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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: AHWP on 8 March 2024: Proposal for a Regulation establishing a common data platform on chemicals - Presidency's steering note - CALL FOR COMMENTS

With a view to the above Ad Hoc Working Party, delegations will find attached the Presidency's steering note together with its Annexes.

Delegations are invited to send written comments, article per article, and possible text suggestions using the table provided in ANNEX II, to the Presidency [redacted]) copying the Commission ([redacted] and the Council Secretariat [redacted]) at the latest by **Friday 22 March 2024 at 13h00**. On the basis of which the Presidency will decide on the topics to be discussed at the next Ad Hoc Working Party meeting, scheduled for the 12th of April 2024.

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)

Presidency Steering note
Ad Hoc Working Party on One Substance One Assessment (WP2) – 8 March 2024

On 7 December 2023, the Commission launched proposal COM_2023_779_1. At the meeting of the Ad Hoc Working Party on One Substance One Assessment on 23 January 2024, the Commission presented its proposal. Delegations had the opportunity to ask questions and to express their initial views on the text. Afterwards, delegations were invited to send in written comments by Friday, 23 February cob.

Comments received from MS show general support for the proposal and its objectives and already provided some proposals/requests for content and editorial amendments. MS expressed also that several issues still need to be clarified and concerns are expressed on several subjects (see ANNEX 1 which contains **a summary of the topics raised, and all the MS comments received, article per article**).

The following **discussion blocks** are considered a priority **to be discussed at the 2nd WP** for clarification of the proposal and determination of MS positions:

a. Data/metadata to be included in the data platform (art.3), and the resources requested from MS (art.3,6,13,18,19) and agencies/committees (art.19). This point on resources will be handled transversally over the three OSOA proposals.
b. Presidency amendment proposals (presented in the ANNEX 2).
c. Provision regarding medicinal products.
d. Human biomonitoring data (HBM) constituting personal data subject to protection.
e. Confidentiality and data use (art 16,17).
f. The desired level of MS participation/consultation in the foreseen processes, and the legal procedures choice.

If time allows, the following discussion blocks will be discussed at the 2nd WP, otherwise they will be re-scheduled:

g. The timeline of the proposal: clarification and potential need for amendments of art.3(11), 4, 7, 13, 19, 20,22 that contains time specifications.
h. Studies notification & enforcement

Considering the wide range of topics raised by MS, **a Presidency proposal, article per article**, is presented in ANNEX 2. The proposal includes the amendments proposed by the presidency, details on the proposed discussion blocks, and indications on topics left for further written comments.

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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 I to PRES steering note:
WRITTEN COMMENTS FROM THE MS AFTER THE 1st WP for consideration at the OSOA AHWP
8/3/2024

MS expressed that several issues still need to be clarified and concerns are expressed on the following subjects:

Data to be included in the platform; scope in relation to the medicines regulation; scope in relation to the term “products”; expertise available; budget and resources including in the agencies/committees/EIONET, practical implementation; high number of actors and regulations; conflicts/contradictions/ambiguities in the data, management and preservation of confidential data; additional data to be provided by MS or additional data to be included that the agencies don’t manage presently; possible outdating of the data; provisions on personal data protection and HBM; considerations on the proposed timeline for the proposal; participation of MS to various parts of the processes described; participation/consultation of other actors such as scientists and industry; responsibility/burden of proof of the companies to guarantee safety vs the data generation mechanisms; studies notification (several clarification requests, as well as questions on when and how MS can access the notifications).

	ORIGINAL COM text	Questions/Comments
Proposal Title		
1	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)	Welcomes the proposal: • SI: welcomes all three legislative proposals introduced by the European Commission for ensuring "One Substance, One Assessment" approach. With that, more efficient consolidation of technical and scientific work in the area of chemicals will be ensured. • SI: welcome the proposal. SI agrees that having a uniform platform collecting various data related to chemicals will be beneficial to all. • AT: generally welcomes the overarching aim of the OSOA package to achieve a more efficient use of data and synergies in the work of the various EU agencies. • NL: We welcome the implementation of the one substance, one assessment approach of the Chemicals Strategy for Sustainability. We think that improving the cooperation among EU agencies can contribute to the goals of the one substance, one assessment approach. • DE considers in general the common data platform on chemicals as an important tool for achieving the goals of OSOA. • FR: The French authorities thank the European Commission for the presentation of its proposals during the last group and wish to reiterate their support for this initiative aimed at rationalising the work between the European agencies involved in the evaluation of chemicals. • PT: We support the initiative of this legislative package, considering it as an important step towards the objectives set up in the “Strategy for the Sustainability of Chemical Products” (CSS) such as the simplification and consolidation of the EU's comprehensive and complex chemical products regulatory framework.

		• PT: We also believe that this initiative will contribute to improve overall coherence, quality, efficiency and transparency of the safety assessment of chemicals across the legislation, as well as to strength confidence in the scientific basis of the EU decision-making process in the field of chemicals. • PT: We support in general the development of a common data platform in alignment with the CSS, which allows the collection of relevant information on chemicals and early warning signs of chemical risks, ensuring interoperability between the databases and thus facilitating the sharing, access and re-use of information on chemicals coming from all sources. • PT: It is considered that this measure is an important step towards assuring that data meets the FAIR guiding principles and building greater trust in the scientific highlighting of the EU decision-making process for chemicals. • ES: The Spanish delegation appreciates the proposal from the COM for the legislative creation of a common data platform, where all information related to chemicals will be hosted. • IE : Overall, we welcome the proposal for a regulation to establish a common data platform on chemicals Scrutiny reservations: • SI,AT,DE + DK general parliamentary scrutiny reservation Comments: • ES: We think that this is a very necessary proposal, it is also a very ambitious text and should be implemented cautiously due to the involvement of numerous regulations, agencies, authorities, and stakeholders. The concerns and doubts arising from a preliminary analysis of the proposal are [PRESIDENCY: listed here below in the respective articles] • AT: several issues will need to be further clarified and concretised

		• PT: We are concerned that the aim of interoperability is not fully achieved if data treatment is not foreseen. We are aware that assuring the interoperability of such a platform will be quite challenging, as we are dealing with a significant amount of data coming from different sources and using different terminologies and formats (Art. 14 and 15). Additionally, we also have concerns relating to conflicting results and analyses of data from studies (art. 3(2)) and not only with harmonisation of vocabularies and formats Questions: • NL: The establishment of a central data platform and re-attribution of tasks to EU-agencies do require the necessary infrastructure and resources. We request if the Commission can elaborate on how they will ensure that the EU-agencies are adequately equipped for the new tasks. • NL: Can the Commission confirm that the initial and the operational costs for all three proposals will be covered by already existing funding or does the Commission foresee that additional budgetary claims will follow? • NL: Regarding the central data platform, it is noted that both public data and confidential data will come together in one database. We kindly ask the Commission to elaborate on how it will be ensured that the confidentiality of data as currently laid down in the existing regulations will not change. • NL: We agree with the Commission that the data platform can function also as an early warning tool on chemicals. We propose that the database also plays a role in Safe and Sustainable-by-Design, the concept in which chemical substances are already assessed at the design table for safety for people and the environment and sustainability. Could the Commission consider adding this to the role of the data platform in the decision? • DE: How can it be ensured that ECHA and its Committees remain fully operational and can deliver the necessary high-quality scientific output in its existing and its new tasks?

		• DE: In that respect, does the Commission consider the proposed additional resources to be sufficient or which further measures could become necessary?
		• DE: Concerning data platform elements:
		  ○ DE: Will member states and the public be consulted during implementation of the platform, e.g. on formats or vocabulary?
		  ○ DE: Will data that are not already in the possession of the Agencies and the Commission be included or utilised within this platform?
		  ○ DE, Concerning updating of information: The Commission proposal does not specify how often agencies are expected to update information provided for the common data platform on chemicals. How does Commission plan to organize this? Did Commission assess the problem that the platform's information could become outdated?
		  ○ DE: concerning contradictions or ambiguities of information: It is planned to bring together data about substances from different legislations. It can be expected that contradictions or ambiguities will arise, for example because studies in different regulatory areas are carried out differently or evaluated differently. Such contradictions/ambiguities might lead to public debate. Who will resolve these contradictions and ambiguities and with what resources? In the explanatory memorandum the Commission mentions the solving of divergences in scientific output. We ask Commission to illustrate that mechanism with relevant examples.
		• FR: generally, the French authorities question the consultation modalities, in particular for the Member States, before the Commission adopts the implementing decisions provided in Articles 4, 13 and 20 of the draft regulation.

Formula		

2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN	
Citation 1		
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,	
Citation 2		
4	Having regard to the proposal from the European Commission,	
Citation 3		
5	After transmission of the draft legislative act to the national parliaments,	
Citation 4		
6	Having regard to the opinion of the European Economic and Social Committee[1]	
Citation 5		
7	Acting in accordance with the ordinary legislative procedure,	
Formula		
8	Whereas:	
Recital 1		
9	(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.	
Recital 2		

10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.	
Recital 3		
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.	
Recital 4		
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.	
Recital 5		
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.	
Recital 6		
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.	
Recital 7		
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.	
Recital 8		
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.	Questions: • DE: Recital 8 & 9 contain statements that can be interpreted as a strong limitation of the data to be included in the common data platform. Could you please specify "relevant substances" with regard to medicinal active substances?
Recital 9		
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.	Questions: • DE: Is it intended that other active substances whose data were submitted to the European Medicines Agency (EMA) before the regulation came into force will also be included in the database?

		• DE: As part of the current revision of the EU's general pharmaceutical legislation, i.a. the setting up of an active substance monograph system on environmental data is being considered. Are there plans to integrate these pharmaceutical substances monographs into the central database? If not, how would the two systems work together?
Recital 10		
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.	
Recital 11		
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.	
Recital 12		
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.	
Recital 13		
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.	
Recital 14		
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.	
Recital 15		
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.	
Recital 16		
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.	
Recital 17		
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 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.	
Recital 18		
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the 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, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.	
Recital 19		
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.	
Recital 20		
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.	
Recital 21		
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.	
Recital 22		
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 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').	
Recital 23		
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.	
Recital 24		
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 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.	
Recital 25		
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.	
Recital 26		
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.	
Recital 27		
35	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.	
Recital 28		
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.	
Recital 29		
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.	
Recital 30		
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.	
Recital 31		
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 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.	
Recital 32		
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.	
Recital 33		
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.	
Recital 34		
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 to be notified under this Regulation.	
Recital 35		
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.	

