commission or ***Agencies*** 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 ***of the European Parliament and of the Council***[1]**.**

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***, and shall at least include the datasets as set out in Annex IIIa by that date. Further*** relevant datasets ***of chemicals data, including chemicals data generated or submitted before the entry into force of this Regulation, unless specified otherwise,*** 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. ***Chemicals data related to human and veterinary medicinal products, as specified in paragraphs 2a(a), (b) and (c) of this Article, resulting from procedures that were concluded before the entry into force of this Regulation, shall be progressively integrated from [the date six*** years from the date of entry into force of this Regulation]**.** When the ECHA receives chemicals data in accordance with Article 5 ***belonging to a dataset which has already been integrated***, it shall make that data available through the common data platform ***at the latest within 90 days of receipt***.

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).

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 ***by means of an implementing act*** adopt ▌ an implementation plan identifying datasets ***of chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion ▌. Subsequent 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 ***act***, establish and manage a platform steering committee, which shall include ***at least*** one representative from ***each of the Agencies and as many*** representatives from the Commission ***as from all those Agencies combined***.

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 ▌ implementing ***acts. While setting up the governance scheme, the Commission shall take into account the different levels of responsibility of the Commission and the Agencies in the management and operation of the common data platform.***

5. ***The*** governance scheme 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;

(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 ***and the use of the data it contains*** such as the data update, archiving and deletion policy ***and the terms and conditions of use***;

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

Article 5

Data flows for the purpose of the common data platform

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

2. Where the Commission or the Agencies hold data or information referred to in Article 3(2) ***or 3(2a)***, they shall make that data available to the ECHA, ***who shall integrate it in the common data platform. The Commission and the Agencies shall provide the data or information to the ECHA*** in a standard format, where available, together with the relevant context data as referred to in Article ***4(5)***, point (c). ***Where*** that data or information is ***not*** made available to the public under the originating Union act***, the Commission and the Agencies shall so indicate***.

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

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

5. ▌From [OP please insert: date of the entry into force of this Regulation]***, researchers or research consortia funded by Union framework programmes or national programmes shall make any human biomonitoring data they collect or generate available to the EEA, who shall host the data***. ***For human biomonitoring data constituting personal data, the EEA shall specify which type of data is to be made available to it.***

6. ***From [OP please insert: date of the entry into force of this Regulation],*** researchers or research consortia funded by Union framework programmes shall make ▌any environmental sustainability ***related*** data ▌they collect or generate ***available to the ECHA, who shall host the data***.

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. ***The ECHA shall provide support to the Authorities and national agencies to facilitate the integration of the chemicals data provided in accordance with paragraph 2.***

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

9. ***The Authorities and national*** agencies shall ensure***, when making data*** available to the ECHA***, that such data is*** downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing ***it*** to the ECHA.

***9a. Without prejudice to Article 6(6), the Commission and the Agencies shall act as data controller for any personal data they provide to the ECHA for integration in the common data platform.***

Article 6

Human biomonitoring data

1. The EEA shall collect ▌ human biomonitoring data generated within the territory of the EEA's member and cooperating countries. ***Where it concerns occupational human biomonitoring data, the EEA shall cooperate with the ECHA.***

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.

▌

4. ***The EEA may process*** human biomonitoring data constituting personal data ▌ for the following purposes ***only***:

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

(b) monitoring time and spatial trends in exposure;

(c) developing health risk and impact indicators;

(d) monitoring the impact of regulatory intervention;

(e) supporting regulatory risk assessments ***and regulatory risk management***.

***(ea) supporting policy making and legislative developments at Union level;***

***(eb) facilitating the processing by the Commission, the ECHA, the EFSA, the EMA, and the EU-OSHA in accordance with paragraphs 4a, 4b, 4c, 4d and 4e of this Article.***

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

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

***(b) monitoring time and spatial trends in exposure;***

***(c) developing health risk and impact indicators;***

***(d) monitoring the impact of regulatory intervention;***

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

***(f) performing regulatory risk assessment and regulatory risk management.***

***(g) supporting policy making and legislation, including performing scientific research to that effect***

***(h) in the context of studies under the data generation mechanism referred to in Article 21 and the human biomonitoring study referred to in Article 21a.***

***4b. The ECHA may process human biomonitoring data constituting personal data for the following purposes only:***

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

***(b) monitoring time and spatial trends in exposure;***

***(c) developing health risk and impact indicators;***

***(d) monitoring the impact of regulatory intervention;***

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

***(f) in the context of studies under the data generation mechanism referred to in Article 21 and the human biomonitoring study referred to in Article 21a.***

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

***(h) supporting policy making and legislation, including performing scientific research to that effect***

***(i) facilitating the processing by the Commission, the EEA, the EFSA, the EMA, and the EU-OSHA in accordance with paragraphs 4a, 4b, 4c, 4d and 4e of this Article.***

***4c. The EFSA may process human biomonitoring data constituting personal data for the following purposes only:***

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

***(b) monitoring time and spatial trends in exposure***

***(c) developing health risk and impact indicators***

***(d) in the context of studies under the data generation mechanism referred to in Article 21 and the human biomonitoring study referred to in Article 21a.***

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

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

***(g) monitoring the impact of regulatory intervention***

***(h) supporting policy making and legislation, including performing scientific research to that effect***

***4d. The EMA may process human biomonitoring data constituting personal data for the following purposes only:***

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

***(b) monitoring time and spatial trends in exposure***

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

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

***(e) monitoring the impact of regulatory intervention***

***(f) supporting policy making and legislation, including performing scientific research to that effect***

***4e. The EU-OSHA may process human biomonitoring data constituting personal data for the following purposes only:***

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

***(b) monitoring time and spatial trends in exposure;***

***(c) monitoring the impact of regulatory intervention;***

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

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

***(f) supporting policy making and legislation, including performing scientific research to that effect***

***(g) developing health risk and impact indicators***

***4f. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA, the EMA, the EU-OSHA, or the Commission for the purposes referred to in paragraphs 4, 4a, 4b, 4c, 4d, and 4e shall not entail the sharing of such data with third parties other than those within the meaning of Article 3, point (10) of Regulation (EU) 2016/679 and Article 3, point (14) of Regulation (EU) 2018/1725.***

5. The EEA ***and ECHA*** shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.

6. The EEA***, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission*** shall act as data controller for the human biomonitoring ***data constituting*** personal data ***they hold or host or process*** for the purposes referred to in ***paragraphs 4, 4a, 4b, 4c, 4d and 4e***.

