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From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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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 - Mandate for negotiations with the European Parliament

With a view to the meeting of the Permanent Representatives Committee on 12 June 2024, delegations will find in the Annex the Presidency compromise text on the abovementioned proposal. Changes compared to the Commission proposal are marked in ***bold italic*** for the additions, in ~~strikethrough~~ for the deletions.

ANNEX

Proposal for a

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

(Text with EEA relevance)

PUBLIC

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 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.

PUBLIC

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) 640 final.

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) 667 final,

(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to ***modernise the integration of information with a view to reducing the administrative burden and to*** facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals *acquis*. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the ~~general~~ public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.

(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[3], harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of 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.

[3] Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p. 22).

(4) In its communication of 19 February 2020 on a European strategy for data[4], 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 relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.

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

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

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

(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the ~~general~~ public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the ~~general~~ public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution. ***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 ***all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I, ***unless specified 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 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.

PUBLIC

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

While some medicinal products are also chemicals and could 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, identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment. 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.

PUBLIC

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

Considering the format thiese data ~~are~~ is in and the effort it would require to transform ~~them~~ it into an appropriate format, for efficiency reasons, only data that is submitted to the EMA in the context of the relevant procedures that ~~are~~ are ~~is~~ finalised after the entry into force of this Regulation should be included in the common data platform.

(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, data related to other substances contained in medicinal products besides active substances and data that is submitted to the EMA in the context of the relevant procedures that are finalised before the entry into force of this Regulation. 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 close cooperation 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.

PUBLIC

(9b) 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 ~~the~~ coherence~~y~~ and the efficient~~ey~~ delivery of hazard and risk assessments of chemicals, and to adapt to technical and scientific progress in the field of chemicals, the power to adopt acts in accordance with Article 290 of the Treaty of the Functionning 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[6], 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[7] of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.

(11) To safeguard the ability of the European Commission, of the Union agencies working on chemicals and of the competent Member State authorities (hereinafter 'the Authorities'), to carry out their tasks, documents with chemicals data relating to their internal work or decision-making should in principle not be included in the common data platform.

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6 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).

7 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).

PUBLIC

(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and 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 this data is processed by the Authorities.***

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

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

(15) To ensure the protection of legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities, exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I should apply only to the disclosure of the data and information submitted or generated in compliance with those acts. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[8], 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[9] 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.

PUBLIC

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8 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).

9 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[10], and the Member State competent authorities should comply with Regulation (EU) 2016/679 of the European Parliament and of the Council[11].

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

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

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10 ***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).***

11 ***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. 1–88).***

(18) The Commission should adopt an implementation plan identifying initial 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[12]. 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, ***and*** 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.

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

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

(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available. ***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, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. ***Other parties, such as Member States, scientific bodies of Member States or national authorities, should be able to offer chemicals data to the Agencies or the Commission for hosting and maintenance. In such case, it should be for the Agencies or the Commission, as the case may be, to decide whether to respond positively to the offer.***

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

PUBLIC

(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA. ***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, hosting, and maintaining human biomonitoring data. ~~To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA should process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council[13]. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.~~

[13] 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).

(24a) The EEA, ECHA, EFSA, EMA 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, the Commission, the ECHA, the EFSA and the EMA 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 the 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.

PUBLIC

(24b) The EEA 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 develop health risk and impact indicators, to monitor the impact of regulatory intervention., and to support regulatory risk assessments, risk management and policy making. The Commission should be allowed to process human biomonitoring data constituting personal data, notably for scientific research, to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure of populations to chemicals, to develop indicators on health risks associated to such exposure, as well as to measure the efficiency and effectiveness of regulatory measures in preventing exposure by analysing, for example, co-exposure to multiple chemicals for which data on co-occurrence of various chemicals per individual is necessary to observe common patterns and draw conclusions for populations, and supporting further risk assessments and risk management. The ECHA should also be allowed to act as a data processor for human biomonitoring data constituting personal data for the performance of assessments on chemicals, such as risk and safety assessments. Individual measurements of chemicals in human matrices may assist regulatory exposure and risk assessment, such as in the formulation of an opinion of the ECHA's Risk Assessment Committee, and lead to recommendations of risk management measures. The EFSA and the EMA should also be allowed to act as a data processor for human biomonitoring data constituting personal data, notably to support the prioritisation of regulatory actions. Such data is also useful for EFSA when conducting assessments of chemicals in food and for understanding the effectiveness of existing measures in preventing human contamination through the food and feed chains. When processing human biomonitoring data constituting personal data, the EEA, the ECHA, the EFSA, the EMA and the Commission should pay particular attention to compliance with Article 13 of Regulation (EU) No 2018/1725.

