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Common data platform on chemicals, establishing a monitoring and outlook framework for chemicals

Amendments adopted by the European Parliament on 1 April 2025 on the 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 (COM(2023)0779 – C9-0449/2023 – 2023/0453(COD)) [1]

(Ordinary legislative procedure: first reading)

(C/2025/4376)

Amendment 1

Proposal for a regulation

Recital 1

Text proposed by the Commission	*Amendment*
(1) The European Green Deal [1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability [2] is a crucial delivery of this zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, 'safe and sustainable by design' criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.	(1) The European Green Deal [1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability [2] is a crucial delivery of this zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation. According to that Strategy, 'safe and sustainable by design' criteria should be developed to enable the production and use of chemicals that are safe and sustainable throughout their entire lifecycle. The Strategy also sets out that the interaction between scientific developments and policy-making should be strengthened by means of an early warning system for chemicals ***and groups of chemicals*** to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation. This Regulation aims to implement these objectives.
[1] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM (2019) 640 final.	[1] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM (2019) 640 final.

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 60(4), fourth subparagraph (A10-0018/2025).

Text proposed by the Commission	*Amendment*
([2]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM (2020) 667 final,	([2]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM (2020) 667 final,

Amendment 2

Proposal for a regulation

Recital 2

Text proposed by the Commission	*Amendment*
(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.	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from chemicals, as well as to facilitate the functioning of the internal market for chemicals***. Improving the integration of information from different sources, and establishing a cost-effective digital infrastructure will improve the predictability and transparency of regulatory processes and result in a reduction of the administrative burden and overlaps***. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the ***transparency,*** accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation ***and thereby contribute to ensuring that testing on animals only takes place as a last resort***. 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. ***By collecting and making available all data on chemicals that exist in the Union, the database will also foster innovation and support the development of advanced biologically-relevant tools, methods and models, and data analysis capacities.***

Amendment 3

Proposal for a regulation

Recital 4

Text proposed by the Commission	*Amendment*
(4) In its communication of 19 February 2020 on a European strategy for data ([4]), the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.	(4) In its communication of 19 February 2020 on a European strategy for data ([4]), the Commission described its vision of a common European data space and highlighted the need for the development of sectoral data spaces in strategic areas, since not all sectors of the economy and society are moving at the same speed. This Regulation aims therefore to build a data space for chemicals by establishing a common data platform on chemicals ('common data platform'), which is also part of the Green Deal data space, as referred to in the European strategy for data. Furthermore, in that strategy, the Commission highlighted several issues concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the ***Commission and the*** relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks.
([4]) Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, A European strategy for data, COM(2020)66 final.	([4]) Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, A European strategy for data, COM(2020)66 final.

Amendment 4

Proposal for a regulation

Recital 6

Text proposed by the Commission	*Amendment*
(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	(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

Text proposed by the Commission	*Amendment*
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.	public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution. ***Authorities should take the necessary measures to protect the confidentiality of data, including, where relevant, by means of physical and cybersecurity measures.***

Amendment 5

Proposal for a regulation

Recital 7

Text proposed by the Commission	*Amendment*
(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.	(7) The common data platform should contain***, but not be limited to, all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted ***to them*** as part of the implementation of Union chemicals legislation listed in Annex I***, unless this Regulation specifies otherwise***. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with their reporting obligations ***and enforcement activities***. 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.

Amendment 6

Proposal for a regulation

Recital 8

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

Amendment 7

Proposal for a regulation

Recital 9

Text proposed by the Commission	*Amendment*
(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.	(9) ***Taking due account of the administrative work for EMA coming from the adaptation of such data*** to ***an appropriate format for inclusion in the common data platform, it is appropriate to adopt a stepwise approach, and to include during the first stage only chemical data for active substances which are*** submitted to the EMA in the context of the relevant procedures that are finalised after the entry into force of this Regulation. ***No*** later ***than eight years after the entry into force of this regulation, EMA*** should also include ***the chemical data*** on ***active substances from*** procedures concluded before the entry into force of this Regulation.