Recital 36		
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.	
Recital 37		
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.	
Recital 38		
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.	
Recital 39		
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.	
Recital 40		
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.	
Recital 41		
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 .	
Recital 42		
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 on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.	
Recital 43		
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.	
Recital 44		
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 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.	
Recital 45		
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.	
Recital 46		
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.	
Recital 47		
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.	
Recital 48		
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.	
Recital 49		
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, to expand the specific data types and reference	

	values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 201649. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	
Recital 50		
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.	
Recital 51		
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 [OP: Please insert the date of the opinion of the EDPS].	
Formula		
60	HAVE ADOPTED THIS REGULATION:	
Chapter I		
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS	

Article 1		
62	Article 1 Subject matter and scope	Amendment proposal • IE : Article 1. There is no specific reference to the promotion of data from non-animal methods, perhaps a reference could be included in the subject matter and scope or the recitals.
Article 1(1)		
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 sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	
Article 1(2)		
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:	
Article 1(2), point (a)		
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;	
Article 1(2), point (b)		
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;	
Article 1(2), point (c)		
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;	

Article 1(2), point (c)		
68	(d) establish an early warning and action system for emerging chemical risks.	
Article 1(3)		
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).	
Article 2		
70	Article 2 Definitions	Proposed amendments: • SI: About human biomonitoring/personal data: third parties shall be defined in Article 2 • AT: Art. 22(1)& art.2: It is unclear to us whether the term "products" also includes mixtures and articles (within the meaning of the REACH Regulation). In order to clarify this, the term "products" should be included in the definitions within Art. 2.
Formula		
71	For the purpose of this Regulation, the following definitions shall apply:	
Article 2(1)		
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');	
Article 2(2)		
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;	
Article 2(3)		
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;	

Article 2(4)		
75	4. ‘business operators’ means duty holders which are private or public undertakings;	Amendment proposal • IE: Article 2(4): we suggest to use ‘economic operators’ instead of ‘business operators’ to ensure alignment with other relevant legislation
Article 2(5)		
76	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;	
Article 2(6)		
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;	• AT: Art. 2(6) in conjunction with Art. 8 and Art. 14. For reference values without a toxicological threshold "below which risks related to the adverse effects [...] are considered acceptable or tolerable", the statistical (cancer) risk that is associated with these values should be specified as well. The statistical (cancer) risk should be stated in Art. 8 (Repository of reference values) and a data format should be specified in Art. 14 accordingly.
Article 2(7)		
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;	
Article 2(8)		
79	8. ‘originating Union act’ means the Union act under which chemicals data and information were generated or submitted;	
Article 2(9)		
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;	

Article 2(10)		
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;	
Article 2(11)		
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:	• AT: Art. 2 para. 11 and Art. 13. The term "environmental sustainability related data" is very vague and comprehensive. We believe that this term should be clarified and concretised, since the concrete data content will only be defined at EU level in the coming years (e.g. via "eco-design requirements" as part of the Eco-design Regulation). Therefore, we suggest adding a reference to an Annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information.
Article 2(11), point (a)		
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;	
Article 2(11), point (b)		
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and	
Article 2(11), point (c)		

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.	
Article 2(12)		
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 of the European Parliament and of the Council;	Proposal for editorial amendment: FR: Article 2(12) on "personal data": this definition is specified in article 3(1) of Regulation 2018/1725 and not article 3(16) of Regulation 2018/175. Regulation 2018/1725 also needs to be corrected in paragraphs 13 and 14 of the same article.
Article 2(13)		
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 of the European Parliament and of the Council;	
Article 2(14)		
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 of the European Parliament and of the Council;	
Article 2(15)		
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.	Questions: • DE: Concerning technical interoperability: The creation and maintenance of the platform requires complex data flows for both the collection and distribution of data. Does the Commission intend to promote the use of advanced programming interfaces (API) to organise and facilitate data flows?
Chapter II		

90	Chapter II INFORMATION SYSTEMS AND PLATFORMS	
Article 3		
91	Article 3 Common Data Platform on Chemicals	
Article 3(1)		
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').	
Article 3(2)		
93	2. The common data platform shall provide access to all chemicals data:	Comments • ES: In line with the concern expressed by Germany at the last meeting regarding the classification and grouping of data, we would like to add that we believe data evaluated by authorities or agencies should prevail or be more visible. This would help prevent the platform from becoming a conglomerate of data that complicates finding reliable data for regulatory decision-making. • ES: The proposal, as it is written, does not distinguish between substances and mixtures. Therefore, if data on mixtures are also going to be available, a more in-depth analysis of their implications on the data generated in the evaluations for the authorizations of plant protection products at national level will be necessary. • FR: consider that it is difficult at this stage to verify the exhaustiveness of the regulations listed in Annexes I and III of the proposal and therefore the exhaustiveness of the data that will be taken into account in the platform. However, the French authorities welcome the possibility offered by the Commission to amend its annexes by delegated acts via Article 23 of the proposal. • FR: question the differentiated approach between medicinal products and biocidal and phytopharmaceutical products for which there are no restrictions on access to efficacy data.

		Veterinary medicinal products and biocidal products sometimes have similar uses, for example in TP3 on veterinary hygiene. • IE, on cosmetics: data listed in COM 779 may come into scope under the European Health Data Space (EHDS), and we would welcome further details on how the governance structures developed under COM 23 (779) would link to those within the EHDS. Requests: • FR: recognise the specificity of a certain number of active substances for medicinal products, a specificity that is set to increase in the coming years with immunotherapies. However, it would be useful to have an analysis of the impact of the limitation on data relating to these substances set out in Annex II.
Article 3(2), point (a)		
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;	
Article 3(2), point (b)		
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;	
Article 3(2), point (c)		
96	(c) listed in Annex II and held by the EMA;	
Article 3(3)		
97	3. The following information shall not be included in the common data platform:	Questions: • FR: As regards the exclusion of information on the composition of hazardous mixtures and cosmetic products from the platform, the French authorities approve this

		provision due to the sensitivity of the information. However, they question the appropriateness of making these data only available to the authorities to be able to collect information on the uses of substances and thus improve the risk assessments of substances carried out by the authorities.
Article 3(3), point (a)		
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[50]; 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).	
Article 3(3), point (b)		
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. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).	
Article 3(4)		
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.	Questions • ES: Regarding Article 3.4, the initiative states that documents relating to Authorities' internal work or decision-making processes not need to be included in the common data platform, but there may be situations where it is possible. What kind of situations are these? Has it been assessed how this could impact the work carried out by the Authorities?
Article 3(5)		
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:	

Article 3(5), point (a)		
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;	
Article 3(5), point (b)		
103	(b) the repository of reference values referred to in Article 8;	
Article 3(5), point (c)		
104	(c) the database of study notifications referred to in Article 9;	
Article 3(5), point (d)		
105	(d) information on regulatory processes referred to in Article 10;	
Article 3(5), point (e)		
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;	
Article 3(5), point (f)		
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;	
Article 3(5), point (g)		
108	(g) the database on environmental sustainability-related data referred to in Article 13.	
Article 3(6)		

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.	
Article 3(7)		
110	7. The data contained in the common data platform may be used in accordance with Article 17.	
Article 3(8)		
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.	
Article 3(9)		
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.	
Article 3(10)		
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/200152. 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).	
Article 3(11)		
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 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),	Questions: • FR: In Article 3(11) of the proposal, the French authorities question the mention “unless specified otherwise” with regard to the deadline for establishing the common data platform and its dedicated services.

	first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	The French authorities understand from reading the proposal that only the study notification service has a different deadline set at 2 years following the date of entry into force of the text. They would like the Commission to confirm this interpretation. Proposed amendments: • FR: Where applicable, the mention "unless specified otherwise" could be replaced by "except for the study notification service" to make the text easier to understand. Request for amendments: • FR: the Commission proposes that datasets shall be integrated progressively into the platform in accordance with the implementation plan referred to in Article 4(1), first sentence. The French authorities question this reference to the "first sentence" when the second sentence of Article 4(1) refers to rolling implementation plans and it would seem consistent to also take account of updates to the implementation plan for data integration.
Article 4		
115	Article 4 Implementation plan and governance of the common data platform	Proposals for amendments: • DK: In the light of our wish to make better use of the Common Data Platform in the future for the purpose to use data to make better assessments on chemicals across sectors, DK suggests the following text proposal to Article 4: ○ 5a. The Commission shall prepare a recommendation no later than 24 months after the Common Data Platform is established on how to amend legislation listed in the Annexes to this regulation for the purpose to use all data in the Common Data Platform to improve assessments on chemicals across sectors.

		○ 5b. 5c. By [Month, YEAR], the Commission shall present its recommendation referred to in paragraph 5a, accompanied, if necessary, by appropriate legislative proposals. Comments: • DK: Denmark understands the Commission, the referred implementing decision in Article 4, paragraphs 1 and 2, and Article 13, paragraph 4, is in fact an internal decision prepared only by the Commission. We find that the word implementing may be misleading, in the sense that implementing in the context of EU regulation often refers to implementing acts and the procedures following.
Article 4(1)		
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	Questions • FR: Article 4(1) proposes that the Commission adopt an implementation plan identifying datasets for inclusion in the platform together with a timeline for their inclusion. The French authorities question the procedure for adopting such a plan, particularly in terms of consultation. The French authorities would like confirmation from the Commission that this procedure will be defined in the governance scheme defined in Article 4(5). They also question the Commission's intention regarding the involvement of Member States in this procedure.
Article 4(2)		
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.	
Article 4(3)		
118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.	

Article 4(4)		
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	
Article 4(5)		
120	5. That governance scheme shall describe:	
Article 4(5), point (a)		
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;	
Article 4(5), point (b)		
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;	
Article 4(5), point (c)		
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;	
Article 4(5), point (d)		
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;	
Article 4(5), point (e)		
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;	
Article 4(5), point (f)		

126	(f) the operation of the steering committee itself.	
Article 5		
127	Article 5 Data Flows for the purpose of the common data platform	
Article 5(1)		
128	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.	Comments: • AT: The wording "chemicals data generated as part of [...] national [...] legislation" potentially also includes, for example, requirements regarding the emission of chemicals in individual notifications by the authorities of the Member States. This would be a disproportionate effort that should be limited.
Article 5(2)		
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as referred to in Article 4(4), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	Proposals for editorial amendment: • FR: Article 5(2): reference is made to relevant context data, these data are referred to in article 4(5)(c) and not article 4(4)(c).
Article 5(3)		
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.	
Article 5(4)		
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	Questions: • DE: Does the Commission pursue plans for systematic or regular surveys of indoor air quality data?
Article 5(5)		
132	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].	

Article 5(6)		
133	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].	
Article 5(7)		
134	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.	
Article 5(8)		
135	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.	
Article 5(9)		
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.	
Article 6		
137	Article 6 Human biomonitoring data	General comments: • SI: already collected a substantial amount of data on human biomonitoring, which to a lesser extent has already been forwarded to the IPCHEM database. Questions: • DE: In some cases harmonization and communication of individual data requires unequivocal consent from study participants. Such consent cannot be obtained retrospectively. Did the Commission consider this issue and if so, how will this be addressed?