***6a. The EEA and the ECHA, shall define the storage period as well as the criteria used to define the storage period, and carry out any review thereof, for the human biomonitoring data constituting personal data that they hold.***

***6b. The human biomonitoring data referred to in this Article includes personal data lawfully collected before the entry into force of this Regulation.***

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 ▌ 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, ***Part 1,*** or the reference values referred to in Annex II, ▌ 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.

***4a. The ECHA shall include in the repository of reference values, without undue delay, any reference value it considers relevant and that is generated as part of Union, national or international programmes or research activities and made available to the ECHA in the standard formats as referred to in Article 14, where such a standard format has been developed.***

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 [*OP 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 ***chemicals*** data notified to it in accordance with Article 22.

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

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.

***4a.*** ***Without prejudice to paragraph 4, where the Commission or any of the Agencies makes available to the ECHA, in accordance with Article 5(2), a registration, application, notification or other relevant regulatory dossier in the context of which a notification was submitted under Article 22, it shall indicate which elements of the study notifications are confidential when included in the common data platform. Only those elements shall be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant regulatory dossier in accordance with the provisions on confidentiality under the originating Union act.***

***4b.*** ***Upon receipt by the ECHA, in accordance with Article 5(2), of a registration, application, notification or other relevant regulatory dossier, in the context of which a notification was submitted under Article 22, the ECHA shall make the related notification information available to the public through the common data platform, respecting the confidentiality indicated in accordance with paragraph 4a.***

***4c.*** ***Authorities and national enforcement authorities shall have access to the data contained in the Database of Study Notifications before that data is integrated in the common data platform.***

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 ***chemicals*** or groups of ***chemicals*** that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States 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. ***For each regulatory process or activity, at least the following information shall be included:(a) chemical identity;***

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

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

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

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

***(f) where applicable, the intended date for starting the regulatory process or activity, and the date of its completion and latest update.***

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) ***chemical*** 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 10a***

***Data on chemicals in articles or products***

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

***2. Where the Commission or the Agencies hold the information referred to in paragraph 1, they shall make that data available to the ECHA for integration in the common data platform in the standard formats as referred to in Article 14, where available, without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment.***

***3. Where Member State competent authorities hold the data referred to in paragraph 1, they may make that data available in the standard formats as referred to in Article 14, where available, to the Union agency responsible under the respective Union act listed in Annex IIIb, or to the ECHA in the absence of such agency, who may host the data.***

***4. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of data on chemicals in articles or products in the related database.***

***Article 10b***

***Data on alternatives to substances of concern***

***1.*** ***The ECHA shall establish and manage, as part of the common data platform, a database containing data on alternatives to substances of concern as defined in Article 2(27) of Regulation (EU) 2024/1781 as well as substances that meet the criteria for classification in hazard classes referred to in Article 2(27)(b) of Regulation (EU) 2024/1781, including on alternative technologies or materials not requiring such substances. At a minimum, the ECHA shall include in the database data provided by applicants in accordance with Article 62, paragraph 4, point (e) of Regulation (EC) 1907/2006.***

***2.*** ***Where the Commission or the Agencies hold the data referred to in the first subparagraph of paragraph 1, they shall make that data available to the ECHA for integration in the common data platform.***

***3.*** ***Where Member State competent authorities hold the data referred to in the first subparagraph of paragraph 1, they may make that data available in the standard formats as referred to in Article 14, where available, to the Union agency responsible under the respective Union act listed in Annex I , or to the ECHA in the absence of such agency, who may host the data.***

***4.*** ***The ECHA shall facilitate the voluntary submission by interested parties of information on alternatives to substances of concern, including information on alternative technologies to substances of concern, or of materials not requiring such substances.***

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 ▌ ***, Part 1.***

2. The ECHA shall update the information in the database on a regular basis***, and at least annually,*** 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 ***Annex I***, 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 ***by [OP please insert date: six*** years after the ***date of entry into force of this regulation]***, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data ***and providing the functionalities designed in accordance with paragraph 4***.

2. Where the Commission or the Agencies host or hold environmental sustainability related data ▌, they shall make that data available to the ECHA without undue delay ***for integration in the database on environmental sustainability related data*** once the Commission or the agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. ***In addition, in accordance with Article 5(1), Member States or other parties, including national agencies, research institutes, and third countries' organisations may submit environmental sustainability related data to the ECHA.*** The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data. ***The ECHA shall provide the necessary support to the Commission and the Agencies to facilitate the integration of those 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***, in consultation with the Member States, design database functionalities and identify*** existing datasets ***of chemicals data*** on environmental sustainability related data, other than those referred to in paragraph 2, ***which*** shall ***be hosted and maintained by the ECHA***.

## 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 (2a)*** 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 ***Authorities or national*** agencies shall exchange data contained in the common data platform in the relevant standard format.

5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making 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[1];

   (b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[2];

   (c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[3];

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

[2] 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).

[3] 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).

(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[1];

(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[2];

(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[3];

(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [4];

[1] 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).

[2] 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).

[3] 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).

[4] 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).

(h) Commission Regulation (EU) No 234/2011[1];

(i) Directive 2009/48/EC of the European Parliament and of the Council***;***[2]

***(j) Regulation (EC) No 1107/2009 of the European Parliament and of the Council***[3]***;***

***(k) Regulation (EC) No 396/2005 of the European Parliament and of the Council***[4]***.***

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 ***act*** to remedy the divergence.

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1 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).

2 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).

3 ***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).***

4 ***Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70 16.3.2005, p. 1).***

Article 15

Controlled vocabularies

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) ***and 3(2a)***, 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 ▌ as open datasets***, supporting their re-use***;

   (b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I***, Part 1*** and referred to in Article ***3, paragraph 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.