Amendment 8

Proposal for a regulation

Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Active substances contained in medicinal products are covered by Annex II to this Regulation, but may also be regulated in legislation referred to in Annex I since active substances in medicinal products may also be used in applications that fall under Union legislation listed under Annex I. In order to protect the confidentiality of certain data, the provisions on confidentiality under the originating Union act apply.

Amendment 9

Proposal for a regulation

Recital 12

Text proposed by the Commission	*Amendment*
(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.	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework***, granting, as a general principle, the widest possible access to chemicals data and, where appropriate,*** specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies. ***Access to personal data should be limited to what is necessary in relation to the purposes for which those data are processed by the Authorities.***

Amendment 10

Proposal for a regulation

Recital 14

Text proposed by the Commission	*Amendment*
(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.	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks. ***The common data platform should also include terms and conditions, particularly regarding the respect of intellectual property rights and other related rights.***

Amendment 11

Proposal for a regulation

Recital 17

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

Amendment 12

Proposal for a regulation

Recital 18

Text proposed by the Commission	*Amendment*
(18) The Commission should adopt an implementation plan identifying ***initial*** datasets to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ([10]). 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.	(18) The Commission should adopt an implementation plan identifying datasets ***of chemicals data*** to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies ([10]). The Commission should set up a governance scheme to support and steer the common data platform's operation and evolution covering the organisation of work structures and coordination between ECHA and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets ***of chemicals data*** and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. 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.
([10]) European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023.	([10]) European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023.

Amendment 13

Proposal for a regulation

Recital 19

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

Amendment 14

Proposal for a regulation

Recital 21

Text proposed by the Commission	*Amendment*
(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.	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, ***chemicals*** data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I ***or other obligations laid down in this Regulation***. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. ***Other parties, such as Member States, national agencies, scientific bodies of Member States, national authorities or researchers or research consortia should be able to submit on a voluntary basis chemicals data to the Agencies or the Commission. Where such data are submitted, a standard format appropriate for the inclusion in the common data platform should be used, where available.***

Amendment 15

Proposal for a regulation

Recital 22

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

Amendment 16

Proposal for a regulation

Recital 23

Text proposed by the Commission	*Amendment*
(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.	(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 ***national or*** 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.

Amendment 17

Proposal for a regulation

Recital 24

Text proposed by the Commission	*Amendment*
(24) The EEA, as the agency responsible for monitoring data and information on chemicals in the environment, should also be responsible for collecting, hosting, and maintaining human biomonitoring data***. To the extent that*** human biomonitoring data ***constitutes a special category of personal data, namely, health data, the EEA*** should ***process that data only where the processing is necessary for reasons of substantial public interest, as required by Article 10(2)(g) of the Regulation (EU) No 2018/1725 of the European Parliament and of the Council ([11]). 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***.	(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***, with the exception of occupational*** human biomonitoring data***, which*** should ***be collected, hosted and maintained by the ECHA***.
([11]) ***Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).***	

Amendment 18

Proposal for a regulation

Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitute a special category of personal data, namely, health data, the EEA, the Commission, the ECHA, the EFSA, the EU-OSHA and the EMA should process those data only where the processing is necessary for reasons of substantial public interest, as laid down in Article 10(2)(g) and for scientific research as laid down in Article 10(2)(j) of Regulation (EU) 2018/1725. The present Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data constituting personal data.

Amendment 19

Proposal for a regulation

Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) The inclusion of human biomonitoring data collected prior to the entry into force of this Regulation in the common data platform is necessary to ensure the completeness and quality of the human biomonitoring datasets for the purposes of this Regulation.

