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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16961/23 + ADD 1
Subject:	OSOA Package: Ad Hoc Working Party on One Substance One Assessment on 13 May 2024: Regulation on common data platform on chemicals - Revised Presidency text

With a view to the above AHWP, delegations will find attached a revised Presidency text concerning the common data platform on chemicals.

Final version

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)

ANNEX to the Steering note:
PRESIDENCY revised text for consideration at the OSOA AHWP 13/5/2024

PRESIDENCY REVISED TEXT

Delegations will find below a **revised** Presidency text proposal.

Changes to the Commission proposal are marked in ***red bold underline italics*** for additions and in ~~red strikethrough~~ for deletions. The changes in the PRES proposal compared to WP3 are highlighted in yellow (be aware that the yellow might not appear if you activated in word the option review>tracking>all markup, please chose "simple markup").

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)

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

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

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Green Deal34 sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability35 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.

(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 reduce 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-

Commented [A1]: PRES: to meet the requests of certain delegations, suggestion to further specify the objectives of the regulation.

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.

Commented [A2]: PRES: for consistency, as this was deleted elswhere

11 (3) Under Decision (EU) 2022/591 of the European Parliament and of the Council36, 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.

12 (4) In its communication of 19 February 2020 on a European strategy for data37, 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.

13 (5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act38 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.

14 (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, where relevant, including by means of physical and cybersecurity measures.***

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

16 (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.~~

~~The following chemicals data that the European Medicines Agency ('EMA') holds, related to active substances subject to Union acts on medicinal products present an interest for the objectives of this regulation: chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines, maximum residue limit values, as well as specific reference values, and should thus be included in the common data platform. 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. 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.~~

~~Medicinal data might present an interest for other regulatory areas. However, due to their particular nature, it is not yet clear if the cost-benefits balance of including those data is favourable, and thus clinical data should not be included in the common data platform. In order to further clarify this, the Commission should review the scope of the data to be included in the common data platform to assess whether it should be extended, and in particular for clinical data, to further support the objectives of this Regulation. The review should be conducted on the basis of an in-depth analysis, in close cooperation with the Member States and the Agencies.~~

(8) 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 EMA, only chemicals data related to active substances contained in medicinal products with a known added value. Relevant active substances are those covered by the medicines legislation and 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. 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 the EMA holds, as well as specific reference values.

16.a. new ***(8a) Other medicinal data hold by the EMA might present an interest for other regulatory areas, such as data related to other active substances of concern, clinical data, and data related to products and not only to active substances, amongst others. However, due to their particular nature,***

it is not yet clear if the cost-benefits balance of including those data is favourable, in particular for the workload of the EMA and confidentiality concerns.

~~*In order to further clarify this, the Commission should review the scope of the data to be included in the common data platform to assess whether it should be extended to further support the objectives of this Regulation. The review should be conducted on the basis of an in-depth analysis, in close cooperation with the Member States and the Agencies.*~~

16.b. new *(8b) Moreover, it is known from some of the regulatory regimes listed in Annex I that a relevant part of the data covered by this Regulation is held by the National Competent Authorities.*

Commented [A3]: PRES: to meet the requests of certain delegations

17 (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.~~

Commented [A4]: PRES: in order to have the scope clarified in a single place, this is moved to recital (8)

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

17.a *The Commission should therefore review the scope of the data to be included in the common data platform to assess whether it should be extended to further support the objectives of this Regulation. The review should be conducted on the basis of an in-depth analysis, in close cooperation with the Member States and the Agencies.*

18 (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 Council39, 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 1223/200940 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.

19 (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.

20 (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.*

21 (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.

22 (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. ***When the Authorities use data in the common data platform they shall respect Intellectual Property Rights.***

23 (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 Council41, 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 Council42 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.

23.a. new ***(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[XXX.1], and the Member State competent authorities ~~and any other user~~ should comply with Regulation (EU) 2016/679 of the European Parliament and of the Council[XXX.2] .***

footnote XXX.1
Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L, 295, 21.11.2018, p. 39 – 98).

footnote XXX.2
Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). (OJ L 119, 4.5.2016, p. 1–88).

24 (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.

25 (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

Commented [A5]: PRES: considering that only data that is not (or no longer) personal data may be made accessible to the public on the platform, PRES suggest to include a recital to recall that a data creator shall comply with GDPR

Commented [A6]: PRES: it has been indicated that this is not needed. PRES refers to the definition of Authorities provided in the proposal, and thus agrees with deletion. PRES proposes then to delete this part of the amendment.