***Article 15a***

***Uptake of peer-reviewed published research data***

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

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

Chapter IV

CHEMICALS DATA CONFIDENTIALITY AND USE

Article 16

Access rights and transparency

***-1. Without prejudice to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents the public shall have access to all the chemicals data contained in the common data platform, except data which is indicated in accordance with Article 5(2) as not being made available to the public under the originating Union act.***

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

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

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 ***or in the Database of Study Notifications*** in the performance of any of their activities, where those activities support the development***,*** implementation ***or enforcement*** of ▌ legislation and policy.

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

3. When using chemicals data contained in the common data platform that is ***indicated in accordance with*** Article 5(2) ***as not being made available to the public,*** the Authorities shall respect ***that indication*** 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 ***and the ECHA shall***, in collaboration with ▌ the EFSA, the EMA, the EU-OSHA and the Commission, ***and in consultation with Member States,*** establish, operate, ▌ maintain ***and update as appropriate*** a framework of indicators ***to monitor chemical pollution throughout a chemical's lifecycle, including emissions, occurrence and fate,*** to monitor the drivers and impacts of exposure to chemicals, ***and to*** measure the effectiveness of chemicals legislation and ▌ the transition towards the production of safe and sustainable chemicals.

***1a. The framework of indicators referred to in paragraph 1 shall, where meaningful and to the extent possible, include an aggregated territory-based risk indicator to monitor time and spatial trends in exposure of populations to individual and multiple chemicals and health risks associated with such exposure.***

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) ▌ national early warning systems;

(c) data that the EEA holds***, including data from human biomonitoring as referred to in Article 6, and data from the framework of indicators as referred to in Article 18***;

(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;

***(ea) relevant datasets from the EU dataset catalogue established by Article 79 of Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space;***

***(eb) relevant information resulting from the implementation of Union legislation***.

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***, including data obtained pursuant to this Regulation,*** 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 ***Authorities. Within nine months of the presentation of the report, the*** Authorities ***shall consider undertaking*** regulatory***,*** policy ***or enforcement actions accordingly or provide justification if they decide not to proceed with any*** action ▌ .

5. The EEA shall make all ▌ data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for 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 or groups of*** 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 ***act***. The Commission shall review the list of selected chemicals regularly ***and*** adopt any revision thereof by the same means. ***Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.***

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 ***chemicals data*** 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 the identification of potential further research needs or risk management measures***, 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***:***

***a.*** support the implementation of Union acts on chemicals ***or groups of chemicals*** in Annex I ***, Part 1,*** within its mandate***;***

***b.*** contribute to the support, evaluation or development of a Union chemicals policy***;***

***c.*** ***investigate further emerging chemical risks identified in the report referred to in Article 19(4) of this Regulation;***

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

3. ***Upon request by*** the ▌Commission***, the ECHA shall commission the*** scientific studies ***referred to in paragraph 1 and paragraph 2***.

***3a. 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, Part 1. It shall give priority to the use of validated non-animal methods, with animal testing on vertebrate animals used only as a last resort. 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. ***The ECHA shall consult Member States prior to commissioning those scientific studies.***

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.

***6a. The ECHA may request a sample of a substance or mixture necessary for performing the scientific studies referred to in paragraph 1 from a business operator manufacturing, importing, formulating or placing such substance or mixture on the market. In order to request a sample, the ECHA shall send a draft request to the business operator explaining the request and specifying the quantity and form of the sample as well as the time within which the sample shall be provided. The ECHA may also ask the business operator to provide substance or mixture characterisation. The ECHA shall inform the business operator of its right to comment within 30 days of receipt of the request. Any such comment received shall be taken into account by the ECHA who shall confirm or amend the request. The business operator shall act upon receipt of the that request and shall, as the case may be, provide the requested sample free of charge to the ECHA or to anyone commissioned by the ECHA to perform the scientific study within the deadline set by ECHA. The business operator may request the ECHA not to disclose certain characterisation information of the provided sample if he demonstrates that the disclosure would undermine the protection of its commercial interests. If the ECHA deems the request is justified, that information shall be considered confidential and shall not be made available to the public.***

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

***Article 21a***

***Human biomonitoring study***

***1. At the latest by [OP: please insert 4 years after entry into force], the ECHA and EFSA, in cooperation with the EEA, shall, in the context of the data generation mechanism referred to in Article 21, commission a Union-wide human biomonitoring study covering all Member States.***

***2. Member States shall cooperate with the ECHA, the EFSA and the EEA in the planning and organisation of the human biomonitoring study and provide the necessary technical assistance and administrative support to the parties contracted by the ECHA or EFSA and performing the sampling in order to enable sampling in their territories and to ensure adequate representativeness of the samples. The human biomonitoring studies shall adhere to ethical and confidentiality standards.***

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 ▌ delay, any studies ***that generate*** chemicals ***data which*** 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 ▌ under the Union acts listed in Annex I***,*** ***Part 1***. 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. ***At the time of the commissioning of a study, business operators shall inform the laboratory or testing facility in which the study is carried out that this study falls under the notification obligation of paragraph 3.***

2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** 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 ▌ delay, notify any ***information referred to in paragraph 2 related to studies*** commissioned by business operators to support ***an application, notification or*** regulatory dossier ***notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that they commission as part of a risk or safety assessment***, under the Union acts listed in Annex I**,** ***Part 1***. 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 ***following information: the identity of the chemicals concerned,*** 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: ***22*** months after the date of entry into force of this Regulation].

***6a. Member States may allow for exemptions from the obligations set out under paragraphs 1 to 5 of this Article for studies conducted in the interest of defence.Where the Union legislation listed in Annex I, Part 1 provides that Member States may allow for exemptions from the obligations of one of these acts in the interests of national security, Member States may allow for exemptions from the obligations set out under paragraphs 1 to 5 of this Article.***

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

Chapter VIII

DELEGATED POWERS ***AND COMMITTEE PROCEDURE***

Article 23

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

1. ***In order to keep Annex I complete, since it lists all the Union acts under which chemicals data is generated or submitted to the Agencies or to the Commission, and in order to keep the common data platform up to date, as soon as new Union acts under which chemicals data is generated or submitted enter into force or an existing Union act is amended to the extent of introducing provisions on the generation or submission of data,*** the Commission ***shall*** adopt delegated acts in accordance with Article 24 to amend Annex I in order to ***list those*** new Union acts***, if the new Union act did not amend Annex I***.