Amendment 20

Proposal for a regulation

Recital 27

Text proposed by the Commission	*Amendment*
(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable.	(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II**.** The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable. ***The ECHA should also include in the repository of reference values reference values that are generated through other programmes or research activities and that are made available to it.***

Amendment 21

Proposal for a regulation

Recital 28

Text proposed by the Commission	*Amendment*
(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	(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

Text proposed by the Commission	*Amendment*
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.	requirements under the Union acts listed in Annex I. ***Scientific studies that are conducted only for research purposes***, ***that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that are not part of a risk or safety assessment under Union acts listed in Annex I, do not need to be notified.*** The ECHA should establish and manage a database of study notifications to store the information related to those studies***. That database should be a separate database in which notification information is kept confidential. The ECHA, in cooperation with the relevant Agencies, should take the necessary measures to protect the safe transmission of chemicals data***. 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 ***18 months*** after the date of entry into force of this Regulation. ***The ECHA should also set up a mechanism to cooperate with authorities in third countries in order to exchange information about studies that are notified or submitted for regulatory purposes.***

Amendment 22

Proposal for a regulation

Recital 30

Text proposed by the Commission	*Amendment*
(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was	(30) To ensure the coherence between those two study notification mechanisms, as well as to ensure certainty for business operators submitting notifications, the rules on the public dissemination of study notifications should, where relevant, correspond in that the notifications should only be made available through the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was

Text proposed by the Commission	*Amendment*
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.	submitted to the relevant Union or national institution***. In order to respect the*** confidentiality of ***relevant elements of study notifications when they are integrated in the common data platform, where the Commission or an Agency makes available to the ECHA the corresponding registration, application, notification or other relevant regulatory dossiers, it should also indicate which elements of the study notification are to be confidential when they will be included in the common data platform. Only those elements should be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant*** regulatory dossier ***in accordance with the provisions on confidentiality under the originating*** Union ***act***. In order to facilitate compliance with the requirement to notify a study, the ECHA and the EFSA should cooperate to ensure a common approach for the identification of notified information in order to facilitate the traceability of studies notified to their respective databases. ***To avoid uncertainties for business operators resulting from the existence of two databases of study notifications, managed by ECHA and EFSA, respectively, the practical arrangements laid down by ECHA for implementing the provisions on notification of studies should as much as possible be aligned with the related practical arrangements of EFSA.***

Amendment 23

Proposal for a regulation

Recital 31

Text proposed by the Commission	*Amendment*
(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	(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 ***an application, notification or*** regulatory ***dossier intended to be notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, to ensure*** compliance

Text proposed by the Commission	*Amendment*
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.	under ***the*** Union acts listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated ***with*** non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

Amendment 24

Proposal for a regulation

Recital 33

Text proposed by the Commission	*Amendment*
(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.	(33) In order to facilitate enforcement by Member States, the Agencies responsible for assessing and providing scientific output, including scientific opinions, on regulatory dossiers containing studies subject to notification to ECHA should, where relevant, cooperate and exchange information with the Member State enforcement authorities ***to help them to verify*** compliance with the obligations laid out in Article 22. ***Information on enforcement should be made public to enhance public trust in the effective implementation of Union law.***

Amendment 25

Proposal for a regulation

Recital 36

Text proposed by the Commission	*Amendment*
(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,	(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,

Text proposed by the Commission	*Amendment*
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.	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***, including whether it involves animal testing***. 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.

Amendment 26

Proposal for a regulation

Recital 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) There are data gaps on the occurrence of hazardous and other harmful chemicals in articles on the Union market. In order to enhance visibility on the availability of data, and to promote research and development activities as regards safer alternatives, as well as the uptake of such alternatives, ECHA should establish and manage a repository of information on chemicals in articles generated or submitted under Union acts listed in Annex I. This database should integrate the information required under Article 9(1)(i) of Directive 2008/98/EC and the web portal under Article 14 of Regulation (EU) 2024/1781. In addition, ECHA should also establish and manage a database collecting available information from Agencies, Member States and business operators on safer alternatives to substances of concern, as defined in Article 2(27) of Regulation (EU) 2024/1781 as well as substances that meet the criteria for classification in hazard classes referred to in Article 2(27)(b) of Regulation (EU) 2024/1781.