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.

26 (18) The Commission should adopt an implementation plan identifying initial ***datasets of chemicals data*** ~~datasets~~ to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies43. 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*** ~~datasets~~ and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. The Commission should be represented by the services responsible for relevant chemicals related work areas. ~~The Commission should ensure that work areas related to chemicals but not under the remit of the EEA, EFSA, EMA, ECHA are considered by the steering committee.~~ ***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.

26 a. new ***(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.***

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

28 (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. ~~Other functions, such as those related to data quality management (such as completeness, accuracy and validity), shall be controlled by the originator in accordance with the originating Union act under which it was submitted.~~ ***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.***

29 (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 for hosting and maintenance. In such case, it should be for the Commission, as the case may be, to decide whether to respond positively to the offer.***

30 (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

Commented [A7]: PRES: considering inputs received from delegations, PRES proposes an alternative drafting proposal to clarify the involvement of the COM and the Agencies within the steering committee

Commented [A8]: PRES: in order to clarify which expert groups or in which format the Member States will be involved on different aspects of the legal text, PRES made multiple proposals throughout the text.

Referring to MS "experts" would not be advisable as it is not appropriate to have such a reference in a legislative act and there is no a legal definition in the text of what is "expert level", and how COM liaise is a matter of internal procedure.

PRES refers for the rest to point 3 of the steering note.

Commented [A9]: PRES: rewording suggestion

Commented [A10]: PRES: while Art 5(1) provides for the obligations for Agencies to host, maintain and make available data via the common data platform. This does not preclude the possibility for or right of the MS to offer chemicals data to the Agencies/COM for hosting and maintenance and further inclusion in the CDPC. This can be inferred from Article 5(1). To clarify this possibility, it is suggested to insert this amendment

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').

31 (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).***

32 (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, the ECHA, the EFSA, and the Commission 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 Council44. 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~~.

~~32.a. new~~ ~~(XXX) The ECHA, the EFSA and the Commission should also be able to process human biomonitoring data constituting personal data, including pseudonymised single measurement data, within their respective spheres of responsibility. The Commission should be allowed to act as a processor for human biomonitoring data constituting personal data to effectively monitor and oversee the effectiveness of existing measures, 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 those populations. The processing by the Commission would also enable the analysis and monitoring of the relations between exposure to chemicals and certain outcome diseases, as well as enable linking human biomonitoring data with other exposure sources such as environmental exposure, dietary exposure, and consumer product use. The processing would also assist in assessing the need for further regulatory action and prioritising such action. 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 should be able to support regulatory exposure and risk assessment, such as in the formulation of an opinion of the Risk Assessment Committee, and lead to recommendations of risk management measures. The EFSA should also be allowed to act as a data processor for human biomonitoring data constituting personal data. Such data is specifically useful for EFSA 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 and the Commission should pay particular attention to compliance with Article 13 of Regulation (EU) No 2018/1725 and article 89 of Regulation No 2016/679.~~

32.b. new ***(24a) The EEA, ECHA, EFSA and the Commission should be able to process human biomonitoring data constituting personal data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA, the Commission, the ECHA and the EFSA 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. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data.***

32.c. new	***(24b) The EEA, ECHA, EFSA and the Commission should be able to process human biomonitoring data constituting personal data. 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 act as a processor for human biomonitoring data constituting personal data for policy making, for monitoring and assessing the effectiveness of measures 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 for research purposes supporting policy making. 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 Risk Assessment Committee, and lead to recommendations of risk management measures. The EFSA 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 are 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. The Commission should also be allowed to process human biomonitoring data, notably to assess the impact of chemicals on human health and the environment, to support regularity risk assessment and risk management, and to support policy making. When processing human biomonitoring data constituting personal data, the EEA, the ECHA, the EFSA and the Commission should pay particular attention to compliance with Article 13 of Regulation (EU) No 2018/1725.***
32.d. new	***(24c) The lawful gathering of human biomonitoring data prior to the coming into force of this Regulation in full respect of personal data protection principles and other relevant legal provisions, is necessary to ensure the quality, accuracy, adequacy 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 human biomonitoring data gathered prior to the coming into force of this Regulation should be processed by the EEA, the ECHA, the EFSA and the Commission after this Regulation comes into force as part of any available human biomonitoring datasets.***
33	(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.
34	(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.
35	(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 level of a substance for which no maximum exposure level can be specified below which no harmful effects on human health are to be expected, the quantification of the statistical (cancer) risk associated with the respective reference level should also be specified, if available.