2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II ***to this Regulation*** by adding ***new reference values derived under Union legislation on medicinal products, taking into account advances in digitalisation and interoperability as well as the values' relevance for other chemicals policy and regulatory areas***.

3. ***In order to keep Annex III complete, since it lists all the Union acts under which regulatory processes on chemicals or groups of chemicals are undertaken by Member States' competent authorities, the ECHA, the EEA, the EFSA, the EU-OSHA, and the Commission, and in order to keep the common data platform up to date, as soon as new Union acts under which new regulatory processes are established enter into force or an existing Union act is amended to the extent of establishing new regulatory procedures,*** the Commission ***shall*** adopt delegated acts in accordance with Article 24 to amend Annex III in order to ***list those new*** Union acts***, if the new Union act did not amend Annex III***.

***3a. The Commission shall adopt delegated acts in accordance with Article 24, where necessary to keep Annex IIIb as complete as possible, and to keep the common data platform up to date, to amend Annex IIIb by adding***

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

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

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

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 3(3) and*** 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 3(3) and*** 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 3(3) and*** 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.

***Article 24a***

***Committee procedure***

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

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

[1] ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementaing powers (OJ L 55, 28.2.2011, p. 13).***

## Chapter IX
## ENFORCEMENT AND PENALTIES

### Article 25
### *Cooperation on compliance*

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

## *Chapter X*
## *REVIEW AND ENTRY INTO FORCE*

### *Article 26a*
### *Reports and review*

***1.*** ***No later than … [OP: please insert six years after the entry into force of this Regulation], the Commission shall assess and adopt a report on the appropriateness and cost-benefit balance of including in the common data platform the following chemicals data relating to medicinal products pursuant to Article 3(2a) of this Regulation:***

***(a) new categories of data types;***

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

***(c) chemicals data on active substances not meeting the criteria referred to in Article 3(2a)(b);***

***(d) chemicals data collected and submitted in the context of Union acts listed in Annex I, Part 2, and held by national competent authorities and not by the Agencies.***

***2. No later than ... [OP: please insert the date: 4 years after the entry into force of this Regulation], and taking into account the work done by the Organisation for Economic Co-operation and Development on the generation, reporting, and use of peer-reviewed published research data for regulatory assessments, the Commission shall assess whether to initiate collaboration with scientific and academic publishers and operators of databases containing contents of peer-reviewed journals on:***

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

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

***3. Within two years after the finalisation of the human biomonitoring study referred to in Article 21a, the Commission shall assess the appropriateness of requiring the ECHA and the EFSA, in cooperation with the EEA, to commission regular human biomonitoring studies, as well as the resource needs for and modalities to involve Member States in such studies.***

***On the basis of the assessment carried out in accordance with the first subparagraph, the Commission may present a legislative proposal.***

***4. By … [OP: please insert 6 years after the entry into force of this Regulation], the Commission shall carry out a general review of this Regulation, and present a report to the European Parliament and the Council, accompanied, if appropriate, by a legislative proposal. The report shall assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has contributed sufficiently to achieve its objectives, in particular to allow a better reuse of data across the Union acts referred to in Annex I, and the appropriateness of resource allocation to the Agencies and the Commission.***

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 |

Annex I

***Part 1 -*** UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23

Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.

1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)

2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)

3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)

4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)

6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)

7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)

8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)

9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)

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

11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)

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

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

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

15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)

16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)

18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)

19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)

20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)

21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)

22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)

23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)

24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)

25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)

26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26)

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

29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)

30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)

31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)

32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)

33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

34. 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)

35. 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)

36. 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)

37. 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)

38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products

39. 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)

40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)

41. 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)

42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)

43. 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)

44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)

45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)

46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)

47. 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)

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

49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)

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

51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)

52. 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)

53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)

54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)

55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)

56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)

57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)

58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)

59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)

60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)

61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)

62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)

63. Regulation (EU) 2017/745 of the European Parliament and of the Council 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)

64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)

65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).

66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)

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

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

69. Regulation (EU) …/… of the European Parliament and of the Council on nature restoration (OJ …/ELI: … [OP: please add number and publication reference].

70. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].

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

***Part 2 - UNION ACTS REFERRED TO IN ARTICLE 3(2a)***

***Reference each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.***

***71. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).***

***72. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).***

***73. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).***

***74. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).***

Annex II

REFERENCE VALUES REFERRED TO IN ARTICLE 8

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

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

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

Annex III

Union acts referred to in Articles 2, 10 and 23

Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.

1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)

2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)

4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)

5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)

6. 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)

7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)

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

9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)

10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)

11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)

12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)

13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)

14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)

15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)

16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

17. 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)

18. 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)

19. 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)

20. 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)

22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)

23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products

24. 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)

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

26. 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)

27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)

28. 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)

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

30. 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)

31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).

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

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

34. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].