PUBLIC

(24c) Human biomonitoring data collected prior to the coming into force of this Regulation is necessary to ensure the completeness, quality, and relevance of the human biomonitoring datasets for the purposes of guaranteeing the substantial public interests, and scientific research purposes as listed in 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.

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

(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.

(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II. The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the ~~general~~ public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable. ***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. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. ***The ECHA should also develop guidance for duty holders to facilitate the implementation of the notification obligation, including details as regards the ty~~p~~pe of studies requiring notification.*** In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.

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

(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution and a decision on the confidentiality of the data contained in that regulatory dossier was taken by that Union or national institution. In addition, in order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases.

PUBLIC

(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated ***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 on the compliance with the obligations laid out in Article 22.

PUBLIC

(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that ~~is~~ ***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 substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.

PUBLIC

(37) The existing 'The EU Chemicals Legislation Finder'[14] 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.

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

[14] 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).

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

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

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[15] and (EU) No 528/2012[16] 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 .

(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, 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 ***of chemicals data***, implementing powers should be conferred on the Commission.

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15 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).

16 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).

(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA and the ECHA should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. The EFSA, the EMA, the EU-OSHA and the Commission shall regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of indicators into the common data platform.

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

PUBLIC

(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[17] ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market.

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

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

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

(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy. ***Where relevant and whenever possible, information generated through studies commissioned by the ECHA should be generated by means other than vertebrate animal tests***.

PUBLIC

(49) In order to adjust the contents of Annex I ~~and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted~~***, which should list all Union acts under which chemicals data is generated or submitted to the Authorities, 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,*** ~~and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance-One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[11]. 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.~~

(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.

~~[11] OJ L 123, 12.5.2016, p. 1.~~

(***49b***) ***In order to adjust the content of Annex III, which should list all Union acts under which chemicals data is generated or submitted to the Authorities 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 chemicals data and information is generated or submitted, as soon as these Union acts enter into force or are revised, unless otherwise provided.***

(49c) 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[18]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on ***29 January 2024*** ~~[*OP: Please insert the date of the opinion of the EDPS*]~~.

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

HAVE ADOPTED THIS REGULATION:

PUBLIC

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' trust in the scientific base for the decisions taken under Union legal acts on chemicals.

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

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

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

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

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

The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3***,*** ***paragraphs*** 2 ***and 2a***.

PUBLIC

Article 2

Definitions

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

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

2. ‘Authorities’ means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;

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

4. ‘business operators’ means duty holders which are private or public undertakings;

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

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

7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I ~~or Annex II~~;

8. ‘originating Union act’ means the Union act under which chemicals data and information were generated or submitted;

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

10. ‘chemicals data’ means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;

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

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

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

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

12. ‘personal data’ means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 ~~of the European Parliament and of the Council~~ and as defined in Article 3, point ~~(16)~~ ***(1)***, of Regulation (EU) 2018/~~175~~ ***1725*** ~~of the European Parliament and of the Council~~;

PUBLIC

13. ‘processing’ means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 ~~of the European Parliament and of the Council~~ and as defined in Article 3, point (3), of Regulation (EU) 2018/~~175~~ ***1725*** ~~of the European Parliament and of the Council~~;

14. ‘data controller’ means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of Regulation (EU) 2018/~~175~~ ***1725*** ~~of the European Parliament and of the Council~~;

14a. ‘third party’ means third party as defined in Article 3, point (14) of Regulation (EU) 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’).