36 (28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.

37 (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.

38 (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 EN 27 EN
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.

39 (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.

40 (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.

41 (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.

42 (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.

43 (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.

44 (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.

45 (37) The existing 'The EU Chemicals Legislation Finder'45 project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service.

46 (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.***

Commented [A11]: PRES: suggestion to further clarify that MS will have the possibility to be involved in the development of the controlled vocabularies and standard formats.

47 (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.

48 (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.

49 (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 1107/200946 and (EU) No 528/201247 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 .

50 (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*** ~~datasets~~ on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability ***datasets of chemicals data*** ~~datasets~~, implementing powers should be conferred on the Commission.

51 (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.

52 (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.

53 (45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials48 ('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.

54 (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.

55 (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.

56 (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, through the use of alternative methods.*** ~~Information shall be generated, in particular for human toxicity, whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across).~~

57 (49) ~~In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant,~~ ***In order*** to expand, ***where relevant,*** 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 Annex~~es 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 201649. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all

Commented [A12]: PRES: general support for including text in this recital to clarify that animal testing should be minimalized; PRES suggests an alternative wording

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.

58 (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.

59 (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~~].

60 HAVE ADOPTED THIS REGULATION:

61 Chapter I
SUBJECT MATTER, SCOPE AND DEFINITIONS

62 Article 1
Subject matter and scope

63 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 ~~by design~~ 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.

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

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

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

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

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

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

70 Article 2
Definitions

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

72 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');

73 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;

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

75 4. 'business operators' means duty holders which are private or public undertakings;

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

77 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;

78 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;

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

80 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;

81 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;

82 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:

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

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

85 (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.

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

87 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 Regulation (EU) 2018/1725 ~~of the European Parliament and of the Council~~;

88 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~~ 2018/1725 ~~of the European Parliament and of the Council~~;

88.b. new ***14a. "third party" means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data; as defined in Article 3, point (14), of Regulation (EU) 2018/1725;***

89 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.

89.a. new ***16. 'The public' means one or more natural or legal persons, and associations, organisations or groups of such persons.***

89.b. new ~~17. 'Study to be notified' means any relevant experiment,~~ model or ~~measurement or set thereof in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties or its safety, that is commissioned 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 commissioned as part of a risk or safety assessment , prior to placing on the market, under~~

Commented [A13]: PRES: addition of the word "the" to the definition as the wording of public has different meanings throughout the text

~~the Union acts listed in Annex I.~~

90 Chapter II
INFORMATION SYSTEMS AND PLATFORMS

91 Article 3
Common Data Platform on Chemicals

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

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

94 (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;

95 (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~~;~~.

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

96.a. new (ca) ~~as well as to~~ (d) ~~the available context data of the data mentioned in the preceding paragraphs a, b~~ and c~~, to the extent that it is relevant for the purposes of the present regulation.~~

Commented [A14]: PRES: moved this to para 6, and rewording.

2a. The common data platform shall also provide access to data generated or submitted as part of the implementation of Directive 2001/83/EC of the European Parliament and of the CouncilXXX1 and Regulation (EC) No 726/2004 of the European Parliament and of the CouncilXXX2, Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3 and Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX4, as far as:

(a) they are held by EMA and submitted to EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation,
(b) either relates to active substances used for other applications regulated by other Union legislation covered by this Regulation, or is related to other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment,
(c) falls at least in one of the following category:
- 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 CouncilXXX and Regulation (EC) No 726/2004 of the European Parliament and of the CouncilXXX; or
- Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX; or
- Data used to derive Maximum residue levels ~~data~~ compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX

footnotes

XXX1 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).
XXX2 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).
XXX3 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).
XXX4 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).

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

98 (a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[50];

Footnote: 50 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

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

Footnote: 51 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).

99.a. new ~~(c) clinical data held by EMA under Directive 2001/83/EC of the European Parliament and of the CouncilXXX1 and Regulation (EC) No 726/2004 of the European Parliament and of the CouncilXXX2, Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3 and Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX4~~

~~Where relevant, by derogation to paragraph (a), 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.~~

3a. The common data platform shall also provide access to data submitted before the entry into force of this Regulation.

100 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.

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

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

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

104 (c) the database of study notifications referred to in Article 9;

105 (d) information on regulatory processes referred to in Article 10;

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

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

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

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

110 7. The data contained in the common data platform may be used in accordance with Article 17.

111 8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.

112 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.