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

***Annex IIIa***

***Datasets to be included at the date of establishment of the common data platform referred to in Article 3***

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

| *Dataset* | *Description* | *Data provider* |
|---|---|---|
| *Datasets behind dedicated services* | *Chemicals data covered by:* | |
| | *Information Platform for Chemical Monitoring (Article 7)*<br>*This includes all chemicals data contained in the Information Platform for Chemical Monitoring operated by the Commission before transfer of the operation to ECHA.* | *Commission* |
| | *Repository of reference values (Article 8)*<br>*This includes the following data:*<br>*a. regulatory reference values formally adopted under Union acts listed in Annex I;*<br>*b. scientific reference values available in formal opinions delivered under Union acts listed in Annex I, Part 1; and*<br>*c. scientific reference values specified in Annex II resulting from relevant procedures that are concluded after the entry into force of this Regulation.* | *Agencies* |
| | *Information on regulatory processes on chemicals (Article 10):*<br>*This includes the following information:*<br>*a. information contained in the existing Activities Coordination Tool of the ECHA;*<br>*b. information on regulatory processes on chemicals available via the existing Open EFSA of the EFSA; and*<br>*c. other information as provided to the ECHA in accordance with Article 10.* | *Authorities* |
| | *Information on the obligations under Union acts on chemicals (Article 11)*<br>*This includes information on the obligations under Union acts listed in Annex I, including information available through the existing European Union Legislation Finder of the ECHA.* | *ECHA* |
| | *Repository of standard formats and controlled vocabularies (Article 12)*<br>*This includes standard formats and* | *Agencies, Commission* |

| *Dataset* | *Description* | *Data provider* |
|---|---|---|
| | ***controlled vocabularies available in accordance with Article 12.*** | |
| ***REACH registrations*** | ***Registration dossiers submitted under Title II of the Regulation (EC) 1907/2006*** | ***ECHA*** |
| ***CLP Classification and labelling inventory*** | ***- Classification and labelling information submitted in registration dossiers under Title II of the Regulation (EC) No 1907/2006 and notified under Title V of the Regulation (EC) No 1272/2008; and<br>- Harmonised classification and labelling entries from Annex VI of Regulation (EC) No 1272/2008.*** | ***ECHA*** |
| ***BPR applications for approval and renewal of active substances and summaries of biocidal product characteristics*** | ***- Applications for approval or renewal of approval of biocidal active substances under Chapter II and III of Regulation (EU) No 528/2012 and available in IUCLID; and<br>- Summaries of biocidal product characteristics submitted by applicants for Union authorisation under Chapter VIII of Regulation (EU) No 528/2012 and by applicants under Regulation (EU) No 414/2013 and available in IUCLID.*** | ***ECHA*** |
| ***DWD applications for inclusion of substances in the European positive lists*** | ***Applications to add new entries, and to amend or remove existing entries from the European positive lists of substances in contact with drinking water, submitted by economic operators or relevant authorities under Article 11 of the Directive (EU) 2020/2184*** | ***ECHA*** |
| ***Study notifications*** | ***Study notification information once a corresponding registration, application or other relevant regulatory dossier has been submitted and any confidentiality claims assessed:<br>- from the ECHA database of study notifications under Article 9 of this Regulation; and<br>- the EFSA database referred to in Article 32b of Regulation (EC) No 178/2002 as made available to the ECHA in accordance with Article 9(4)*** | ***ECHA, EFSA*** |

| *Dataset* | *Description* | *Data provider* |
|---|---|---|
| | *of this Regulation* | |
| *OpenFoodTox* | *EFSA's chemicals hazard database that compiles, in a structured format, EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs* | *EFSA* |
| *Chemical Monitoring Data* | *EFSA chemical monitoring data*[1] *covering multiple regulations under EFSA's remit and including*<br>*- chemical monitoring data for pesticides and veterinary medicinal product residues and contaminants data;*<br>*- the individual measurements of chemicals in food/feed and other materials sampled as part of official controls and enforcement activities;*<br>*- measurements of chemicals in food and feed received from industry; and*<br>*- other sources in response to a call for data.*<br>*data collection: chemical monitoring \| EFSA* | *EFSA* |
| *Food chain* | *Food chain application dossiers containing chemicals data submitted through the E-submission Food Chain Platform by applicants under different regulated product areas under Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004, Regulation (EC) No 1924/2006 and Regulation (EU) 2015/2283 and available in structured formats.* | *EFSA* |
| *Applications under PPPR* | *Dossiers submitted by applicants under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, including the active substance, maximum residue levels and basic substance submission types and available in IUCLID.* | *EFSA* |
| *AirQuality* | *Air quality data from a range of sources* | *EEA* |

[1] *data collection: chemical monitoring | EFSA*

| *Dataset* | *Description* | *Data provider* |
|---|---|---|
| | ***including***<br>***- time series of measurements from Europe's air quality monitoring network; and***<br>***- statistics for air pollutants calculated from officially verified country data as compiled under Directive (EU) 2024/2881***<br>***but not including EEA-held near-real time information on air quality and associated data products e.g. Air Quality Index.*** | |
| ***Waterbase WaterQuality*** | ***Time series of concentrations of nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters as reported in accordance with Watch List for chemicals in surface waters under Directive 2000/60/EC (also identified as WISE-6).*** | ***EEA*** |
| ***Waterbase Emissions*** | ***Time series of emissions of nutrients and hazardous substances to water, reported on yearly riverine input loads to transitional, coastal and marine waters under Directive 2000/60/EC (also identified as WISE-1).*** | ***EEA*** |
| ***Industrial Emissions*** | ***Chemicals data on releases, transfers and emissions of regulated pollutants as reported by Member States into the European Pollutant Release and Transfer Register under the Regulation (EU) 166/2006 and the Directive 2010/75/EU.*** | ***EEA*** |
| ***NEC emissions inventory*** | ***Data on emissions of air pollutants as reported by Member states under the Directive (EU) 2016/2284 and contained in the emission inventory.*** | ***EEA*** |
| ***Human medicinal products data on environmental risk assessment and non-clinical safety data*** | ***Environmental risk assessment and non-clinical safety data from marketing authorisation applications for medicinal products for human use under Directive 2001/83/EC and Regulation (EC) No 726/2004.***<br>***This includes only data on relevant*** | ***EMA*** |

| *Dataset* | *Description* | *Data provider* |
|---|---|---|
| | ***active substances submitted to the EMA in the context of the relevant procedures that are concluded after the entry into force of this Regulation.*** | |
| ***Veterinary medicinal products data on environmental risk assessment and on maximum residue limits*** | ***Environmental risk assessment data, maximum residue limits (MRLs) values and MRL assessment data from marketing authorisation applications for medicinal products for veterinary use under Regulation (EU) 2019/6 and Regulation (EC) No 470/2009.***<br>***This includes only data on relevant active substances submitted to the EMA in the context of the relevant procedures that are concluded after the entry into force of this Regulation.*** | ***EMA*** |

***ANNEX IIIb***

***UNION ACTS REFERRED TO IN ARTICLE 10A***

***Reference to each Union act listed herein shall be understood as a reference to the data on chemicals in articles or products generated or submitted as part of the implementation of the respective Union act.***

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

2. ***Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives***

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

Council of the European Union

Brussels, 26 June 2025
(OR. en)

10883/25
ADD 2

**Interinstitutional File:**
**2023/0454 (COD)**

ENV 600
MI 478
COMPET 625
CHIMIE 62
ENT 117
IND 232
RECH 307
CODEC 910

**OUTCOME OF PROCEEDINGS**

| | |
|---|---|
| From: | General Secretariat of the Council |
| To: | Delegations |
| Subject: | Proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency |

Delegations will find in the Annex the final consolidated text of the abovementioned proposal endorsed by the Permanent Representatives Committee meeting on 25 June 2025.