		• ES: Regarding Article 6, are MS required to submit biomonitoring data carried out in their respective territories under national programs? Need for clarification: • SI: The role and processes of the European Chemicals Agency regarding the new platform on chemicals; • SI: Different entities providing personal data to which the platform provides access; • SI: Sources of the received human biomonitoring data from sources other than the Commission or researchers; • SI: to inform providers of human biomonitoring data about the proper type of data needed; • SI: compliance with Article 89 of GDPR and with Article 13 of EUDPR regarding the processing of personal data for scientific research and statistics • DE: The Commission proposal describes some purposes that require the use of personal data. These purposes are not sufficiently defined and require further specification. • PT: We have concerns related to Art. 6 - Human Biomonitoring data - such a task will involve allocating additional resources to the EEA, however, it is mentioned no significant impact on the EEA network. The network may be asked to assist in the collection of human biomonitoring data and early warning signals from the activities of EEA member countries and "providing assistance" means carrying out new/increased tasks, which raises the question of why COM considers there to be an impact on the EEA - providing financial and human resources for this purpose - but not a similar impact on the Eionet Network. The table "Future workload and resource needs" (SWD, p. 184) identifies a series of tasks in this area which, due to their number and content, corroborate what we consider to be a greater impact on the Eionet Network. There´s a need to further develop what this competence entails for the Eionet Network. •

Article 6(1)		
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.	
Article 6(2)		
139	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.	
Article 6(3)		
140	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.	
Article 6(4)		
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:	Amendment proposal : • IE : Article 6(4): we propose to add 6(4)(f) supporting regulatory risk management Need for clarification: • SI: processing of biomonitoring data constituting personal data (at EEA) shall not entail sharing of such data with third parties
Article 6(4), point (a)		
142	(a) assessing the impact of chemicals on human health and the environment;	
Article 6(4), point (b)		
143	(b) monitoring time and spatial trends in exposure;	
Article 6(4), point (c)		

144	(c) developing health risk and impact indicators;	
Article 6(4), point (d)		
145	(d) monitoring the impact of regulatory intervention;	
Article 6(4), point (e)		
146	(e) supporting regulatory risk assessments.	
Article 6(5)		
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.	
Article 6(6)		
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2.	Proposals for editorial amendments: • FR: Article 6(6): the European Environment Agency shall process human biomonitoring data for the purposes referred to in paragraph 4 (and not paragraph 2). Need for clarification: • SI: reference to paragraphs 3, 4, and 5 in Article 6(6) instead of the reference to paragraph 2 and to include the same reference to Articles 6(3) and 6(4) •
Article 7		
149	Article 7 Information Platform for Chemical Monitoring	
Article 7(1)		
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.	Question • IE : Article 7(1): we query as to what is envisaged to be covered by the term 'products' here

Article 7(2)		
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.	
Article 7(3)		
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.	
Article 7(4)		
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.	
Article 7(5)		
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.	
Article 7(6)		
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.	
Article 8		
156	Article 8 Repository of reference values	Comments • FR: With regard to the repository of reference values introduced in Article 8 of the proposal, the French authorities would like to point out that a similar database exists in the United States entitled CompTox/ToxValDB. It would be

		interesting to benefit from the experience of the American authorities in building such a repository Amendments requests: • AT: Art. 2(6) in conjunction with Art. 8 and Art. 14. For reference values without a toxicological threshold "below which risks related to the adverse effects [...] are considered acceptable or tolerable", the statistical (cancer) risk that is associated with these values should be specified as well. The statistical (cancer) risk should be stated in Art. 8 (Repository of reference values) and a data format should be specified in Art. 14 accordingly.
Article 8(1)		
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.	
Article 8(2)		
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.	
Article 8(3)		
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.	
Article 8(4)		
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.	

Article 8(5)		
161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.	
Article 9		
162	Article 9 Database of Study Notifications	
Article 9(1)		
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].	
Article 9(2)		
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.	
Article 9(3)		
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 on confidentiality.	• AT: considers that the concept of Article 9 (3) needs further discussion, as it seems to prevent Member States authorities from getting relevant information on notified studies in time.
Article 9(4)		
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.	
Article 9(5)		
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.	
Article 10		
168	Article 10 Information on regulatory processes on chemicals	Questions: • ES: Is there a specific communication channel foreseen for competent Authorities evaluating substances to convey information on the stage of the evaluation, as indicated in Article 10? Some regulations listed in the Annex already do so; would they need to be adapted in case of a new communication channel, or would the existing one be sufficient?
Article 10(1)		
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.	Questions: • DK: Denmark notes that it is not clear whether regulatory processes mentioned in Article 10, paragraph 1, refers to national law processes, EU law processes, e.g. a submission of a dossier under REACH, or both? Could the Commission please specify/explain?
Article 10(2)		
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.	Questions: • DK: As also stated January AHWP during Q&A, regarding the proposed obligation in Article 10, paragraph 2, we are keen to understand which voluntary notifications the Commissions referred to in its explanation on the obligation. Could be Commission please provide examples? • DK: As Denmark understands the Commission, Article 10, paragraph 2, does in fact introduce a new obligation for the Member States to inform about information on regulatory processes of individual substances or substance groups in addition to the obligations that already exist in the different EU legislations, the information directive and the treaty. The Commission explained during the first ADWP that the new obligation reflects a transition from voluntary notifications that already exist in the different EU legislations listed in Annex III towards an actual obligation where these voluntary notifications exist under EU legislations listed in

		Annex III. Denmark is aware of the existing ACT-PACT. In general, DK is keen to understand the reference to voluntary notifications under EU legislation listed in Annex III.
Article 10(3)		•
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:	Request for clarification: • PT: As part of the provision of regulatory information (Art. 10), it is not clear what it refers to, as far as the EEA is concerned, since it does not have competences about regulatory processes on chemical products.
Article 10(3), point (a)		
172	(a) substance identity;	
Article 10(3), point (b)		
173	(b) the Union act and the regulatory process under which the activity takes place;	
Article 10(3), point (c)		
174	(c) submitter or actor responsible for the regulatory process or activity;	
Article 10(3), point (d)		
175	(d) status of the regulatory process or activity;	
Article 10(3), point (e)		
176	(e) **where applicable,** outcome of the regulatory process or activity, including, where applicable, reports or opinions adopted;	Proposal for amendment: • FR: In Article 10(3) of the proposal, the French authorities consider that point e) relating to the outcome of the regulatory process cannot be systematically indicated

		according to the state of play of the process and propose adding the mention "where appropriate".
Article 10(3), point (f)		
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.	
Article 10(4)		
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.	
Article 11		
179	Article 11 Information on the obligations under Union acts on chemicals	Comments • FR: would like to point out that the use of artificial intelligence could facilitate implementation and enhance the database introduced in Article 11 on the legal provisions and obligations applicable to chemicals.
Article 11(1)		
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.	
Article 11(2)		
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).	
Article 12		
182	Article 12 Repository of standards formats and controlled vocabularies	
Article 12(1)		
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.	

Article 12(2)		
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.	
Article 12(3)		
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.	
Article 13		
186	Article 13 Database on environmental sustainability related data	Requests for amendments: • AT: Art. 2 para. 11 and Art. 13. the term "environmental sustainability related data" is very vague and comprehensive. We believe that this term should be clarified and concretised, since the concrete data content will only be defined at EU level in the coming years (e.g. via "eco-design requirements" as part of the Eco-design Regulation). Therefore, we suggest adding a reference to an Annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. Requests for clarifications: • PT: Regarding the database on information related to environmental sustainability (Art. 13) it is not clear whether the Eionet network will be utilised (taking into account that the EEA does not currently have any relevant data for this database).
Article 13(1)		
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.	

Article 13(2)		
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.	
Article 13(3)		
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.	
Article 13(4)		
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 identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	Comments: • DK: Denmark understands the Commission, the referred implementing decision in Article 4, paragraphs 1 and 2, and Article 13, paragraph 4, is in fact an internal decision prepared only by the Commission. We find that the word implementing may be misleading, in the sense that implementing in the context of EU regulation often refers to implementing acts and the procedures following.
Chapter III		
191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	Requests: • FR: consider it necessary that data related to the hazard of chemical substances should eventually be provided in the form of study reports and raw data and not in the form of study summaries. This format is necessary to enable the use of high-performance data processing tools. Questions:

		• IE, on cosmetics: Regarding streamlining standard formats and vocabularies: for cosmetics the INCI name is that which is established and used on the labelling. Can we get confirmation that the proposed regulation (e.g. Articles 14 and 15) will not impact cosmetic substance identification and product labelling? •
Article 14		
192	Article 14 Standard formats	Proposals for amendment: • AT: Art. 2(6) in conjunction with Art. 8 and Art. 14. For reference values without a toxicological threshold "below which risks related to the adverse effects [...] are considered acceptable or ”tolerable", the statistical (cancer) risk that is associated with these values should be specified as well. The statistical (cancer) risk should be stated in Art. 8 (Repository of reference values) and a data format should be specified in Art. 14 accordingly.
Article 14(1)		
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.	
Article 14(2)		
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:	
Article 14(2), point (a)		
195	(a) avoid the use of proprietary standards;	
Article 14(2), point (b)		
196	(b) re-use existing data formats or parts of them;	

Article 14(2), point (c)		
197	(c) use OECD or other internationally agreed formats;	
Article 14(2), point (d)		
198	(d) be coherent with other existing data formats;	
Article 14(2), point (e)		
199	(e) ensure interoperability with existing data submission approaches.	
Article 14(3)		
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.	
Article 14(4)		
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.	
Article 14(5)		
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:	
Article 14(5), point (a)203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[53]; [53] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).	
Article 14(5), point (b)		

204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[54]; [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).	
Article 14(5), point (c)		
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[55]; [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).	
Article 14(5), point (d)		
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[56]; [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).	
Article 14(5), point (e)		
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[57]; [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).	
Article 14(5), point (f)		

208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[58]; [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).	
Article 14(5), point (g)		
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).	
Article 14(5), point (h)		
210	(h) Commission Regulation (EU) No 234/2011[60]; [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).	
Article 14(5), point (i)		
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).	
Article 14(6)		
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.	

Article 14(7)		
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.	
Article 14(8)		
214	8. The Commission shall adopt an implementing decision to remedy the divergence.	
Article 15		
215	Article 15 Controlled vocabularies	Questions: • DE: the different vocabulary used in different legislations so far might lead to inconsistencies and ambiguities when combining existing data pools. How does the Commission intend to deal with such problems? • DE: Concerning the description of substance identity: It is known that substance identity is defined and handled inconsistently in different regulatory areas. Which mechanism could be used to solve this problem, for example if two pieces of information about a substance differ because the definition of the substance identity is different?
Article 15(1)		
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.	
Article 15(2)		

217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.	
Article 15(3)		
218	3. Those controlled vocabularies shall:	
Article 15(3), point (a)		
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;	
Article 15(3), point (b)		
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;	
Article 15(3), point (c)		
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;	
Article 15(3), point (d)		
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.	
Article 15(4)		
223	4. Those controlled vocabularies shall be interoperable with the common data platform.	
Article 15(5)		
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:	

Article 15(5), point (a)		
225	(a) make them available free of charge through the common data platform and as open datasets;	
Article 15(5), point (b)		
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	
Article 15(5), point (c)		
227	(c) use them when exchanging data between them through the common data platform.	
Article 15(6)		
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.	
Article 15(7)		
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.	
Article 15(8)		
230	8. The Commission shall adopt an implementing decision to remedy the divergence.	
Chapter IV		

231	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	Comments: • FR: The French authorities have taken note of the provisions for managing the confidentiality of the data published on the platform. However, they are concerned about the management of the intellectual property of this data in the context of its re-use. Requests for clarification: • PT: Although the reuse/sharing of data was considered by the authorities as one of the important parameters to be taken into consideration in the OSOA Package, it seems that this issue did not receive attention within the scope of the proposal. The reason behind this option could be related to data ownership aspects, we would ask the COM to better clarify this issue. The possibility in art. 17(1) for Authorities to use the data will not override the ownership and use of data. • PT: Regarding the confidentiality of data (art. 16 and 17), we still have some doubts on the procedure that will be applied when the same study is submitted under different legislative instruments with different levels of confidentiality. We would like to confirm if the level of confidentiality in the origin is going to be maintained.
Article 16		
232	Article 16 Access rights and transparency	Requests: • SI: the rights to access to personal data by Authorities and the general public in Article 16 should be limited according to the purposes claimed Questions: • DE, Concerning the common data platform and the use for scientific bodies: Will it be possible to use the information in the common data platform for scientific purposes? • DE: Did Commission assess whether and how it could be made possible that scientific bodies also feed data into the platform? How could that be organized?