113 10. The Commission or Agenc***ies*** ~~y~~ under whose authority chemicals data is included in the common

Commented [A15]: PRES: One delegation proposes to add an additional exclusion to the scope:

Article 3(3)(d) The information referred to in Article 9 of the Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents.

on the grounds that this information is similar to the information in Article 45 of the CLP regulation which is excluded from the data platform.

PRES invites delegations to indicate if this might be supported.

Commented [A16]: PRES: a review of the scope of the data to be included in the CDP could only be done through the normal legislative procedure. PRES then moves this to the review clause.

Commented [A17]: PRES: see para 2

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***[52].

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

114 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~~ ***chemicals data, according to paragraphs 2, 2a, 3 and 3a,*** ~~submitted under any of the Union acts listed in Annex I, including chemicals data submitted before the entry into force of this Regulation,~~ 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~~ ***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.

115 Article 4
Implementation plan and governance of the common data platform

116 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*** ~~decision~~ ***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~~. ***[That implementing act shall be adopted in accordance with the procedure referred to in paragraph 2 3 of Article 24a.]*** Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.

117 2. The Commission shall, by means of an implementing ~~decision~~ ***act***, establish and manage a platform steering committee, which shall include ***representatives from each of the Agencies and the Commission.*** ~~one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission. The Commission shall ensure that work areas related to chemicals but not under the remit of the EEA, EFSA, EMA, ECHA are considered by the steering committee.~~

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

119 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. [These implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 3 of Article 24a.]***

120 5. That governance scheme shall describe:

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

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

123 (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;

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

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

126 (f) the operation of the steering committee itself.

127 Article 5
Data Flows for the purpose of the common data platform

Commented [A18]: PRES considered that the establishment of the steering committee and the appointment of representatives would not need the explicit involvement of Member States, PRES therefore proposed to remove the implementing procedure in the WP3 proposal. After legal analysis and advice it was made clear that the COM would need to use implementing powers for establishing the steering committee, regardless of whether it is specifically mentioned in the Article. For clarity PRES proposes to revert back to the original wording by the Commission.

WP4 proposal:

2. The Commission shall**,** by means of an implementing ~~***decision***~~ ***act***, establish and manage a platform steering committee, which shall include,...

PRES noted that the COM made an additional proposal in written to specify the text, presenting two options, either making minor wording adjustments, or proposing to establish the steering committee within the governance scheme. PRES considered that the second option of creating the steering committee via the governance scheme would be a to drastic change of the text and thus proposes to include the first option instead.

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. ***Upon suggestion of a Member State,*** ~~a national Authority or a scientific body of a Member State~~***, after approval of the Commission, the Agencies shall host and maintain chemical data which are additional to the data mentioned in the first sentence.***

2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~ ***referred to in Article 4(5), point (c).***

~~2a.~~ The Commission and the Agencies shall indicate whether that data or information ~~is made available to the public under the originating Union act~~

~~shall not be made available to the public in accordance with provisions on confidentiality under the originating Union act.~~

is confidential in accordance with 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, ~~screening data and~~ occurrence data for the environment and ~~screening 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, after consultation of the Agencies, 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].

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

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

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

136.a.new ***10. The Commission and the Agencies shall act as*** ~~*joint*~~ ***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***, in cooperation with ECHA regarding occupational biomonitoring data***.

2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.

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

~~4~~ ***3. The EEA may process h***~~H~~uman biomonitoring data constituting personal data ~~may be processed by the EEA~~ for the following purposes:

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

Commented [A19]: PRES: upon request of a MS, this is deleted. PRES sees merit in not multiplying the number of different actors, which are covered anyway by the wording "Member State"

Commented [A20]: PRES: in addition to the amendment included in recital 21, PRES still sees merits in having an explicit wording here

Commented [A21]: PRES: uncertainties linked to large volumes and identification of those data were indicated. PRES highlights that now a review clause is introduced that allows for such an inclusion in the future. PRES thus proposes to delete this proposal.

Commented [A22]: PRES: One delegation prefers to delete the word "joint". Problems of shared responsability with the wording "joint" was indicated. PRES agrees to the need of deleting this.

Commented [A23]: PRES: there is a need to be more precise on the types of processing each processor is allowed to do.

(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 the adoption by the European Parliament, the Council of the European Union and the European Commission of a legally binding act.