**ANNEX**

2023/0454 (COD)

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

[1] OJ C […], […], p. […].

Whereas:

(1) The Commission has, in its Communication 'European Green Deal'[2], set an objective that chemical safety assessments should move towards a process of 'one-substance, one-assessment', calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability[3] concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources. ***This approach is also expected to promote cost-effectiveness and competitiveness by simplifying regulatory procedures and reducing administrative burdens, ensuring that businesses can adapt efficiently to evolving regulatory frameworks.***

(2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with the 'one-substance, one-assessment' ambition. ***Moreover, digitalisation and streamlined processes will reduce duplicative efforts and administrative delays, providing significant cost savings and efficiency gains for both Member States and economic operators.***

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[2] 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 of 11 December 2019).

[3] 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 of 14 October 2020).

***(2a) The amendment of Directive 2011/65/EU introduced by this Directive expands the tasks, workload and remit of scientific committees of the European Chemicals Agency (ECHA). In order to provide adequate expertise, support, and thorough scientific evaluations, appropriate and stable resources and governance of the scientific committees should be ensured. In this respect, it is appropriate to provide for a review clause to ensure that the Commission takes account of any future regulatory developments relating to the governance of the scientific committees of the European Chemicals Agency in order to revise, if necessary, Directive 2011/65/EU on the relevant points.***

(3) Directive 2011/65/EU of the European Parliament and of the Council[4] contains two procedures related to the assessment of chemicals: the evaluation of economic operators' applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.

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

(4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5] can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.

(5) To ensure consistency between the evaluation of economic operators' applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.

***(5a) The submitted information within the confidential version of an exemption application should be subject to an assessment by the European Chemicals Agency. Such assessment should comply with Union law concerning confidential data and protection of personal data, in particular regarding dissemination and confidentiality criteria established under Regulation (EC) No 1907/2006.***

***(5b) Most exemption requests are expected to require the expertise of the Committee for Socio-economic Analysis set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. The Members States' representatives should be consulted by the Commission when adopting guidelines on the involvement of the Committee for Risk Assessment.***

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[5] 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.

(6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69 to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.

***(6a) The list of restricted substances referred to in Directive 2011/65/EU should be periodically reviewed to ensure a high level of protection of human health, the environment and consumer safety. It is appropriate to set a review period of at least 4 years, taking into account market developments and technical and scientific progress, and the fact that restriction dossiers can be submitted by Member States at any time and horizontal restriction measures can be initiated and adopted under Regulation (EC) No 1907/2006, Regulation (EU) 2019/1021 or other Union law concerning sustainability criteria for hazardous substances and chemicals.***

▌

***(6c) The European Chemicals Agency can develop guidance to the new Annex IX under Directive 2011/65/EU and, when applicable in this regard, reference can be made to the already available guidance for Annex XV to Regulation (EC) No 1907/2006 in respect of the specific aim of the Directive 2011/65/EU and the criteria given in Article 6(1).***

(7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.

***(8) In order to ensure that this Directive is coherent with any future amendment of Regulation (EC) No 1907/2006, or of other future Union law concerning sustainability criteria for hazardous substances and chemicals, the Commission should assess whether an amendment of Articles 5 and 6 of this Directive is required. Where appropriate, the Commission should propose amendments to this Directive in a future regulation amending Regulation (EC) No 1907/2006 or in other future Union law concerning sustainably criteria for hazardous substances and chemicals.***

(8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of ***20*** months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.

(9) Directive 2011/65/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Amendments to Directive 2011/65/EU**

Directive 2011/65/EU is amended as follows:

(1) Article 5 is amended as follows:

(a) paragraphs 3 and 4 are replaced by the following:

‘3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 (‘the Agency’) in accordance with Annex V.

4. The Agency shall:

(a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;

(b) verify that the application contains all the elements laid out in Annex V;

(c) if necessary ***and within 45 days of receipt of the application***, request the applicant to complete the application ▌ and provide an appropriate deadline ***of maximum 60 days to do so. If the volume and the complexity of the application is such that the Agency cannot comply with the 45 days period, the Agency shall inform the applicant of any extension and of the reasons for it, as soon as possible, and in any case before the end of that period. Upon duly justified request of the applicant introduced within the period provided for completing the application and where the volume and the complexity of the application is such that the 60 days period cannot be complied with, the Agency may extend that period. The Agency shall decide on such extension within 5 working days of the request***;

(d) make the application and any supplementary information supplied by the applicant available to Member States;

(e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency's website;

(f) invite interested parties to submit information within 3 months of its publication on the Agency's website.

Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in accordance with the first subparagraph, point (c), the Agency ***shall*** reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete.

Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).**'**;'

(b) the following paragraph 4a is inserted after paragraph 4:

'4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.

The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:

(a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);

(b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;

(c) may request the applicant or third parties to submit, within a specified period, additional information;

(d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;

(e) shall adopt their final opinions, taking into account the comments from the applicant.

Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c).

The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency.

The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website***, including any requests made in accordance with point (c) of the second subparagraph***.