Article 16(1)		
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), second sentence.	
Article 16(2)		
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	Comments: • ES: As mentioned by the Swedish delegation in the meeting held on January 23rd, we believe that everything related to data confidentiality should be carefully considered when developing this instrument, and we should be equipped with the necessary tools to ensure this principle. Questions : • IE : Article 16(2); Will MSs access the platform in a similar manner as to how they access REACH IT and ECHA MSCA applications and so be required to have similar security requirements in place? • IE: We query as to how the provision of information in the common data platform will align itself with article 25(3) of REACH and the 12 year rule on access to data?
Article 16(3)		
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.	
Article 17		
236	Article 17 Use of chemicals data contained in the common data platform	Comments: • IE, about cosmetics: While the collation of data on a substance is welcomed, data used to demonstrate the safety of a cosmetic ingredient cannot have been generated via animal testing. Determining how these sets of data can be distinguished in practice in the database will be something to bear in mind for those planning to use data for carrying out safety assessments of cosmetics.

		• DK: Has the Commission reached clarity on the possibility to add an overview available in the Common Data Platform across the different pieces of legislation on confidential data with respect to existing provisions on confidentiality? And if the Commission did reach clarity, would the Commission share its insights? We first raised this question at the January AHWP during Q&A by asking wether the Commission could consider to make an overview available in the platform across the different pieces of legislation on confidential data with respect to existing provisions on confidentiality, so that any duty holder will be aware that confidential data exists and possibly take advantage of that knowledge providing that confidentiality, ownership and formal rules on data sharing within each relevant legislation are duly respected. The suggestion to add an overview on confidential data with respect to existing provisions on confidentiality reflects Danish Information Act. By way of illustration, the Danish Information Act shows how confidential data held by the national authorities cannot be shared with the general public, but a disclosure of an overview of the confidential held by the authorities is mandatory, when the general public apply for disclosure of information. • DK: Denmark welcomes the requirements set in Article 17 regarding when Member States competent authorities may use and share of information on chemical data contained in the Common Data Platform. We do also believe it to be important to raise the question on how to best make use of the Common Data Platform introduced in the proposed regulation. • DK: During the January AHWP, DK suggested an overview available in the platform across the different pieces of legislation on confidential data with respect to existing provisions on confidentiality. As Denmark understands, the Commission did consider the legal consequences in terms of confidential data generated

		as part of chemical products already placed on the internal market oppose to confidential data generated in connection to chemical products not yet placed on the market. In the light of the Commission's considerations, Denmark is keen to understand, that was meant by chemical products in the Commission's consideration. Is to be understood as mixtures, articles or substances? Could be Commission please provide examples?
Article 17(1)		
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 of chemicals legislation and policy.	Proposals for amendments: • DK: It is our understanding that development or implementation of chemicals legislation and policy in Article 17, paragraph 1, refers to both national and EU chemicals legislation and policy. • DK: In the light of our understanding, we suggest the following text amendment to Article 17, paragraph 1: *Article 17, paragraph 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 of both national and EU chemicals legislation and policy or implementation of both national and EU chemicals legislation and policy.*
Article 17(2)		
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.	Questions: • DE: Article 17 (2) of the proposal states that data in the platform shall not be used to fulfill the duty holder's obligations. Could the Commission elaborate more about the practical use of the data under a specific regulation under which the duty holder has to provide the data? (i.e. can it only be used to check plausibility of the data provided by the duty holder?).
Article 17(3)		
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.	
Chapter V		
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS	
Article 18		
241	Article 18 Framework of indicators	Questions: • DE: Are Member States going to be involved in the development of the indicators (Art. 18)? • IE, on cosmetics: Regarding the use of the database for trending, and also emerging risks to health: caution is needed in relation to administrative burden on authorities and clarity in relation to the data sought. For example, will undesirable effects from cosmetic products where a specific substance has been confirmed to be the culprit be expected to be notified to the database (in addition to the current notification to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009) and will there be scope to justify the continued use of such a product in particular, critical circumstances? • PT: The framework of indicators established in article 18, we would like to clarify how these indicators will be related to the existent statistics systems as we believe that they can be a relevant added value in this process. • PT: In addition, under the monitoring framework of the 8EAP, resources (human and financial) were allocated to the EEA, but no resources were allocated to the Eionet network, which raises the question of whether the impact for the Eionet network will be the same (low) as for the EEA. • Comments: FR: The French authorities are concerned about the timescales for establishing the framework of indicators for monitoring the drivers and impacts of exposure to chemicals referred to in Article 18 of the proposal.

Article 18(1)		
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.	
Article 18(2)		
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.	
Article 19		
244	Article 19 Early warning and action system for emerging chemical risks	Questions: • DE: What is the relation between indicators (Article 18) and the early warning signals (Article 19)? • DE: Is it planned to employ scientific expertise of the Member States and the Agency's committees (i.e. ECHA Committee for Risk Assessment) in identifying the early warning signals? • PT: The early warning system is to be based on a framework of indicators that will monitor the chemical pollution. In this sense, we would like to be informed about the level of ambition of this process taking into consideration those situations where: pollution is not directly detected; the cause-effect relationship is difficult to claim; the risk is becoming more systemic (e.g. considering climate related risks). Comments: • PT: We would also like to underline the importance of the inclusion of the item "prevention of emerging risks related to chemicals", which we also consider very challenging. Requests for clarification:

		• PT: As other MS mentioned in the meeting, we also have some concerns on which will be the involvement of MS in the early warning and action system (art. 19), since details on the operation of the early warning and action system are lacking, as MS hold data which EEA needs to consider, as this is a new task for EEA (with allocation of resources). We believe that there is a need for better clarification of what is considered to be the process of collecting this data from the MS and the involvement of the Eionet Network for this purpose.
Article 19(1)		
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].	
Article 19(2)		
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:	
Article 19(2), point (a)		
247	(a) the EFSA's emerging risks exchange network;	
Article 19(2), point (b)		
248	(b) existing national early warning systems;	
Article 19(2), point (c)		
249	(c) data that the EEA holds;	
Article 19(2), point (d)		
250	(d) targeted literature searches performed by the EEA;	

Article 19(2), point (e)		
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.	
Article 19(2)		
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.	
Article 19(3)		
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.	
Article 19(4)		
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. [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 who shall consider the need for regulatory or policy action related to the early warning signals.	Comments: • FR: Article 19(4) of the proposal provides for an annual report by the European Environment Agency to compile and analyse the data collected on early warning signals in order to examine the need for regulatory measures or action strategies. The French authorities question the appropriateness and relevance of requesting that the European Environment Agency highlight, in the report, the areas on which to focus attention to enable the various parties concerned to take up the issue.
Article 19(5)		
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.	
Article 20		
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	Questions: • DE: Does the Commission target specific chemical risks under Article 20 or should all possible risks be covered under this

		mechanism? If so, could the Commission elaborate a bit more on the interplay with existing chemicals legislation?
Article 20(1)		
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.	
Article 20(2)		
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. The Commission shall review the list of selected chemicals regularly **and** adopt any revision thereof by the same means.	Proposal for editorial amendment: • FR: Article 20(2), second sentence: the linking word "and" is missing before the proposal "shall adopt any revision in accordance with the same procedures". Request for amendments: • DK: Could the Commission consider to adopt and publish the list of selected chemicals referred to in Article 20, paragraph 2, by means of an implementing decision and in accordance with the advisory procedure in article 4 in Regulation (EU) No 182/2011 of the European Parliament and the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers? • DK: We welcome an observatory for specific chemicals, which the Commission considers requiring additional scrutiny. We do at the same time believe that a list on specific chemicals that require further scrutiny would benefit from Member State involvement and propose to include a process to secure this. • DK: Furthermore, as Denmark understands the Commission, the referred implementing decision in Article 4, paragraphs 1 and 2, and Article 13, paragraph 4, is in fact an internal decision prepared only by the Commission. We find that the word implementing may be misleading, in the sense that implementing in the context of EU regulation often refers to implementing acts and the procedures following.

Article 20(3)		
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.	
Article 20(4)		
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:	
Article 20(4), point (a)		
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;	
Article 20(4), point (b)		
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;	
Article 20(4), point (c)		
263	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.	
Chapter VI		
264	Chapter VI DATA GENERATION MECHANISM	Suggested amendments: • NL: With the new proposal on the central data platform, ECHA will be given the mandate to generate data or studies

		on chemicals. Although in general we can support such a mandate, we would like to emphasize that this should not be at the expense of the responsibility of companies that import or produce a chemical substance to guarantee its safety . Can the Commission confirm that this principle will remain the central principle of the EU chemicals legislation? Furthermore, we suggest to frame the new mandate accordingly in the proposed decision.
Article 21		
265	Article 21 Data generation mechanism	Questions: • DE: Is it planned to implement a cross-check with industry expertise/stakeholders on a draft testing proposal? • ES: Regarding Article 21, will MS be able to use the Data Generation mechanism by requesting it through ECHA, for example, or will it be restricted to only the Commission and Agencies? Comments: • ES: Furthermore, we would like to insist that this mechanism should only be used in exceptional cases and always keeping the burden of proof on the industry. The procedure and the responsible parties for the requests and financing of required studies should be clearly established.
Article 21(1)		
266	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.	Questions: • DK: Could the Commission clarify what is meant by scientific studies introduced in Article 21? What types of studies are covered and are there some types of studies, that will not be covered? • DK: Can we assume that animal studies commissioned will be notified in the Database of Study Notification introduced in Article 9 and in accordance with Article 22 of the proposal?
Article 21(2)		
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.	

Article 21(3)		
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.	
Article 21(4)		
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.	
Article 21(5)		
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	Proposal for amendments • DK suggests the following addition to Article 21, paragraph 5: *5a. The ECHA shall consult Member States prior to commission of scientific studies.*
Article 21(6)		
271	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.	
Article 21(7)		
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.	
Chapter VII		
273	Chapter VII NOTIFICATION OF STUDIES	Comments: • FR: support the introduction of a study notification system but have questions about several aspects of the system. • FR: concerned about the planned interaction between notifications from economic operators and those from laboratories for the same studies. A system will be needed to group together notifications for the same study in order to avoid duplication.