~~4. The Commission may process human biomonitoring data constituting personal data for the following purposes, in relation to chemicals:~~
~~(a) monitoring the effectiveness of regulatory action;~~
~~(b) assessing the need for further regulatory action and prioritising such actions;~~
~~(c) supporting policy making,, regulatory risk assessment and risk management.~~

The Commission may process human biomonitoring data constituting personal data for the following purposes:
(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;
(h) supporting policy making and the adoption by the European Parliament, the Council of the European Union and the European Commission of a legally binding act;

The human biomonitoring data referred to in this paragraph includes personal data lawfully collected by national research institutions and made available to the research community on the IPCHEM platform before the entry into force of the present Regulation.

5. The ECHA may process human biomonitoring data constituting personal data for the following purposes:
(a) evaluating and prioritising required regulatory action;
(b) performing asssessments 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:
(a) evaluating and prioritising regulatory action;
(b) performing asssessments of chemicals;
(c) supporting regulatory risk management.

7. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA 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 ***, Commission, ECHA and EFSA*** shall act as ~~joint~~ data controller~~s~~ for the human biomonitoring ***data constituting*** personal data ~~it~~***they*** hold~~s~~ or host~~s~~ and processe~~s~~ for the purposes referred to
~~in paragraph 2.~~
in paragraphs ~~4~~ ***3,4,5,6,8.***

Commented [A24]: PRES: since EEA is not doing risk assessment and risk managment, while ECHA, EFSA and COM do, it was suggested to delete points (e) and (f). PRES considers however that those paras might apply also to MS requests. It is therefore suitable to retain those purposes

Commented [A25]: PRES: COM proposes to expand the purposes to cover JRC activies on behalf of the COM, and to introduce provisions to allow the use of existing data before the entry into force

Commented [A26]: PRES: COM proposed to avoid joint liability, PRES proposes thus to delete this.

Commented [A27]: PRES: one delegation suggested to delete the reference to para 8. PRES seeks guidance on whether making available in anonymised form is to be considered under the tasks of a data controller or constitutes a "processing".

148. b	**10. The storage period for human biomonitoring data constituting personal data held in accordance with Article 6 , as well as the criteria used to define the storage period and the foreseen reviews of the storage needs of the Commission, EEA, ECHA and EFSA, shall be defined by the ~~joint~~ data controllers defined in art. 6(9).**
149	Article 7 Information Platform for Chemical Monitoring
150	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.
151	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.
152	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.
153	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.
154	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.
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.
156	Article 8 Repository of reference values
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform. ~~The repository will contain also the available context data of the reference values, to the extent that it is relevant for the purposes of the present regulation.~~
158	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.
159	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.
160	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.
161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.
162	Article 9 Database of Study Notifications
163	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].
164	2. The ECHA shall store in the Database of Study Notifications the ***chemicals*** data notified to it in accordance with Article 22 ~~studies to be notified as defined under Article 2.~~
165	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

Commented [A28]: PRES: this is now taken into account line 109 (art.3(6))

Commented [A29]: PRES: see proposal under line 275 for the explanation of the proposed change.

on confidentiality.

165a ***(3a). ~~The ECHA will make available the data in the Database of Study Notifications through a permanent access to Member States Competent authorities of regulations listed in Annex 1.~~ Authorities and national enforcement authorities shall have a permanent access to the data contained in the Database of Study Notifications before that data is integrated in the common data platform.***

166 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.

167 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.

168 Article 10
Information on regulatory processes on chemicals

169 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.

170 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.

171 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:

172 (a) substance identity;

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

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

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

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

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

178 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.

179 Article 11
Information on the obligations under Union acts on chemicals

Commented [A30]: PRES: new wording to clarify the timeline and to delete the reference to Annex 1

Commented [A31]: PRES: it was suggested to add provisions at the end of art.10(2), to make more precise the information to provide. PRES invites delegations to indicate if they can support the following addition

180 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.

181 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).

182 Article 12
Repository of standards formats and controlled vocabularies

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

184 2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.

185 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.

186 Article 13
Database on environmental sustainability related data

187 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.

188 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.

189 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.

190 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~~ ***act*** identifying existing datasets ***of chemicals data*** 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. ***These implementing acts shall be adopted in accordance with the procedure referred to in paragraph*** ~~3~~ ***2 of Article 24a.***

191 Chapter III
DATA FORMATS AND CONTROLLED VOCABULARIES

192 Article 14
Standard formats

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

194 2. The standard formats referred to in paragraph 1 shall, to the extent possible:

195 (a) avoid the use of proprietary standards;

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

197 (c) use OECD or other internationally agreed formats;

198 (d) be coherent with other existing data formats;

199 (e) ensure interoperability with existing data submission approaches.