For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.;’

***(ba) paragraph 5 is replaced by the following:***

***'5. An application for renewal of an exemption shall be made no later than 18 months before the exemption expires. The Commission shall adopt the decision on the application within 9 months of receipt of the opinions from the Agency. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.''***

(c) paragraph 8 is replaced by the following:

'8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.;'

***(d) the following paragraph 9 is added:***

***'9. The Commission shall publish guidelines to facilitate the harmonised application of this Article.''***

(2) in Annex V, the following paragraph is added:

'In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application. '

(3) Article 6 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

'With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission periodically ***and at least every four years*** on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.;'

(b) in paragraph 1, the fourth subparagraph is deleted.

(c) paragraph 2 is replaced by the following:

‘2. The review and amendment of the list of restricted substances***, or a group of substances,*** in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State.

The Agency or a Member State shall take into account any available information and any relevant ▌ assessment submitted for the purposes of other Union legislation covering ***any part of*** the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.

The restriction dossier shall comply with the requirements set out in ***Article 6(1)***, ▌ and shall, in addition, contain the information ***contained in Annex IX.***

(4) the following Articles 6a, 6b and 6c are inserted:

‘Article 6a

Initiation of procedure for review and amendment of the list of restricted substances

1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.

2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.

3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II ***on the Agency's website***.

4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.

5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.

   Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.

6. Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the publication of the dossier, the following:

   (a) comments on dossiers and the suggested restrictions;

(b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.

The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) ***No 1907/2006 for those requirements that relate to the criteria set out in Article 6(1).***

Article 6b

Opinion of the Agency's Committees

1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction ***according to Annex IX,*** is appropriate in reducing the ***detrimental effects and exposure described in*** Article 6(1)▌. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).

2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).

3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.

4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.

5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.

6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

Article 6c

Submission of an opinion to the Commission

1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.

2. The Agency shall publish the opinions of both Committees on its website without delay.

3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.;’

*(4a) Article 20 is amended as follows:*

*‘(a) paragraph 1 is replaced by the following:*

*‘1. The power to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21. '*

*(b) the following paragraph 1a is inserted after paragraph 1:*

*‘1a. 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) In Article 24, the following paragraph 3 is added:*

*‘3. Taking due account of any regulatory developments concerning the status of the resources and the governance of the scientific committees of the European Chemicals Agency, the Commission shall monitor the situation regarding the tasks, workload and remit of the scientific committees, and where necessary present a legislative proposal to amend accordingly this directive.’*

*(6) The following Annex IX is added:*

*'ANNEX IX*

*Dossiers for restriction proposals*

*The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:*

*(1) The identity of the substance or substances;*

*(2) a precise and clear wording of the entry of the proposed restriction in Annex II;*

*(3) references and scientific evidence for the restriction;*

*(4) information on the use of the substance or the group of similar substances in EEE;*

*(5) information on detrimental effects and exposure in particular during waste EEE management operations;*

*(6) information on possible substitutes and other alternatives, their availability and reliability;*

*(7) justification for considering a Union-wide restriction as the most appropriate measure;*

*(8) socioeconomic assessment.'*

*Article 2*

The provisions under this Directive shall be applicable from [OJ: ***20*** months after the publication of this Directive].

*Article 3*

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

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels,

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

Council of the European Union

**Brussels, 26 June 2025**
**(OR. en)**

**10883/25**
**ADD 3**

**Interinstitutional File:**
**2023/0455 (COD)**

**ENV 600**
**CHIMIE 62**
**FOOD 56**
**SAN 386**
**AGRI 311**
**MI 478**
**RECH 307**
**COMPET 625**
**CODEC 910**

**OUTCOME OF PROCEEDINGS**

| | |
|---|---|
| From: | General Secretariat of the Council |
| To: | Delegations |
| Subject: | Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals |

Delegations will find in the Annex the final consolidated text of the abovementioned proposal endorsed by the Permanent Representatives Committee meeting on 25 June 2025.

**ANNEX**

**PE-CONS No /YY - 2023/0455(COD)**

# REGULATION (EU) 2025/...
# OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**of...**

**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**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, 168(4)(c), 192(1) and 207 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,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability[2] ('the Strategy') is a crucial delivery of the 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.

(2) In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.

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1 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)0640).

2 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)0667).

(3) The reattribution of certain existing scientific and technical tasks to the European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the 'one substance, one assessment' aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council[3], aiming to achieve the same objectives.

(4) As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation. [4]

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[3] Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency.

[4] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)0193) [*OJ:Please insert correct reference once the Regulation is adopted*].

(5) To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.

(6) To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009 of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.

(7) To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have ***led*** to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.

(8) Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies***, taking into consideration the objective of ensuring a high level of protection of the environment and human health, including of vulnerable groups***. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve ***divergence in*** scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the divergence, should they refer to risk managers. ***In addition, when referring to risk managers, they should explain the reasons underlying the divergence in opinions, including potential methodological differences.***

(9) In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance ***with*** Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the 'one substance, one assessment' vision as regards uniformity of hazard assessments of chemicals across the Union***, enhancing the protection of human health and the environment***. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002.

(10) To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council[5], the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[6]. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines.

(11) To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

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5 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).

6 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).

(12) The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.

***(12a) For the preparation and update of the guidelines referred to in Article 3(2) and 3(3) of this Regulation, the European Chemicals Agency should involve the necessary expertise in the field of medical devices.***

(13) Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022[7], reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices.

(14) To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021[8]. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated.

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7 Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7).

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

***(14b) The amendment of the Regulation (EU) 2019/1021 introduced by this Regulation expands the tasks, workload and remit of scientific committees of the European Chemicals Agency, in particular of its Committee for Socio-economic Analysis. In order to provide adequate expertise, support, and thorough scientific evaluations, appropriate and stable resources, capacity and governance of the scientific committees should be ensured. For that purpose, Regulation (EU) 2019/1021 should be adapted to reflect any future revision of the provisions governing the functioning of the committees of the European Chemicals Agency. In line with any such revision, the Commission should assess whether an amendment of Article 8 of Regulation (EU) 2019/1021 is required.***

(15) In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.

(16) As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.

(17) The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council[9] requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and 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[10] will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021.