PUBLIC

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

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

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

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

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 submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation; and

(b) 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

PUBLIC

(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 2011/83/EC of the European Parliament and of the Council[19] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[20]; or*
- *data related to environmental risk assessments, compiled pursuant to Regulation (EU) No 470/2009 of the European Parliament and of the Coucil[21]; 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[22]*

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

- *point a of Article 3(2a), by including, where necessary to ensure coherence and the efficient delivery of hazard and risk assessment of chemicals and to consider new scientific discoveries, in particular on the hazard or risk to the environment or human health, data that EMA holds on procedures concluded before the entry into force of this Regulation;*

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19 *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).*

20 *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).*

21 *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).*

22 *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).*

PUBLIC

- ***point b of Article 3(2a), by including, other data related to substances contained in medicinal products besides active substances or active substances with other properties 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;***
- ***point c of Article 3(2a), by adding new categories of data types presenting an interest for the objectives of this Regulation or, in view of developed scientific knowledge, there is new data on the hazard or risk to the environment or human health.***

3***a***. 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[23];

(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[24] 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.

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23 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).

24 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;

(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 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 of Article 4, point c), 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 and transmission of chemicals data to the common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.

PUBLIC

10. The Commission or ***a*** ~~A~~gency~~*y*~~***ies*** 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***[25].

11. The common data platform and its dedicated services shall be established by [*OP: please insert date: three years after the date of entry into force of this Regulation*], unless specified otherwise. The relevant datasets ***of chemicals data, including chemicals data generated or submitted before the entry into force of this Regulation, unless spcified 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. Upon integration of those datasets ***of chemicals data*** in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.

Article 4

Implementation plan and governance of the common data platform

1. By [*OP please insert date: 6 months after the date of entry into force of this Regulation*] the Commission shall ***by means of an implementing act*** adopt ~~and publish~~ an implementation plan identifying ~~datasets~~ ***chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion ~~by means of an implementing decision~~. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.

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25 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).

2. The Commission shall, by means of an implementing ~~decision~~ ***act***, establish and manage a platform steering committee, which shall include ~~one~~ representative***s*** from ~~the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from~~ ***each of the Agencies and*** the Commission.

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

4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing ~~decision~~ ***act.***

5. That governance scheme shall describe:

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

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

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

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

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

   (f) the operation of the steering committee itself.

PUBLIC

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 according to their mandate and offered to them by Member States or other parties.***

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, in a standard format, where available, together with the relevant context data as referred to in Article 4(4) ***(5)***, point (c). The Commission and the Agencies shall indicate whether that data or information is ~~made available to the public~~ ***confidential in accordance with the provisions on confidentiality*** under the originating Union act.

3. The ECHA shall host and maintain occurrence data related to workplace monitoring.

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

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

6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [*OP please insert: date of the entry into force of this Regulation*].

PUBLIC

7. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.

8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.

9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing ~~them~~ ***it*** to the ECHA.

10. The Commission and the Agencies shall act as data controllers for any personal data stored in the platform.

Article 6

Human biomonitoring data

1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries. ***Where it concerns occupational human biomonitoring data, the EEA shal 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.

~~3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.~~

PUBLIC

4.*3.* ***The EEA may process h***uman biomonitoring data constituting personal data ~~may be processed by the EEA~~ 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***;***

(f) supporting regulatory risk management;

(g) supporting policy making and legislative ~~process~~developments at Union level;~~.~~

(h) facilitating the processing by the Commission, the ECHA, the EFSA and the EMA in accordance with ~~to~~ paragraphs~~rpals,~~ 4, 5, 6 and 6a of this article. ~~eile~~

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

(a) scientific research aimed at policy making

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

(c) monitoring time and spatial trends in exposure;

(d) developing health risk and impact indicators;

(e) monitoring the impact of regulatory intervention;

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

(g) supporting regulatory risk assessment and risk management.

PUBLIC

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

(a) evaluating and prioritising required regulatory action;

(b) performing assessments of chemicals;

(c) supporting regulatory risk management;

(d) as part of the commissioning of studies under the data generation mechanism referred to in Article 21.

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

(a) evaluating and prioritising required regulatory action;

(b) performing assessments of chemicals;

(c) supporting regulatory risk management.

6a. The EMA may process human biomonitoring data constituting personal data for the following purposes only:

(a) evaluating and prioritising required regulatory action;

(b) performing assessments of chemicals

(c) supporting regulatory risk management.

7. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA, the EMA or the Commission for the abovementioned purposes shall not entail the sharing of such data with third parties.

~~5~~ ***8***. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.