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

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

202 5. The Commission and the Agencies shall use the International Uniform Chemical Information

Commented [A32]: PRES: taking into account that the examination procedure might be too burdensome for including environmental sustainability data into the common data platform, PRES proposes to provide for the advisory procedure instead.

Legal analysis and advice explained that the decision on whether advisory or examination procedure should be used in this case is whether the decision will have a direct impact on the environment.

PRES understands that including data related to environmental sustainability does not have a direct impact on the environment, it is therefore proposed to replace the examination procedure to the advisory procedure.

Commented [A33]: PRES: based on comments received from Delegations PRES considers that the changes made to the standard formats (Article 14) text should be similar to the changes proposes to the controlled vocabularies text (Article 15).
See line 216 for more detailed explanation.

PRES proposal WP4: keep original wording. Additional wording added in recital 38 (see line 46).

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:

203 (a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council53;

53 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.~~20~~***10***.2003, p. 29).

204 (b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council54;

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

205 (c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council55;

55 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1).

206 (d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council56;

56 Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).

207 (e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council57;

57 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).

208 (f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council58;

58 Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).

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

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

210 (h) Commission Regulation (EU) No 234/201160;

60 Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).

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

61 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).

211.a.new ***(j) (EC) No 1272/2008 (CLP XXX)***

211.b.new ***(k) (EC) No 1107/2009 (PPPR XXX)***

211.c.new ***(l) (EC) No 396/2005 (pesticide residues in food and feed)***

211.d.new ***(m) (EU) No 528/2012 (BPR XXX)***

212 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.

213 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.

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

215 Article 15
Controlled vocabularies

216 1. The Commission and the Agencies~~, after consulting the experts designated by each Member States referred to in article 24(4),~~ shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.

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

218 3. Those controlled vocabularies shall:

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

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

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

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

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

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

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

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

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

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

229 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.

230 8. The Commission shall adopt an implementing ~~decision~~ ***act*** to remedy the divergence. ~~Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.~~

231 Chapter IV
CHEMICALS DATA CONFIDENTIALITY AND USE

232 Article 16
Access rights and transparency

232.a.new ***XXX. 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. To help the public understand the content of the data, the Commission can provide references to scientific publications and outreach.***

Commented [A34]: PRES proposal to take into account compatibility with regulations in some MS

Commented [A35]: upon request of a delegation to help the public understanding.

233 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 ~~a~~***), second sentence.***

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

235 3. ~~The general public shall have access to all the chemicals data contained in the commondata~~

~~platform and considered as available to the public in accordance with the Unionact under which the data was generated or submitted.~~

~~All chemicals data contained in the common data platform, excluding data which is deemed to be confidential under Article 5(2a), shall be made available to the public.~~

236 Article 17
Use of chemicals data contained in the common data platform

237 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.

238 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.

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

~~When making data used by the Authorities available to the public, information or data marked by the originator as confidential shall not be disclosed without prior consultation with the originator.~~

Where an Authority receives a request for data or information marked as confidential under Article 5(2) that the Authority is using, unless it is clear that the data or information shall not be disclosed, the Authority shall consult with the originator in order to take a decision that does not jeopardise the confidentiality of the data or information.

Commented [A36]: PRES: a delegation states that it is unclear whether the proposed wording is an improvement. The wording proposed by COM has the advantage that Article 5(2) refers to the confidentiality rules of the respective underlying legislations. The new wording contains no reference when data may be declared confidential.

Commented [A37]: PRES: in line 129 a reference to the undelying legislation is already introduced. However since further emphasis on this is requested, PRES agrees to introduce here a reference to art5(2). A modification is thus proposed.

240 Chapter V
MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS

241 Article 18
Framework of indicators

242 1. The EEA, in collaboration with the ECHA, the EFSA, the EMA and the EU-OSHA and the Commission, shall, ***in consultation with the Member States,*** establish, operate, and maintain ~~present a report to the Commission and the experts designated by each Member State. The report shall contain a proposal for~~ a***n indicative*** framework of indicators to monitor ***chemical pollution,*** the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.

~~242.a.new~~ ~~1a. Based on that report, the Commission shall adopt a delegated act by ... [OP: please insert one year after the entry into force of this regulation] in order to establish the framework of indicators referred to in paragraph 1.~~

~~242.b.new~~ ~~1b. The EEA, in collaboration with the ECHA, the EFSA, the EMA and the EU-OSHA, shall operate and maintain the framework of indicators~~

243 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.