		• FR: The proposal states that notifications of studies will only be made available on the platform once the regulatory dossiers taking account of these studies have been submitted. The French authorities have taken due note of the Commission's justifications in recital 30 of the proposal. However, they question the point of setting up such a system if the information is not made available as soon as a study is launched. This strategy does not enable operators and authorities to optimise the conduct of studies and therefore limit animal experimentation. At the very least, the French authorities consider that the authorities of the Member States should have access to the database on study notifications before it is published on the common data platform.
Article 22		
274	Article 22 Notification of studies	Questions: • DE: Laboratories and business operators are expected to notify studies on the properties of substances before they are carried out. Can Commission explain this system further? For example, how does Commission want to deal with studies conducted outside the EU without notification that are submitted afterwards? • DE: Is reference made to any definition of the term “study” in other legislation (or how will it be implemented)? Is it intended to target specific cases/study endpoints by the notification requirement? • DE: Is a mechanism analogous to Art. 32b of the EFSA transparency regulation foreseen for late notifications? • DE: Can the Commission provide more details, which studies/data are potentially affected by the notification requirement related to regulations listed in annex I? • ES: With regard to Article 22 and the notification of studies, does the Commission consider that not having a transitional period for the entry into force of this Regulation could negatively affect obliged companies, potentially leading to

		non-compliance with Article 22 and therefore subjecting them to penalties under Article 26? • ES: Furthermore, can this method of notification be made available to companies prior to the adoption of the Regulation so that they can familiarise themselves with it?
Article 22(1)		
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	• AT: Art. 22(1)& art.2: It is unclear to us whether the term "products" also includes mixtures and articles (within the meaning of the REACH Regulation). In order to clarify this, the term "products" should be included in the definitions within Art. 2.
Article 22(2)		
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.	
Article 22(3)		
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	
Article 22(4)		
278	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope,	

	intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.	
Article 22(5)		
279	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.	Comments: • PT: Regarding the notification of studies (art. 22), we welcome the inclusion of the item "to prevent withholding of specific study results" related to the notification of studies, although we have some concerns on how ECHA will manage to merge all the information that will be notified to "Database of Study Notifications" by business operators, the laboratories and testing facilities, especially those that are established in third countries (art. 22(5)).
Article 22(6)		
280	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].	
Article 22(7)		
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.	
Chapter VIII		
282	Chapter VIII DELEGATED POWERS	
Article 23		
283	Article 23 Amendment of Annexes I, II and III	Support: • FR: welcome the possibility offered by the Commission to amend its annexes by delegated acts via Article 23 of the proposal.
Article 23(1)		
284	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.	
Article 23(2)		
285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.	
Article 23(3)		
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.	
Article 24		
287	Article 24 Exercise of the delegation	
Article 24 (1)		
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
Article 24(2)		
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.	
Article 24(3)		

290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	
Article 24(4)		
291	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.	
Article 24(5)		
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
Article 24(6)		
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	
Chapter IX		
294	Chapter IX ENFORCEMENT AND PENALTIES	Comments: • PT: We have also some concerns on how the enforcement of this notification can be guaranteed if commissioned to third countries. • FR: regret the absence of means of coercion defined at European level with regard to the obligation to notify studies. Experience shows that the existence of sanctions at national level, as proposed in the Commission's draft text, is not always enough of an incentive for regulations to be properly applied (for example, in the case of REACH registration,

		where there is no provision for withdrawal of the registration number in the event of manifest and persistent non-compliance).
Article 25		
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.	
Article 26		
296	Article 26 Penalties for non-compliance	
Article 26(1)		
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.	
Article 26(2)		
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.	
Article 27		
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.	
Formula		
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	
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 toall 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	Comments:

	the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)	• FR: Annex I to the proposal: Regulation 108/2008 on the addition of vitamins and minerals and of certain other substances to foods is listed in point 28 of Annex I, whereas this regulation appears to be already covered by Regulation 1925/2006 mentioned in point 26 of Annex I.
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)	
331	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)	
332	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)	
333	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)	
334	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)	
335	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)	
336	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)	
337	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)	
338	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)	
339	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	Comments in relation to the overlap with ESPR: • IE : We note that Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products will soon be repealed and replaced by the ESPR Regulation. Political agreement has been reached and we are awaiting a final draft for proofreading before it is adopted and published in the OJ. It is essential that the common data platform for chemicals is aligned to the greatest extent possible with plans for a digital product passport under ESPR. One of the sustainability criteria likely to be included in many ecodesign measures under ESPR will be presence of substances of concern in the product being regulated. It is essential that the economic operators will be able to easily access this information and share it with consumers, authorities and other actors in the supply chain via the DPP.
340	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)	
341	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)	
342	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)	
343	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)	
344	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)	
345	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]	
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 Council[1] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[2]; [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 Council[3]; 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 Council[4]. [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.	
Part 2		
378	Part 2 - Reference values to be included in the repository of reference values followingArticle 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 relevantprocedures that are concluded after the date of entry into force of this Regulation. Whererelevant, data held by the EMA resulting from procedures concluded before the date of entryinto force of this Regulation shall also be considered for inclusion into the common data platform.	
Annex III		
381	UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND 23	
382	Reference to each Union act listed herein should be understood also as reference toall 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)	Editorial questions: • AT: We are wondering why Reg. (EC) No 1331/2008 is mentioned twice (No. 17 and No. 21). Maybe this is a an editorial mistake/error. • FR: Annex III of the proposal: Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings is listed twice in Annex III, in points 17 and 21.

380	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	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	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	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)	Editorial: • AT: We are wondering why Reg. (EC) No 1331/2008 is mentioned twice (No. 17 and No. 21). Maybe this is a an editorial mistake/error.
384	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	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	Comments in relation to the overlap with ESPR: • IE : We note that Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products will soon be repealed and replaced by the ESPR Regulation. Political agreement has been reached and we are awaiting a final draft for proofreading before it is adopted and published in the OJ. It is essential that the common data platform for chemicals is aligned to the greatest extent possible with plans for a digital product passport under ESPR. One of the sustainability criteria likely to be included in many ecodesign measures under ESPR will be presence of

		substances of concern in the product being regulated. It is essential that the economic operators will be able to easily access this information and share it with consumers, authorities and other actors in the supply chain via the DPP.
386	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	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	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	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	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	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	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	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	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	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	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].	

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 II to the Steering note:
PRESIDENCY PROPOSALS for consideration at the OSOA AHWP
8/3/2024

A) Proposed blocs of discussion at the 2nd WP- details and presidency expectations for the discussions.

a) **<u>Data/metadata to be included in the data platform (art.3), and the effort requested from MS (art.3,6,13,18,19) and agencies/committees (art.19)</u>**
PRES EXPECTATIONS: seeks reactions on whether the concerns are clarified, and if not, to ear which amendments are suggested.
PRES would like to focus on the following topics:
- Opportunity to request explicitly in the proposal to tag, highlight or prioritize data evaluated by authorities or agencies (should this be left for the implementation?);
- Implications of the proposal on data related to mixtures and in particular in authorizations of plant protection products at national level;
- Potential alignment between the approaches taken for data related to medicinal products and biocidal and phytopharmaceutical products data;
- Links between this proposal and the EHDS (European Health Data Space)
- Potential inclusion of the national emissions notifications into the scope and the level of effort required for that
- Clarification of EIONET role, potential impacts on EIONET resources (art 6/HBM, art 13/sustainability data, art.18 framework indicators, art.19 early warning system), data collection by MS (art.19).
- Impacts of the early warning and action system on MS and RAC (MS experts' role + is there any RAC involvement?)

b) **<u>Amendment proposals by the presidency</u>**
PRES EXPECTATIONS: determine the level of support to the track changes in the table here below (i.e. ***additions***/~~deletions~~).
PRES EXPECTATIONS: clarity on the support to the proposed amendments

c) <u>Medicinal products and cosmetics provisions in COM proposal</u>: chemicals data that should be included in the platform (scope)
PRES EXPECTATIONS: close subject OR enough support for amendments from MS
This includes a discussion on the need for a definition of "relevant substances" with regard to medicinal active substances, the obligations for EMA regarding data submitted before the entry into force of the medicines regulation, and the environmental data contained in the monographs.

d) **<u>HBM data constituting personal data subject to protection</u>**
PRES EXPECTATIONS: reactions to the EDPS report and other topics identified here below, tours the table on concrete amendments responding to the remaining concerns. Based on the discussions and suggestions from MS, the PRES might work on amendments related to this topic (if that is the case, written comments afterwards will be requested).
For discussion:
- Clarity of the differences between anonymised, pseudonymised, aggregated data and how this is take into account in the proposal regarding personal data.
- Member states raised several questions, concerns and clarification needs on human biomonitoring data (SI,DE,ES, PT). Amongst others, PRES highlights: how to cope with the needed study participants consent? Is it required to provide national programs data? Compliance with EUDPR, GDPR. Sources of data, roles of EEA and other institutions. Unclear specification of the use of personal data. SI requests that the right to access personal data in art.16 is limited to the purpose claimed.
- There is a suggestion of amendment by IE to introduce provisions to prevent the sharing of such data by EEA with "third parties", a term IE suggests to define in art.2. PRES understands that this concerns only personal data and at the same time that under the current practices, HBM data are used and

needed by several actors that might fall under the definition of "third parties" (e.g. PARC research publications, authorities research subcontractors, RAC).

- In addition, recommendations were received from the EDPS (European Data Protection Supervisor) the protection of personal data in the framework of the OSOA proposals.

e) **Confidentiality and data use (art 16,17)**

PRES EXPECTATIONS: overview of the positions related to possible amendments.

Topics for discussion:

- DK already proposed to amend art.17(1) to explicitly allow national use of the data
- COM response to MS questions/concerns on art.16 and 17
- MS indications on remaining concerns about:
- the intellectual property and data ownership in the context of data re-use (FR/PT comments).
- the data confidentiality (ES comments)
- the alignment between REACH art.25(3) on the use of (robust) summaries after 12y, and the present proposal (IE comments). PRES understands that this relates also to art.17(2) of the present proposal regarding the fulfilment of duty holders obligations.
- the use of data by scientific bodies (DE)? Or by authorities for national legislation and policy (DK)? PRES understands that DE questions are related to confidential data and also to HBM data as the rest is public, or maybe also to API access. PRES highlights that DK question may also be related to existing provisions or contractual practices linked to regulations listed in annex I (like the limitations to the use of REACH-IT data by MS), or to the use of data in international processes.

f) **The desired level of MS participation or consultation in the foreseen processes, and the legal procedures choice (delegated acts / implementing acts or decisions / commission decisions / EG opinions).**

PRES EXPECTATIONS: tour the table on the level of participation of MS, the desired legal procedures, the specific processes were more participation is eventually requested, and amendment suggestions.