Amendment 27

Proposal for a regulation

Recital 38

Text proposed by the Commission	*Amendment*
(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.	(38) ***In order to ensure chemicals data are easily findable within the database and to avoid duplicates, each chemical contained in the common data platform should be identified by a unique chemical identifier and a chemical notation specifying its molecular structure.*** In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability with existing data submission approaches. ***When specifying such formats and controlled vocabularies, the Agencies and Commission should, where relevant, take into account input and contributions from Member States and stakeholders.***

Amendment 28

Proposal for a regulation

Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41a) Independent research studies are often given comparatively low weight as evidence in hazard and risk assessment of chemicals, thus creating a gap between independent research and chemicals regulation and policy. It is necessary to provide

Text proposed by the Commission	*Amendment*
	structure and transparency in the evaluation of research data in order to increase their use in regulatory assessment of chemicals. The Commission should publish guidance setting minimum quality and reporting requirements to improve the uptake of research data.

Amendment 29

Proposal for a regulation

Recital 42

Text proposed by the Commission	*Amendment*
(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.	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets ***of chemicals data*** on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental sustainability-related data, collect the data as made available by the Commission, the Agencies***, national agencies,*** and, where relevant, by the researchers and research consortia funded by Union ***and national*** 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.

Amendment 30

Proposal for a regulation

Recital 43

Text proposed by the Commission	*Amendment*
(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.	(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***, in collaboration with the Agencies,*** should jointly develop and regularly, at least every two years, update a set of indicators and present it in the form of a dashboard. ***In order to monitor the aggregated risk for territories associated with the impacts on humans and the environment, including on the climate, of exposure to chemicals and pollutants, the set of indicators should include an aggregated indicator for different territorial levels, developed in collaboration with the Joint Research Centre and drawing inspiration from its European wide vulnerability framework. The EEA should cross-reference the results of this indicator with other health and environment datasets, such as epidemiological data on occupational health, lifestyle factors, and socio-economic factors, in order to assess the impacts and risks of c cumulated risk factors on population at the territorial level. The Agencies*** and the Commission ***should*** 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.

Amendment 31

Proposal for a regulation

Recital 44

Text proposed by the Commission	*Amendment*
(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	(44) ***This Regulation should establish an early warning and action system as regards existing and emerging chemical risks.*** 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 ***and policy*** follow-up actions ***by authorities***. 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

Text proposed by the Commission	*Amendment*
collecting information on emerging risks under Regulation (EC) No 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.	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 (EC) No 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks ***concerning chemicals, groups of chemicals, and cumulative exposure to chemicals***. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. this Regulation sets a deadline for the first report and associated data. ***For any risk and warning signal identified by the report, the Authorities should consider undertaking regulatory, policy or enforcement actions and provide justification when they decide not to proceed with any action. Emerging chemical risks identified in the early warning and action system should also be taken into account when setting priorities for the strategic planning of Horizon Europe.***

Amendment 32

Proposal for a regulation

Recital 46

Text proposed by the Commission	*Amendment*
(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	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific ***chemicals and groups of*** chemicals with potential contribution to emerging chemical risks ('the observatory'), which should cover also other chemicals and innovative (rationally designed complex 'advanced') materials selected by the Commission, using, as appropriate, signals from the early warning and action system. One of the criteria for selecting chemicals for the observatory should be their novelty and disruptive potential that may contribute to an emerging chemical risk. Another criterion for that selection