~~243. b~~ ~~3. The framework of indicators referred to in paragraph 1 shall be shall established, operated, and maintained by [OP: please insert date: 3 1 years after the end of the first calendar year after entry into force of this Regulation].~~

244 Article 19
Early warning and action system for emerging chemical risks

245 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].

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

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

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

249 (c) data that the EEA holds, ***including data from the Framework of indicators mentioned in Article 18***;

250 (d) targeted literature searches performed by the EEA;

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

252 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.

253 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.

254 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. ~~T~~The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities ~~for consideration of the need for regulatory or policy~~ ***who shall undertake regulatory or policy actions accordingly or justify if they decide not to proceed with any*** action related to the early warning signals.

255 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.

256 Article 20
Observatory for specific chemicals with potential contribution to emerging chemical risks

257 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.

258 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 3 of Article 24a.***

259 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.

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

261 (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;

262 (b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;

263 (c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate ***the identification of potential further research needs or risk management measures, to facilitate*** informed societal discussion and ~~increase~~ public

Commented [A38]: PRES: to meet the request of a delegation

Commented [A39]: PRES understands the « identification» as a way to indicate the purpose of the publication of the data, which then will guide the subsequent work on this

Commented [A40]: PRES: it has been indicated that RMM may not be necessary in all cases

Commented [A41]: PRES: upon request of one delegation.

awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.

Chapter VI
DATA GENERATION MECHANISM

Article 21
Data generation mechanism

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

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

3. The ECHA shall only commission scientific studies when results cannot be obtained through ~~existing legal provisions or processes under Union legislation~~ ***Union acts on chemicals*** listed in Annex I. It shall not commission studies with a predominant research objective.

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

5. The ECHA shall commission these scientific studies in an open and transparent manner**.** ***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.

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

Chapter VII
NOTIFICATION OF STUDIES

Article 22
Notification of studies

1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any ***studies*** ~~on~~ ***that generate chemicals data and that are commissioned*** ~~to be notified s as defined in Article 2.~~ ~~any studies on chemicals they commission~~ to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment ~~, prior to placing on the market,~~ under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. study falls under the notification obligation of paragraph 3. ***When a study falls under the notification obligation of paragraph 3, business operators shall inform in this respect the laboratory or testing facility in which the study to be notified is carried out, without undue delay.*** ~~, about the fact that the 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*** ~~identify~~ ***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 ***an 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. 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

Commented [A42]: PRES: 3 delegations indicated the need to maintain the burden of proof in the industry.

Furthermore, PRES highlights that recital (48) line 56 contains a wording on this ("maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder")

Commented [A43]: PRES: several Delegations indicated that they would like to have the possibility of Member State input on the commissioning of studies by ECHA. PRES presented a proposal at WP3 to have general wording to consult Member States. Several Delegations indicated during and after the WP3 that it is not clear in which way the MS would then be consulted, and whether this would be done via the OSOA expert group.

PRES suggests to keep previous drafting proposal

Commented [A44]: PRES: after comments from a delegation:
- PRES re-worded the last sentence to clearly state that it is not in all cases that business operators have to inform the laboratories.
- PRES understands that in a case when a business operator does not inform the laboratory, para 3 still applies, and thus the laboratory cannot hold the business operator responsible. Thus PRES amendments only helps to increase the information available to laboratories to respect their obligations

Commented [A45]: PRES:
Based on comments from a Delegation PRES proposes to remove "prior to placing on the market" wording to ensure that new data on chemicals already on the market would be included.

business operator who commissioned the test.

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

6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].

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

Chapter VIII
DELEGATED POWERS ***AND COMMITTEE PROCEDURE***

Article 23
Amendment of Annexes ~~I,~~ II ~~and III~~

Commented [A46]: PRES: since it is not possible to empower the Commission to amend or supplement the REG for essential elements, PRES suggests to limit the delegated powers to Annex II only.

Annexes I and III can only be amended through the ordinary procedure.

~~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.~~

~~1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I ***of this Regulation*** in order to where the development of Union chemicals legislation so requires supplement that Annex by adding to it Union acts under which relevant chemicals data is generated or submitted.~~

~~2.~~ ***1. T***he Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II ***of this Regulation*** by adding~~, where relevant,~~ ***new reference values when, in view of developed scientific knowledge, there is evidence of an increased hazard or risk to the environment or human health.*** ~~categories of data types.~~

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

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

Article 24
Exercise of the delegation

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

2. The power to adopt delegated acts referred to in ***Article 18 (1a) 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 18(1a) 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.