~~6.~~ ***9.*** The EEA***, the ECHA, the EFSA, the EMA and the Commission*** shall act as data controller for the human biomonitoring ***data constituing*** personal data ~~it~~ ***they*** hold~~s~~ or host~~s~~ ~~and~~ **or** process~~es~~ for the purposes referred to in paragraph***s*** ~~2~~ **2,** ***3,4,5,6 and,8***.

10. The EEA, the ECHA, the EFSA, the-EMA and the Commission shall define the storage period and any review thereof for the human biomonitoring data constituting personal data they hold as well as the criteria used to define the storage period.

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

PUBLIC

Article 7

Information Platform for Chemical Monitoring

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

2. At the latest by [*OP please insert date: 3 years after the date of entry into force of this Regulation*], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.

3. At the latest by [*OP please insert date: 3 years after entry into force of this Regulation*], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5.

4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.

5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.

6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.

Article 8

Repository of reference values

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

2. The ECHA shall include any reference value adopted under Union acts listed in Annex I ~~or Annex II, Part 1,~~ in the repository of reference values without undue delay.

3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I**, *Part 1***, or the reference values referred to in Annex II, ~~Part 2,~~ shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.

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

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

PUBLIC

Article 9

Database of Study Notifications

1. The ECHA shall establish and operate a Database of Study Notifications by [O*P please insert date: two years after the date of entry into force of this Regulation*].

2. The ECHA shall store in the Database of Study Notifications the ***chemicals*** data notified to it in accordance with Article 22.

3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.

3a. 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.

4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.

5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.

PUBLIC

Article 10

Information on regulatory processes on chemicals

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

2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.

   For each regulatory process or activity, the following information shall at least be transmitted:

   (a) the substance identity;

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

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

   (d) status of the regulatory process or activity;

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

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

PUBLIC

3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:

   (a) substance identity;

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

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

   (d) status of the regulatory process or activity;

   (e) ***where applicable,*** 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.

PUBLIC

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 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 Anne~~xxes~~ I ~~and II~~, the ECHA shall include them in the common data platform.

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

Article 13

Database on environmental sustainability related data

1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.

PUBLIC

2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.

3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.

4. By [*OP* please *insert date: three years after the date of entry into force of this Regulation*], the Commission shall**,** ~~adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities~~ ***in consultation with Member States, identify existing datasets of chemicals data on environmental sustainability related data, other than those referred to in paragraphs 2 and 3, and request the ECHA to host and maintain them in accordance with Article 5(1).***

PUBLIC

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 Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.

PUBLIC

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[26];

(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[27];

(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[28];

(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[29];

(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[30];

(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[31];

PUBLIC

[26] 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).

[27] 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).

[28] 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).

[29] 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).

[30] 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).

[31] 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).

(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [32];

(h) Commission Regulation (EU) No 234/2011[33];

(i) Directive 2009/48/EC of the European Parliament and of the Council;[34]

(j) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[35];

(k) Regulation (EC) No 396/2005 of the European Parliament and of the Council[36].

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.

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32 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).

33 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).

34 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).

35 ***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).***

36 ***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).***

8. The Commission shall adopt an implementing ~~decision~~ ***act,*** to remedy the divergence.

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 and as open datasets;

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(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~~ ***act,*** ~~to~~ remedy the divergence.

Chapter IV

CHEMICALS DATA CONFIDENTIALITY AND USE

Article 16

Access rights and transparency

-1. The public shall have access to all the chemicals data contained in the common data platform, except data which is deemed to be confidential under Article 5(2), second sentence.

PUBLIC

1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.

2. The Authorities shall take the necessary measures***, including security measures,*** to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2)***, second sentence,*** is not made ***available to the*** public.

~~3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.~~

Article 17

Use of chemicals data contained in the common data platform

1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development***,*** ~~or~~ implementation ***or enforcement*** of chemicals legislation and policy.

2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.

3. When using chemicals data ~~contained in the common data platform that is deemed confidential under Article 5(2), second sentence~~ ***as provided for in paragraph 1***, the Authorities shall respect the confidentiality of ~~information~~ **that** data as marked by the originator. ~~and shall not disclose that data to the public without the consent of the originator.~~

PUBLIC

Chapter V

MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS

PUBLIC

Article 18

Framework of indicators

1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall***, in consultation with Member States,*** establish, operate, ~~and~~ maintain ***and update as appropriate*** a***n indicative*** framework of indicators to monitor ***chemical pollution along the chemical's lifecycle, including emissions and occurrence, to monitor*** the drivers and impacts of exposure to chemicals, ***and to*** measure the effectiveness of chemicals legislation and ~~measure~~ the transition towards the production of safe and sustainable chemicals.