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 33

Proposal for a regulation

Recital 48

Text proposed by the Commission	*Amendment*
(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.	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on ***chemicals and groups of*** chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy. ***When obtaining a sample of a substance is a precondition for conducting the scientific studies, ECHA should be given the necessary sample by the business operator, upon request, and provided that applicable confidentiality and data protection under Union law is ensured. Whenever possible, information generated through studies commissioned by the ECHA should be generated by means other than animal tests.***

Amendment 34

Proposal for a regulation

Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48a) To support the effective implementation and evaluation of Union acts on chemicals and to contribute to the development of a comprehensive Union chemicals policy, it is essential to conduct Union-wide human biomonitoring studies that provide high-quality and representative data at regular intervals. To support a resource-efficient approach, the ECHA and EFSA should cooperate closely in pooling resources and expertise for such studies. The Member States should cooperate with the Agencies to organise the human bio-monitoring in their respective territories, in terms of planning, coordination, collection and transmission of samples.

Amendment 35

Proposal for a regulation

Recital 48 b (new)

Text proposed by the Commission	*Amendment*
	(48b) In order to contribute to the overall objective of this Regulation 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, this Regulation should require the Commission to draw up a report analysing how adequate the resources of the agencies are in relation to their current tasks and their new tasks under this Regulation, and a prospective view of the resources needed to address key areas of regulatory challenge in the future.

Amendment 36

Proposal for a regulation

Recital 48 c (new)

Text proposed by the Commission	*Amendment*
	(48c) As this Regulation expands the tasks and workload of the European Chemicals Agency, it should be provided with appropriate and stable resources, and stable governance of the scientific committees should be ensured. In this respect, it is appropriate that the Commission takes account of any developments and reflects the needs of the Agency to allow fulfilment of its tasks and potential.

Amendment 37

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of ***safe and*** sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' ***knowledge of, and*** trust in, the scientific base for the decisions taken under Union legal acts on chemicals***, and to contribute to the goal of phasing out animal testing wherever possible***.

Amendment 38

Proposal for a regulation

Article 1 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) keep records of data on studies obtained from relevant third countries through the mechanism referred to in Article 9(1a);

Amendment 39

Proposal for a regulation

Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
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**;**	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***, II*** and III, and the Agencies, excluding their management boards**;**

Amendment 40

Proposal for a regulation

Article 2 – paragraph 1 – point 10

Text proposed by the Commission	*Amendment*
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;	10. 'chemicals data' means any representation of facts or information relating to chemicals and any compilation of such facts or information, including information on physico-chemical properties, hazard properties, use, exposure, risk, occurrence, emissions***, fate*** and manufacturing process of the chemicals, as well as environmental sustainability related information, including climate change related information, on those chemicals, regulatory process-related information on chemicals, ***information on the availability and suitability of alternatives,*** standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals ***and the enforcement thereof***;

Amendment 41

Proposal for a regulation

Article 2 – paragraph 1 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	11a. 'research data' means any hazard, occurrence, exposure and fate data derived from scientific studies published in peer-reviewed literature that are not carried out specifically to inform regulatory assessments;

Amendment 42

Proposal for a regulation

Article 2 – paragraph 1 – point 14 a (new)

Text proposed by the Commission	*Amendment*
	14a. 'data processor' means a processor as defined in Article 4, point (8), of Regulation (EU) 2016/679 of the European Parliament and of the Council;

Amendment 43

Proposal for a regulation

Article 3 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) additional data provided on a voluntary basis by Member States, national agencies, research institutes or other parties;

Amendment 44

Proposal for a regulation

Article 3 – paragraph 2 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) generated in the context of academic research activities in the sphere of chemicals not covered in point (b) and voluntarily submitted to ECHA by a third party;

Amendment 45

Proposal for a regulation

Article 3 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Each chemical or material hosted on the common data platform shall be identified by a unique chemical identifier and a chemical notation specifying its molecular structure without prejudice to any confidentiality requirements in the original act or related legal obligations.