For discussion:

- DE, FR, DK raise questions on the participation of MS in the implementation and other aspects of the proposal (art.4,14,15,13,18,20,20(2),21(5) are mentioned). ES would like to know if MS will be able to use the data generation mechanism.
- DK also raised concerns about the legal procedures mentioned in the proposal, namely the meaning of "implementing" in this context (art.4(1), 4(2),13). DK finds that the use wording refers to "internal decisions" to the COM rather than to implementing acts and the procedures following. DK requests to consider the possibility to use implementing "decisions" in art.20(2) and in accordance with Regulation (EU) No 182/2011. FR supports delegation in art.23.
- **PRES is seeking legal advice (SCG LS)** on comments from DK about the "implementing" wording. PRES highlights that the wording "implementing decision" also appears in art.4(4), art.14(8), art.15(8), art.20(2).

g) **The timeline of the proposal -** clarification and potential need for amendments of art.3(11), 4, 7, 13, 19, 20,22 that contains time specifications.

PRES EXPECTATIONS: clarification of the timeline, indications on the feasibility of the proposed timeline and the necessity for amendments modifying the proposed timeline (including opinions on the FR and DK amendment proposals to art.3(11), art4), FR comments on art.18 and PRES amendment proposal to art.18).

PRES highlights that the timeline is a subject which can be raised potentially in several places in the proposal: the establishment of the platform; integration of the data, actual availability of the data; start of the implementation plan; the timing for the subsequent rolling implementation plans, the transfer of monitoring data from the COM to the ECHA,EEA,EFSA for integration/hosting/making available; establishment of the environmental sustainability database and identification of additional datasets on that subject; establishment of the early warning system; first annual report on early warning signals; the publication of the list of selected chemicals for the observatory; and the application of the obligations of studies notifications.

h) **Studies notification & enforcement**

MS expressed several requests for clarification on notifications (legal scope and definition of studies to be notified, duplications, notification and enforcement for studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies)

PRES EXPECTATIONS:

→ **PRES invites the COM** to respond to MS comments received.

→ **PRES invites MS** to clarify if there are still remaining concerns.

- FR expressed the need for at least an early access for authorities to the notifications before the publication in the data platform, and possibly early access to operators.

→ PRES invites **COM to react** and **MS to express the need for amending** the text on this.

- FR questions the effectiveness of national sanctions

→ PRES invites **COM to react** and **MS to express the need for amending** the text on this.

B) PRESIDENCY PROPOSALS ARTICLE PER ARTICLE AND REACTIONS FROM MS AND COM TO BE PROVIDED IN WRITTEN

MS delegations and COM will be requested to send in written, article per article, comments and possible amendment texts using the table provided here below, at the latest by Friday 22 March 2024, 1 pm, on the basis of which the Presidency will decide on the follow-up and topics to be discussed at the next Working Party meeting, scheduled for the 12th of April 2024.

	Presidency proposals: amendments (~~deletions~~/***additions***)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
Proposal Title			
1	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)		
Formula			
2	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN		
Citation 1			
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		
Citation 2			
4	Having regard to the proposal from the European Commission,		
Citation 3			
5	After transmission of the draft legislative act to the national parliaments,		
Citation 4			
6	Having regard to the opinion of the European Economic and Social Committee[1]		
Citation 5			
7	Acting in accordance with the ordinary legislative procedure,		
Formula			
8	Whereas:		

Recital 1			
9	(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.		
Recital 2			
10	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals. Moreover, the Regulation aims to provide a one-stop-shop on chemicals data and		

	information in the Union accessible to the general public and, thus, to increase the predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.		
Recital 3			
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.		
Recital 4			
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.		

Recital 5			
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.		
Recital 6			
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.		
Recital 7			
15	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.		
Recital 8			
16	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.	Some MS expressed the need for a clarification of the scope and meaning of "relevant substances" for active substances → PRES: this is scheduled for discussion at the 2nd WP	
Recital 9			
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.		
Recital 10			
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.		
Recital 11			
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.		
Recital 12			
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.		
Recital 13			
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.		
Recital 14			
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.		
Recital 15			
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.		
Recital 16			
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.		
Recital 17			
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 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.		
Recital 18			
26	(18) The Commission should adopt an implementation plan identifying initial datasets to be made accessible via the platform and the timeline		

	for their integration, informed by the preparatory work of the Commission and the 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, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission.		
Recital 19			
27	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.		
Recital 20			
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.		
Recital 21			

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.		
Recital 22			
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 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').		
Recital 23			
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.		
Recital 24			
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 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.		
Recital 25			
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.		
Recital 26			
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.		
Recital 27			
35	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.		
Recital 28			
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.		
Recital 29			
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.		
Recital 30			
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.		
Recital 31			
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 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.		
Recital 32			
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.		
Recital 33			
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.		

Recital 34			
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 to be notified under this Regulation.		
Recital 35			
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.		
Recital 36			
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.		
Recital 37			
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.		
Recital 38			
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.		
Recital 39			
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.		
Recital 40			
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.		
Recital 41			
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 .		
Recital 42			
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 on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.		
Recital 43			
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.		
Recital 44			
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 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.		
Recital 45			
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.		
Recital 46			
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.		
Recital 47			
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.		
Recital 48			
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.		
Recital 49			
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, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 201649. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.		
Recital 50			
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.		
Recital 51			
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 [OP: Please insert the date of the opinion of the EDPS].		
Formula			
60	HAVE ADOPTED THIS REGULATION:		
Chapter I			
61	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS		
Article 1			
62	Article 1 Subject matter and scope		
Article 1(1)			
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 sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	NL propose to include SSBD (safe and sustainable by design) as one of the roles for the platform. → PRES propose to work on an amendment introducing explicitly the safe and sustainable by design approach as one of the aims.	
Article 1(2)			
64	2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:		
Article 1(2), point (a)			
65	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and		

	re-usable;		
Article 1(2), point (b)			
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;		
Article 1(2), point(c)			
67	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;		
Article 1(2), point (c)			
68	(d) establish an early warning and action system for emerging chemical risks.		
Article 1(3)			
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).		
Article 2			
70	Article 2 Definitions	• AT request amending art.2 to clarify the meaning of "product" in this proposal. • IE query what is covered by the term "products" in art.7(1) • DK request examples of the meaning of "chemical products" in relation to mixtures, articles, substances. • PRES highlights that the term occurs in recital (8), (10),(25),art.3(3), art.7(1), art.22(1). • PRES highlights also that while some of those occurrences relates to cosmetic or medicinal products, other occurrences do not refer to a particular regulation and might have overlapping meaning with e.g. articles in REACH, or products under the ESPR. → PRES is working on an amendment proposal.	

Formula			
71	For the purpose of this Regulation, the following definitions shall apply:		
Article 2(1)			
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');		
Article 2(2)			
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;		
Article 2(3)			
74	3. 'duty holder' means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;		
Article 2(4)			
75	4. 'business operators' means duty holders which are private or public undertakings;	• IE suggests to "use 'economic operators' instead of 'business operators' to ensure alignment with other relevant legislation". • PRES highlights that the term "business operator" is used in recital (8),(13),(28),(29),(30),(31),(35),(37),(38), and articles 1(2), 22, 25,and 26. Those articles relates to studies commissioned, studies notifications, and related enforcement/penalties. • PRES highlights that the term "duty holder" is defined in art. 2(3) in relation to obligations in acts mentioned in annex I or II. The terms is per se used in recital (13), (15), (48),art 2(4), 15(5), and 17(2). Those later articles relate to the use of the controlled vocabularies, as well as the prohibition for Authorities to use data from the platform to fulfil legal	

		obligations of duty holders. → PRES seeks written comments on the following: ESPR has a definition of "economic operator": 'economic operator' means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider. PRES understands that in the present regulation the meaning of it is much more narrow, and relates only to duty holders that at the same time are undertakings. → PRES seeks for agreement that in consequence there is no correspondence with other EU regulations, and thus no amendment here should be done.	
Article 2(5)			
76	5. 'human biomonitoring data' means concentrations of chemicals measured in human matrices such as blood or urine;		
Article 2(6)			
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;	• AT commented about "acceptable or tolerable" in relation to non-threshold cancerogenic substances. • PRES understands that the intention is to avoid that reference values for non-threshold substances are published without mentioning as metadata the actual statistical risk they represent. → PRES proposes to work on an amendment of art 2(6), 8 and 14 for this.	
Article 2(7)			
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;		
Article 2(8)			

79	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;		
Article 2(9)			
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;		
Article 2(10)			
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;		
Article 2(11)			
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:	• AT finds this definition vague, and proposes to add an annex (e.g. in Art. 13) which can be updated on a regular basis by means of Delegated Acts. This annex should contain the respective legal acts as well as the associated sustainability information. • PRES highlights that the definition here is used in a broader sense than the information available in legal acts (e.g. research in art.5(6), art 13(3) and potentially art.13(4)). → PRES requests written comments on the necessity to add a reference to a new annex IV, containing a list legal acts relevant for environmental sustainability related data. Such a reference would be added here as a new point 2(11)(d) along with related delegated powers in Chapter VIII. → PRES would also like to have comments on the provisions of art.13(4) as this partially overlaps with the concern raised by AT (by	

		having the COM adopting an implementing decision for data not already hosted or hold by agencies/COM or not coming from EU research). Which relevant data are generated through legal acts but are not hold or hosted by COM/agencies listed in this proposal?	
Article 2(11), point (a)			
83	(a) data on resources, including raw materials, water, energy, fossil fuels and land;		
Article 2(11), point (b)			
84	(b) data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances; and		
Article 2(11), point (c)			
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.		
Article 2(12)			
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;	• FR highlighted that this definition is specified in Article 3, point (1) of Regulation 2018/1725 and not in Article 3, point (16) of Regulation 2018/175. → PRES sees this as an editorial amendment and proposes to modify Article 2 (12) consequently.	
Article 2(13)			
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	• FR highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to	

	~~Regulation (EU) 2018/175~~ ***Regulation (EU) 2018/1725*** of the European Parliament and of the Council;	modify Article 2 (13) consequently.	
Article 2(14)			
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~~ ***Regulation (EU) 2018/1725*** of the European Parliament and of the Council;	• FR highlighted that the reference is to Regulation 2018/1725 and not to Regulation 2018/175. → PRES sees that this is an editorial amendment and proposes to modify Article 2 (14) consequently.	
Article 2(15)			
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.	• DE asks if advanced programming interfaces (API) will be used. • PRES highlights that API are tools that MS may use amongst others in order to query the data platform from their own advanced knowledge management systems (i.e. machine readability) instead of relying on "manual" queries in a web interface like in ECHA web site today. • PRES highlights that in the explanatory memorandum the COM mentions that "The proposal also contributes to the objectives of EU data and digital policies by promoting interoperability and **machine readability"**. However only interoperability is explicitly mentioned here. → PRES requests written comments on this and on the necessity to amend the proposal to explicitly mention APIs and the conditions of their use for MS and the public.	
Chapter II			
90	Chapter II INFORMATION SYSTEMS AND PLATFORMS		
Article 3			
91	Article 3 Common Data Platform on Chemicals		
Article			