2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.

Article 19

Early warning and action system for emerging chemical risks

1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [*OP please insert date: one year after the date of entry into force of this Regulation*].

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

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

(b) ~~existing~~ national early warning systems;

(c) data that the EEA holds***, including 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.

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

3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.

4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. ┣The first report shall be prepared by [*OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation*]. The EEA shall present this report to the ~~Commission, relevant Union agencies and Member State competent a~~***A***uthorities ~~for consideration of the need for regulatory or policy~~***. The Authorities ~~who~~ shall consider undertaking regulatory or policy actions accordingly ~~or~~ and justify if they decide not to proceed with any*** action related to the early warning signals.

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

PUBLIC

Article 20

Observatory for specific chemicals with potential contribution to emerging chemical risks

1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.

2. By [*OP please insert date: 6 months after the date of entry into force of this Regulation*] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing ~~decision~~ ***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 ~~datasets~~ ***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~~d~~*** informed societal discussion and ~~increase~~ public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.

Chapter VI

DATA GENERATION MECHANISM

Article 21

Data generation mechanism

1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I**,** ***Part 1*****,** within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.

2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.

3. The ECHA shall only commission scientific studies when results cannot be obtained through ~~existing legal provisions or processes under~~ ***any of the*** Union ~~legislation~~ ***acts on chemiecals*** listed in Annex I, *Part 1*. 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.

PUBLIC

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

PUBLIC

Chapter VII

NOTIFICATION OF STUDIES

Article 22

Notification of studies

1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ~~without undue delay~~ ***within one month from the date of ~~the~~ the commissionning***, any studies ~~on~~ ***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~~, prior to placing on the market,~~ 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***, study falls under the notification obligation of paragraph 3. At the time of the commissionning 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 ***identity of the chemical(s) 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 undue delay, notify any study commissioned by business operators to support a***n application, notification or*** regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I***, 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 ***identity of the chemical(s) 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: 24 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 national security and defence.

7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.

PUBLIC

Chapter VIII

DELEGATED POWERS *AND COMMITTEE PROCEDURE*

Article 23

Amendment of Annexes I, II and III

1. ~~The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.~~ ***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~~, where relevant, new categories of data types~~ ***new reference values derived under Union legislation on medicinal products, taking into account advances in digitalisation and interoperability as well as the values' relevance ~~when~~for other chemicals policy and regulatory areas.***

PUBLIC

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

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.

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 . This committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

PUBLIC

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Chapter IX

ENFORCEMENT AND PENALTIES

Article 25

~~Enforcement~~ ***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~~ ***to inform and notify*** in ***accordance with*** 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.

PUBLIC

Chapter X

REVIEW AND ENTRY INTO FORCE

Article 26a

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 whether it is appropriate to include in the common data platform the following chemicals data relating to medicinal products pursuant to Article 3(2a) of this Regulation:

(a) chemicals data that the EMA holds resulting from procedures concluded before the entry into force of this Regulation and 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 and held by national competent authorities and not by the Agencies;

The cost-benefit balance of incorporating additional data in the common data platform shall be assessed.

2. By … [OP: please insert ten 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 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.

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*

PUBLIC

PUBLIC

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)

PUBLIC

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)
~~28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)~~
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)

PUBLIC

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)

PUBLIC

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)

PUBLIC

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].

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).***

PUBLIC

ANNEX II

~~UNION ACTS REFERRED TO IN ARTICLES 2, 3, 12, 17 AND 23 AND~~ REFERENCE VALUES REFERRED TO IN ARTICLE 8

PUBLIC

~~**Part 1** - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products~~

~~1. 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 and Regulation (EC) No 726/2004 of the European Parliament and of the Council ;~~

~~2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council; and~~

~~3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 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, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.~~

~~**Part 2** -~~ Reference values to be included in the repository of reference values following Article 8(3)

1. 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.

PUBLIC

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)

PUBLIC

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)
~~21. 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)~~
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)

PUBLIC

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].

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