(18) Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

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

10 [OJ Please insert reference once proposal is adopted]

Article 1

Amendments to Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 is amended as follows:

(1) in Article 23, the following point (m) is added:

‘(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals;’

***(1a) in Article 27, paragraph 4, point (b) is replaced by the following:***

***(b) in those circumstances identified in Article 30(2), where the Authority and a national body are obliged to cooperate;***

(2) Article 30 is replaced by the following:

‘Article 30

Diverging scientific opinions

1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues.

The Authority and the body concerned shall cooperate to resolve the divergence***, taking into consideration the objective of a high level of protection of health and the environment.*** If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues***,*** identify the relevant uncertainties in the data ***and the underlying reasons for the diverging opinions, including on methodological differences, and*** be made publicly available.

Where the body concerned is a Union agency or a scientific committee, the Authority shall present the joint report to the Commission.

3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008[1] of the European Parliament and of the Council, the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.’

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[1] 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.

Article 2

Amendments to Regulation (EC) No 401/2009

Regulation (EC) No 401/2009 is amended as follows:

(1) in Article 2, the following point (p) is added:

‘(p) to develop assessment methodologies related to chemicals in the fields falling within its mission;’;

(2) in Article 15, ▌ paragraph ***1 is amended as follows***:

‘***1***. The Agency shall ***actively seek the cooperation of the Commission and*** other ***Union*** bodies ***and programmes, and*** notably ***the Joint Research Centre, the Statistical Office of the Union (Eurostat),*** the European Chemicals Agency, the European Food Safety Authority ▌ and the European Medicines Agency, ***and the Union’s environmental research and*** development ***programmes. In particular:***

***(a) Cooperation with the Joint Research Centre shall include the tasks set out in*** Annex ***I under A;***

***(b) Coordination with Eurostat and the statistical programme of the Union shall follow the guidelines outlined in Annex I under B;***

***(c) Cooperation with the European Chemicals Agency, the European Food Safety Authority and the European Medicines Agency shall relate to the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and to the development of scientific methodologies for the assessment of chemicals.’;***

***(3) in Article 15, paragraph 4 is amended as follows:***

***'4. The cooperation referred to in paragraphs 1, 2 and 3 must take account, amongst others, of the need to enhance coherence, synergies and to avoid any duplication of effort.***'.

Article 3

Amendments to Regulation (EU) 2017/745

Annex I to Regulation (EU) 2017/745 is amended as follows:

(1) in Section 10.4.1, point (b) is replaced by the following:

'(b) substances which are ***classified*** as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.';

(2) in Section 10.4.2, point (d) is replaced by the following:

‘(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.’;

(3) Section 10.4.3 is replaced by the following:

‘10.4.3. Guidelines on phthalates

When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.’;

(4) Section 10.4.4 is replaced by the following:

‘10.4.4. Guidelines on other CMR and endocrine-disrupting substances

The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate. ▌ ’

Article 4

Amendments to Regulation (EU) 2019/1021

Regulation (EU) 2019/1021 is amended as follows:

(1) Article 8(1) is amended as follows:

(a) the following point (i) is added:

‘(i) upon request from the Commission, and within 12 months from that request, draw up and ***submit*** a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.’;

(2) Article 8(1a) is added:

‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:

(a) ▌information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;

(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;

(c) an analysis of the impacts of the different concentration limit values considered;

(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.

The Agency shall, as soon as it receives the request referred to in ***Article 8(1)***, point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.

At the latest 9 months following the submission of ***the*** report ***referred to in Article 8(1), point (i)***, the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.';

(3) in Article 13, paragraph 2 is replaced by the following:

'2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.

Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information**'**;'

(4) in Article 15, paragraph 2 is replaced by the following:

‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, ***in order*** to amend Annexes IV and V ***to this Regulation*** to adapt them to the changes to the list of substances set out in ▌ Annexes ***I, II or III to this Regulation or to modify existing entries in Annex IV and V to this Regulation*** to adapt them to scientific and technical progress***, including developments in waste treatment and decontamination technologies or new scientific information regarding health and environmental impacts associated with a presence of a substance in waste***.’;

(5) Article 18 is amended as follows:

(a) The first sentence of paragraph 2 is replaced by the following:

‘2. ▌ The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 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]***.’;

(b) The first sentence of paragraph 3 is replaced by the following:

‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’;

(c) Paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and 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 two months at the initiative of the European Parliament or of the Council***.’;

***(5a) the following Article 21b is inserted:***

***‘Article 21b***
***Review***

***Taking due account of any regulatory developments concerning the status of the resources and the governance of the scientific committees of the European Chemicals Agency, the Commission shall monitor the situation regarding the tasks, workload and remit of the scientific committees, and where necessary present a legislative proposal to amend accordingly this regulation.’***;

***(5b) in Annex IV, table 1, row 4, the text in the fourth column is replaced by the following:***

‘1 500 mg/kg

***By 30 December 2027,*** the Commission shall review that concentration limit and shall, where appropriate, adopt ***a delegated act in accordance with Article 15(2)*** to lower that value ▌.’;

***(5c) in Annex IV, table 1, row 11, the text in the fourth column is replaced by the following:***

‘5 µg/kg ([2])

***By 30 December 2027,*** the Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value ▌.’;

***(5d) in Annex IV, table 1, row 26, the text in the fourth column is replaced by the following:***

‘500 mg/kg

***By 30 December 2027,*** the Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value to not higher than 200 mg/kg ▌.’;

***(5e) in Annex IV, table 1, row 29, the text in the fourth column is replaced by the following:***

‘1 mg/kg
(PFOA and its salts),
40 mg/kg
(sum of PFOA-related compounds)
***By 30 December 2027,*** the Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value ▌.’;

***(5f) in Annex IV, table 1, row 30, the text in the fourth column is replaced by the following:***

‘1 mg/kg
(PFHxS and its salts), 40 mg/kg
(sum of PFHxS-related compounds)
***By 30 December 2027,*** the Commission shall review that concentration limit and shall, where appropriate, adopt a ***delegated act in accordance with Article 15(2)*** to lower that value ▌.’.

Article 5

Entry into force

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

Done at Brussels,

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