3(1)			
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').		
Article 3(2)			
93	2. The common data platform shall provide access to all chemicals data:	• FR highlights that it is difficult to assess the exhaustiveness of annexes I and III. → PRESID request written comments on any potentially missing relevant regulations in those annexes. • FR question the differentiated approach between medicinal products and biocidal and phytopharmaceutical products. → PRESID would like to know if FR may bring this topic during the corresponding agenda point at the 2nd WP as it is not clear for us which could be the proposal that could be made on this basis.	
Article 3(2), point (a)			
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;		
Article 3(2), point (b)			
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;		
Article 3(2), point (c)			
96	(c) listed in Annex II and held by the EMA;		
Article 3(3)			
97	3. The following information shall not be included in the common data		

	platform:		
Article 3(3), point (a)			
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[50]; 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).		
Article 3(3), point (b)			
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. 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).		
Article 3(4)			
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.		
Article 3(5)			
101	5. The common data platform shall provide the dedicated services identified in the governance scheme referred to in Article 4(3) including:		
Article 3(5), point (a)			
102	(a) the Information Platform for Chemical Monitoring ('IPCHEM')		

	referred to in Article 7;		
Article 3(5), point (b)			
103	(b) the repository of reference values referred to in Article 8;		
Article 3(5),point (c)			
104	(c) the database of study notifications referred to in Article 9;		
Article 3(5), point (d)			
105	(d) information on regulatory processes referred to in Article 10;		
Article 3(5), point (e)			
106	(e) information on obligations under Union chemicals legislation referred to in Article 11;		
Article 3(5), point (f)			
107	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;		
Article 3(5), point (g)			
108	(g) the database on environmental sustainability-related data referred to in Article 13.		
Article 3(6)			
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.		
Article 3(7)			
110	7. The data contained in the common data platform may be used in		

	accordance with Article 17.		
Article 3(8)			
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.		
Article 3(9)			
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.		
Article 3(10)			
113	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/200152. 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).		
Article 3(11)			
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 shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives	• FR requested clarifications on this paragraph (timing for the notification service, lack of specification of the timing for the rolling plans). • FR proposed or suggests amendments accordingly → PRES: we suggest to integrate this into a more general discussion at the 2d WP about the entire timeline of the proposal.	

	chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.		
Article 4			
115	Article 4 Implementation plan and governance of the common data platform	• DK proposed to include new provisions 5a,5b,5c in art.4., requesting that the COM prepares and presents a recommendation on "how to amend legislation listed in the Annexes to this regulation". → PRES would like to receive written comments on this as it is not clear for us if this means amending the annexes of the data platform proposal, or if DK meant to amend the listed regulations. • DK raises concerns about the wording "implementing" appearing at several places and which is seen as "misleading" with respect to the legal definition of "implementing acts". → PRES seeks legal advice on this. The Council legal services agreed to give an opinion on this at the 2nd WP.	
Article 4(1)			
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish an implementation plan identifying datasets for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	• FR questions the procedure for adopting the plan, the consultation procedures and MS involvement. → PRES proposes to integrate this in a WP discussion on the desired level of and procedures for MS participation.	
Article 4(2)			
117	2. The Commission shall, by means of an implementing decision, establish and manage a platform steering committee, which shall include one representative from the ECHA, one representative from the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five representatives from the Commission.		
Article 4(3)			

118	3. The platform steering committee shall advise the Commission in the preparation of the common data platform's governance scheme.		
Article 4(4)			
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		
Article 4(5)			
120	5. That governance scheme shall describe:		
Article 4(5), point (a)			
121	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;		
Article 4(5), point (b)			
122	(b) the preparation and adoption of rolling implementation plans for the common data platform;		
Article 4(5), point (c)			
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;		
Article 4(5), point (d)			
124	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;		
Article 4(5),			

point(e)			
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;		
Article 4(5), point (f)			
126	(f) the operation of the steering committee itself.		
Article 5			
127	Article 5 Data Flows for the purpose of the common data platform		
Article 5(1)			
128	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.		
Article 5(2)			
129	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).*** The Commission and the Agencies shall indicate whether that data or information is made available to the public under the originating Union act.	• FR highlighted that the reference should be to Article 4(5), point (and not Article 4(4), point (c). → PRES sees this as an editorial amendment and proposes to modify Article 5(2) consequently.	
Article 5(3)			
130	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.		
Article 5(4)			
131	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	• DE ask if Commission pursue plans for systematic or regular surveys of indoor air quality data → PRES is requesting written comments on this.	

Article 5(5)			
132	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].		
Article 5(6)			
133	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].		
Article 5(7)			
134	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.		
Article 5(8)			
135	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.		
Article 5(9)			
136	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.		
Article 6			
137	Article 6 Human biomonitoring data	→ PRES: given the numerous comments, questions and clarification requests received, PRES proposes to set this as a discussion point at the 2nd WP (8/3), and invites MS and the COM to react to the EDPS	

		recommendations.	
Article 6(1)			
138	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.		
Article 6(2)			
139	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.		
Article 6(3)			
140	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.		
Article 6(4)			
141	4. Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:		
Article 6(4), point (a)			
142	(a) assessing the impact of chemicals on human health and the environment;		
Article 6(4), point (b)			
143	(b) monitoring time and spatial trends in exposure;		
Article 6(4), point (c)			
144	(c) developing health risk and impact indicators;		
Article 6(4), point (d)			

145	(d) monitoring the impact of regulatory intervention;		
Article 6(4), point (e)			
146	(e) supporting regulatory risk assessments.		
146.a	***(f) supporting regulatory risk management***	• IE proposed to add this amendment. • PRES understands that HBM data are indeed useful for risk management, e.g. trend analysis will give an idea if policy actions are having an impact or not on reducing exposure → PRES proposes thus to add this paragraph (f)	
Article 6(5)			
147	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.		
Article 6(6)			
148	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to ~~in paragraph 2.~~ ***in paragraph 4.***	• FR and SI highlighted that the reference should be to para. 4. → PRES sees this as an editorial amendment and proposes to modify art.6(6) in consequence. • SI proposes to add an additional reference to art.3 and 5 here. → PRES, up to his knowledge, understands that from the definition of a data controller this is logical, but seeks for written opinions on this and will request a legal advice. Discussions at the 2nd WP on the EDPS recommendations might also contribute clarifications on this proposal. • SI suggests to "include the same reference to Articles 6(3) and 6(4)" → PRES is keen to receive a written rationale for this as it seems to introduce a circular reference in the text.	
Article 7			

149	Article 7 Information Platform for Chemical Monitoring		
Article 7(1)			
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.	→ PRES: regarding the meaning of “products”, cfr art.2 (here in line 70).	
Article 7(2)			
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.		
Article 7(3)			
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.		
Article 7(4)			
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.		
Article 7(5)			
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.		
Article			

7(6)			
155	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.		
Article 8			
156	Article 8 Repository of reference values	• AT requested and amendment about the statistical (cancer) risk associated with some reference values. → PRES: see our proposal in art 2(6) here line 77	
Article 8(1)			
157	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.		
Article 8(2)			
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.		
Article 8(3)			
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.		
Article 8(4)			
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.		
Article 8(5)			

161	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.		
Article 9			
162	Article 9 Database of Study Notifications		
Article 9(1)			
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].		
Article 9(2)			
164	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.		
Article 9(3)			
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 on confidentiality.	• AT considers that this deserves clarification as it seems to prevent Member States authorities from getting relevant information on notified studies in time. • PRES notes that this might be related to enforcement. → PRES seeks further written comments on this → PRES is working on an amendment proposal	
Article 9(4)			
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.		
Article 9(5)			
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.		
Article 10			
168	Article 10 Information on regulatory processes on chemicals	→ PRES is seeking written comments on ES question about already existing communication channels in certain regulations, related to the stage of evaluation, and the potential need to modify those regulations. → PRES highlights that this might be the case for TRIS notifications.	
Article 10(1)			
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.	→ PRES is seeking for written comments on DK comment that it is not clear whether the scope of art 10(1) includes national regulations processes.	
Article 10(2)			
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.	→ PRES is seeking for written comments on DK request to clarify the COM reference (during the 1st WP) to voluntary notifications, including examples.	
Article 10(3)			
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:	→ PRES is seeking written comments on PT question about which information EEA might have to make available to ECHA in this context, as EEA has no competences about chemical products.	
Article			

10(3), point (a)			
172	(a) substance identity;		
Article 10(3), point (b)			
173	(b) the Union act and the regulatory process under which the activity takes place;		
Article 10(3), point (c)			
174	(c) submitter or actor responsible for the regulatory process or activity;		
Article 10(3), point (d)			
175	(d) status of the regulatory process or activity;		
Article 10(3), point (e)			
176	(e) ***where applicable,*** outcome of the regulatory process or activity ~~, including, where applicable~~, ***and*** reports or opinions adopted;	• PRES understand from FR comment that it is not always possible to indicate the (future) outcome, so this provision is not always applicable. → PRES propose to amend art 10(3) by inserting "where applicable" as we see it more precise than "where appropriate"	
Article 10(3), point (f)			
177	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.		
Article 10(4)			
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.		
Article 11			
179	Article 11	• PRES notes FR comment on the potentiality of IA in this	

	Information on the obligations under Union acts on chemicals	context.	
Article 11(1)			
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.		
Article 11(2)			
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).		
Article 12			
182	Article 12 Repository of standards formats and controlled vocabularies		
Article 12(1)			
183	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.		
Article 12(2)			
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.		
Article 12(3)			
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.		
Article 13			
186	Article 13 Database on environmental sustainability related data	• AT request for a new annex on relevant legal acts, see discussion of Article 2(11) → PRES: see line 82 here above • About the role of EIONET in this (cfr PT question)	

		→ PRES include this in the discussion at the WP (effort needed by MS)	
Article 13(1)			
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.		
Article 13(2)			
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.		
Article 13(3)			
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.		
Article 13(4)			
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 identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	→ PRES is seeking legal advice about the wording "implanting decision" (cfr DK comment). Council legal services will give an opinion on this at the 2nd WP.	
Chapter III			

191	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	→ PRES seeks written comments on FR request to eventually have study reports and raw data provided → PRES seek written comments on the request by IE to investigate that there is no impact on the use of INCI names for cosmetics regulation, and no impact on substance identification and product labelling in that regulation.	
Article 14			
192	Article 14 Standard formats	• AT amendment proposal on statistical risk: → PRES: see here Article 2(6) line 77	
Article 14(1)			
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.		
Article 14(2)			
194	2. The standard formats referred to in paragraph 1 shall, to the extent possible:		
Article 14(2), point (a)			
195	(a) avoid the use of proprietary standards;		
Article 14(2), point (b)			
196	(b) re-use existing data formats or parts of them;		
Article 14(2), point (c)			
197	(c) use OECD or other internationally agreed formats;		
Article 14(2), point (d)			

198	(d) be coherent with other existing data formats;		
Article 14(2), point (e)			
199	(e) ensure interoperability with existing data submission approaches.		
Article 14(3)			
200	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.		
Article 14(4)			
201	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.		
Article 14(5)			
202	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:		
Article 14(5), point (a)			
203	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[53]; [53] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268 18.20.2003, p. 29).		
Article 14(5), point (b)			
204	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[54]; [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).		
Article 14(5), point (c)			
205	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[55]; [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).		
Article 14(5), point (d)			
206	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[56]; [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).		
Article 14(5), point (e)			
207	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[57]; [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).		
Article 14(5), point (f)			
208	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[58]; [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).		
Article 14(5), point (g)			
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).		
Article 14(5), point (h)			
210	(h) Commission Regulation (EU) No 234/2011[60]; 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).		
Article 14(5), point (i)			
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).		
Article 14(6)			
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.		