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

293 6. A delegated act adopted pursuant to ***Article 18(1a) 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.

293.a.new ***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 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

294 Chapter IX
ENFORCEMENT AND PENALTIES

295 Article 25
Cooperation on compliance ~~Enforcement~~

The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.

Commented [A47]: PRES: from delegations comments, PRES understands that there is a need to clarify the purpose of art.25, which is not on enforcement directly, but on collaboration and compliance information exchange in view of the enforcement, which in its turn is foreseen in art.26. The title is thus changed, and the text of art.25 is set to the original proposal by the COM.

296 Article 26
Penalties for non-compliance

297 1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations ***to inform and notify*** ~~laid out~~ 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.

298 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.

298.a.new ***Chapter X***
REVIEW AND ENTRY INTO FORCE

298.b.new ***Article 26a***
Review

1. No later than … [OP: please insert ~~three~~ six years after the entry into force of this Regulation], the Commission shall adopt ~~present~~ a report ~~an impact assessment~~ accompanied, if appropriate, by a legislative proposal to extend the scope of the data to be included in the common data platform pursuant Article 3 of this Regulation ~~to notably cover medicinal data and in particular clinical data~~ to further support the objectives ~~of this Regulation~~thereof. The review shall include an assessment of the scope regarding medicinal products, as well as the relevancy of 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. ~~relevance to maintain the exclusion of the clinical data from the scope by identifying t~~The cost-benefit balance of incorporating ~~such~~ additional data in the common database platform shall be assessed.

Commented [A48]: PRES: suggestion has been made to have six years before the review of the scope, to let time for collecting the lessons learned (i.e. 3 years after the establishment of the CDB.

Commented [A49]: PRES: cfr remarks received at WP3 on keeping the approach that no impact assessment was performed for this proposal.

2. By … [OP: please insert eight years after the entry into force of this Regulation], the Commission shall carry out a general review of this Regulation, and shall present a report to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal. The report shall assess whether this Regulation have contributed sufficiently to achieve its objective, in particular to

Commented [A50]: PRES: two years after the scope is reviewed, so more general lessons on the contribution to the objective can be collected.

allow a better reuse of data across the Union acts referred to in Annex I.

298.c .new

299 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.

300 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

ANNEXES I,II,III to the Proposal----------

Annex I

301 Annex I
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.

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

303 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)

304 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)

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

306 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)

307 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)

308 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)

309 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)

310 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)

311 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)

312 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)

313 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)

314 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)

315 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)

316 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)

317 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)

318 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)

319 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)

320 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)

321 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)

322 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)

323 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)

324 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)

325 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)

326 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)

327 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)

328 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)

329 ~~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)~~

330 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 energyrelated products

39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network (OJ L 126, 21.5.2009, p. 13)

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

41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)

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

43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)

44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides

(OJ L 309, 24.11.2009, p. 71)

346 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)

347 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 ecomanagement 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)

348 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)

349 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)

350 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)

351 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)

352 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)

353 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)

354 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)

355 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)

356 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)

357 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)

358 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)

359 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)

360 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)

361 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)

362 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)

363 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)

364 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)

365 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)

366 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).

367 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)

368 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)

369 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)

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

371 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]

371.a.new ***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).***

371.b.new ***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).***

371.c.new ***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).***

371.d.new ***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).***

372.e.new ***75. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p.176)"***

Commented [A51]: PRES: at the request of a delegation, expanding the scope to this additional relevant regulation

ANNEX II

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

Part 1

373 ~~Part 1 - Specific data on relevant active substances to be identified in accordance with Article4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human andveterinary medicinal products~~

374 ~~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 Council1 and Regulation (EC) No 726/2004 of the European Parliament and of the Council2;~~

~~1 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).~~
~~2 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).~~

375 ~~2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council3; and~~

~~3 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).~~

376 ~~3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of~~

~~the European Parliament and of the Council4.~~

~~4 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).~~

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

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

379 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.

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

Annex III

381 Annex III
UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23

382 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.

383 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)

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

385 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)

386 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)

387 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)

388 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)

389 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)

390 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)

391 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)

392 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)

393 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)

394 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)

395 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)

396 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)

397 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)

398 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)

399 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)

380.B 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)

381.B 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)

382.B 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)

383.B ~~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)~~

384.B 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)

385.B 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 energyrelated products

386.B 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)

387.B 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)

388.B 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)

389.B 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)

390.B 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)

391.B 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)

392.B 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)

393.B 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).

394.B 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)

395.B 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)

396.B 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].