Article 14(7)			
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.		
Article 14(8)			
214	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Article 15			
215	Article 15 Controlled vocabularies	→ PRES is seeking written comments on the remarks by DE about the difficulties related to differences in vocabularies between legislations. → PRES seeks for comments on the difficulties related to substances identification inconsistencies between regulations (see DE comment). PRES highlights that this problem is also relevant for art.22,25,26 on studies notification (a lack of correct identification might render difficult to implement them)	
Article 15(1)			
216	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.		
Article 15(2)			
217	2. The Commission and the Agencies shall prioritise specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.		

Article 15(3)			
218	3. Those controlled vocabularies shall:		
Article 15(3), point (a)			
219	(a) avoid the use of proprietary controlled vocabularies to the extent possible;		
Article 15(3), point (b)			
220	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;		
Article 15(3), point (c)			
221	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;		
Article 15(3), point (d)			
222	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.		
Article 15(4)			
223	4. Those controlled vocabularies shall be interoperable with the common data platform.		
Article 15(5)			
224	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:		
Article 15(5), point (a)			
225	(a) make them available free of charge through the common data		

	platform and as open datasets;		
Article 15(5), point (b)			
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		
Article 15(5), point (c)			
227	(c) use them when exchanging data between them through the common data platform.		
Article 15(6)			
228	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.		
Article 15(7)			
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.		
Article 15(8)			
230	8. The Commission shall adopt an implementing decision to remedy the divergence.		
Chapter IV			
231	Chapter IV	→ PRES: FR and PT comments here are to be discussed at the WP.	

	CHEMICALS DATA CONFIDENTIALITY AND USE		
Article 16			
232	Article 16 Access rights and transparency	→ PRES: SI request and DE questions (line 232 of the comments file) are to be discussed at the WP	
Article 16(1)			
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), second sentence.		
Article 16(2)			
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	→ PRES: ES comments and IE questions are to be discussed at the WP (line 234 of the comments file)	
Article 16(3)			
235	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.		
Article 17			
236	Article 17 Use of chemicals data contained in the common data platform	• DK comment on the meaning of "products" is addressed here in art.2 (see line 70). • PRES: Regarding the other comments: → PRES seeks written comments on IE concern on the identification in the data platform of cosmetics ingredients that may have been tested on animals. → PRES invites the COM to update MS on the possibility of an overview table on confidentiality provisions requested by DK •	
Article 17(1)			
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 of chemicals legislation and policy.	→ PRES: DK request for amendment to explicitly allow national use of the data is set for discussion at the WP.	

Article 17(2)			
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.	• DE requested clarifications on the use of data in relation to duty holders obligations. → PRES invites for written comments on this.	
Article 17(3)			
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.		
Chapter V			
240	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS		
Article 18			
241	Article 18 Framework of indicators	• DE question on MS involvement is set of discussion at the 2nd WP → PRES sets PT question on EIONET impacts for discussion at the 2nd WP. • IE comments on cosmetics: → PRES invites for written comments on questions raised by IE on cosmetics aspects (notification of undesirable effects, link to the Communication System for Market Surveillance (ICSMS) Art 23 Reg 1223/2009, consequences on the allowance of use for critical circumstances). • PT comment on the relation to existing statistics systems → PRES invites for written comments	
Article 18(1)			
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-		

	OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.		
Article 18(2)			
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.		
Article 18(3)			
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 years after the end of the first calendar year after entry into force of this Regulation].***	• FR expressed concerns on the timescale for establishing the framework • PRES highlights that several other articles contain indications on the timeframe → PRES submits this amendment for consideration, and set this for discussion at the 2nd WP.	
Article 19			
244	Article 19 Early warning and action system for emerging chemical risks	→ PRES: DE question on MS experts and RAC involvement is set for discussion at 2nd WP → PRES: PT request for clarification on implications/role of EIONET and MS is set for discussion at the 2nd WP • Regarding the other comments: → PRES seeks written comments about DE question on the relation between the indicators and the early warning system (art.18,19). → PRES invites for written comments on PT question about the level of ambition of the system in relation to complex systemic risks. → PRES invites written comment on PT proposal to include the word "prevention" in the proposal	
Article 19(1)			

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].		
Article 19(2)			
246	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:		
Article 19(2), point (a)			
247	(a) the EFSA's emerging risks exchange network;		
Article 19(2), point (b)			
248	(b) existing national early warning systems;		
Article 19(2), point (c)			
249	(c) data that the EEA holds;		
Article 19(2), point (d)			
250	(d) targeted literature searches performed by the EEA;		
Article 19(2), point (e)			
251	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.		
Article 19(2)			
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.		
Article 19(3)			

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.		
Article 19(4)			
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. [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~~ ***Member State competent authorities who shall consider the need*** for regulatory or policy action related to the early warning signals.	• FR expressed questions the request to EEA to highlight areas on which to FOCUS, in the report. PRES suppose that this may be solved by a change in the wording (mostly editorial) → PRES submits for consideration the amendment here in trackchanges	
Article 19(5)			
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.		
Article 20			
256	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	→ PRES seeks written comments on DE question about the type of risks covered here, and the interplay with existing chemicals legislation.	
Article 20(1)			
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.		
Article 20(2)			
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. The Commission shall review the list of selected chemicals regularly ***and***	• FR highlighted that the linking word "and" is missing before the proposal "adopt any revision thereof by the same means". → PRES sees this as an editorial amendment and proposes to	

	adopt any revision thereof by the same means.	modify article 20(2) consequently (see ***bold italic***). • DK request for amendments (implementing "decisions"). → PRES: questions on the meaning of "implementing", and MS participation are set for discussion at the 2nd WP.	
Article 20(3)			
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.		
Article 20(4)			
260	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:		
Article 20(4), point (a)			
261	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;		
Article 20(4), point (b)			
262	(b) commission studies and, where relevant, use the data generation mechanism established under Article 21 to address knowledge gaps or significant uncertainties;		
Article 20(4), point (c)			
263	(c) make compiled data publicly available through the common data		

	platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.		
Chapter VI			
264	Chapter VI DATA GENERATION MECHANISM		
Article 21			
265	Article 21 Data generation mechanism	• IE raised the question of the promotion of animal testing in relation to article 1. PRES understands that the type of tests are prescribed in each regulation mentioned in annex I, and thus this regulation is not modifying that. However, art.21 here is new, and thus the question of the minimization of animal testing might be relevant here. DK would like to know if commissioned animal studies will be notified → PRES requests written reactions and proposals on this matter. • NL expressed the need to frame the mandate in such a way that the burden of proof on companies is preserved. ES insist also on the burden of proof on industry and highlights the need for clarify on procedures and financing. → PRES invites for written comments and amendments proposals. • Comments were received in relation to the involvement of MS, industry, stakeholders in the data generation mechanism (DE,ES). → PRES schedule a discussion on this at the 2nd WP	
Article 21(1)			
266	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.	• DK requests clarity on the meaning of scientific studies, and which one will not be covered. → PRES invites for written comments on this	
Article			

21(2)			
267	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.		
Article 21(3)			
268	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.		
Article 21(4)			
269	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.		
Article 21(5)			
270	5. The ECHA shall commission these scientific studies in an open and transparent manner.	• DK suggests to amend this to introduce compulsory prior MS consultation. → PRES schedules this for discussion at the 2nd WP	
Article 21(6)			
271	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.		
Article 21(7)			
272	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.		
Chapter VII			
273	Chapter VII NOTIFICATION OF STUDIES	Several comments were received on this chapter: on the legal scope and definition of studies to be notified, duplications, studies conducted outside the EU, late notifications, absence of a transitional period, practical arrangements for companies, the need for early access before publication in the data platform (FR,DE,ES,AT,PT).	

		→ PRES scheduled this for discussion at the 2nd WP	
Article 22			
274	Article 22 Notification of studies		
Article 22(1)			
275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(2)			
276	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.		
Article 22(3)			
277	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.		
Article 22(4)			
278	4. For the purposes of paragraph 3, laboratories and testing facilities		

	shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.		
Article 22(5)			
279	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.		
Article 22(6)			
280	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].		
Article 22(7)			
281	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.		
Chapter VIII			
282	Chapter VIII DELEGATED POWERS		
Article 23			
283	Article 23 Amendment of Annexes I, II and III		
Article 23(1)			
284	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.		
Article 23(2)			

285	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.		
Article 23(3)			
286	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.		
Article 24			
287	Article 24 Exercise of the delegation		
Article 24 (1)			
288	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
Article 24(2)			
289	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.		
Article 24(3)			
290	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the		

	decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		
Article 24(4)			
291	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.		
Article 24(5)			
292	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
Article 24(6)			
293	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.		
Chapter IX			
294	Chapter IX ENFORCEMENT AND PENALTIES	• PT expressed concerns on enforcement for third countries; FR questions the effectiveness of national sanctions. → PRES schedules this for discussion at the 2nd WP	
Article 25			
295	Article 25 Enforcement The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in		

	accordance with Article 22.		
Article 26			
296	Article 26 Penalties for non-compliance		
Article 26(1)			
297	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.		
Article 26(2)			
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.		
Article 27			
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.		
Formula			
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		

	Presidency proposals: amendments (~~deletions~~/***additions***)	Presidency proposals: follow-up or proposal to work on amendments, or requests for written comments	Reactions from the Commission and MS
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)~~	• FR highlighted the fact that regulation 108/2008 is mentioned in point 28 of Annex I, whereas this regulation is already covered by regulation 1925/2006 mentioned in point 26 of Annex I. →PRES proposes to amend the text (deleting point 28).	
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)		
331	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)		
332	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)		
333	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)		
334	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)		
335	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)		
336	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)		
337	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)		
338	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)		
339	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		
340	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)		
341	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)		
342	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)		
343	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)		
344	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)		
345	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]		
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 Council[1] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[2]; [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 Council[3]; 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 Council[4]. [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.		
Part 2			
378	Part 2 - Reference values to be included in the repository of reference values followingArticle 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 relevantprocedures that are concluded after the date of entry into force of this Regulation. Whererelevant, data held by the EMA resulting from procedures concluded before the date of entryinto 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 toall 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	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	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	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	~~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)~~	• FR and AT highlighted the fact that Regulation 1331/2008 is mentioned twice: in points 17 and 21 of Annex III. → PRES proposes to amend the text (deleting this repetition).	
384	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	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	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	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	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	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	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	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	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	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	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	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	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].		