Amendment 46

Proposal for a regulation

Article 3 – paragraph 5 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) information on chemicals in articles as referred to in Article 10a;

Amendment 47

Proposal for a regulation

Article 3 – paragraph 5 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) information on safer alternatives to substances of concern as referred to in Article 10b;

Amendment 48

Proposal for a regulation

Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Authorities and the general public shall have access to the data contained in the common data platform in accordance with Article 16.	6. The Authorities and the general public shall have ***easy*** access***, free of charge,*** to the data contained in the common data platform in accordance with Article 16.

Amendment 49

Proposal for a regulation

Article 3 – paragraph 9

Text proposed by the Commission	*Amendment*
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.	9. The data contained in the common data platform shall be electronically accessible and searchable. The ECHA shall take measures to ensure a high standard of security appropriate to the security risks at stake for the storage of chemicals data in ***the common data platform. Security measures shall be adopted by the relevant Agencies in cooperation with the ECHA to ensure safe*** transmission of ***chemical*** 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.

Amendment 50

Proposal for a regulation

Article 3 – paragraph 11

Text proposed by the Commission	*Amendment*
11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise**.** ***The*** relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ***ten*** years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform ***without undue delay***.	11. The common data platform and its dedicated services shall be established by **...** [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise***, and shall at least include the datasets set out in Annex IIIa. Further*** relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ***eight*** years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform ***within a period of 30 days***.

Amendment 51

Proposal for a regulation

Article 4 – paragraph 1

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

Amendment 52

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission shall, by means of an implementing ***act***, establish and manage a platform steering committee, which shall include ***at least*** one representative from ***each Union agency required to submit chemicals data to the Platform***, ***and as many*** representatives from the Commission ***as from all those Union agencies combined***.

Amendment 53

Proposal for a regulation

Article 4 – paragraph 4

Text proposed by the Commission	*Amendment*
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***	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of implementing ***acts.*** ***While setting up the governance scheme, the Commission shall consult the Agencies and shall take into account the different level of responsibilities of the Authorities in the management and operation of the common data platform.***

Amendment 54

Proposal for a regulation

Article 4 – paragraph 5 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the organisation and operation of the mechanisms for cooperation and information exchange with databases and similar platforms in third countries and internationally;

Amendment 55

Proposal for a regulation

Article 4 – paragraph 5 – point f

Text proposed by the Commission	*Amendment*
(f) the operation of the steering committee itself.	(f) the operation***, reporting requirements and transparency obligations*** of the steering committee itself.

Amendment 56

Proposal for a regulation

Article 5 – paragraph 1

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

Amendment 57

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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(5)***, point (c). The Commission and the Agencies shall indicate whether ***the*** data or information ***included in the common data platform can be*** made available to the public ***or whether it is or they are deemed confidential in accordance with the provisions on confidentiality*** under the originating Union act.

Amendment 58

Proposal for a regulation

Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA shall host and maintain occurrence data related to workplace monitoring.	3. The ECHA shall host and maintain occurrence data related to workplace monitoring***, including occupational human biomonitoring data***.

Amendment 59

Proposal for a regulation

Article 5 – paragraph 5

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

Amendment 60

Proposal for a regulation

Article 5 – paragraph 6

Text proposed by the Commission	*Amendment*
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].	6. Researchers or research consortia funded by ***national or*** 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 ***+ 6 months***].

Amendment 61

Proposal for a regulation

Article 5 – paragraph 7

Text proposed by the Commission	*Amendment*
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.	7. The ***Authorities and national*** agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform. ***The ECHA shall provide support to the Authorities and national agencies to facilitate the integration of the chemicals data provided in accordance with paragraph 2.***

Amendment 62

Proposal for a regulation

Article 5 – paragraph 8

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

Amendment 63

Proposal for a regulation

Article 5 – paragraph 9

Text proposed by the Commission	*Amendment*
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.	9. The ***Authorities and national*** 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.

Amendment 64

Proposal for a regulation

Article 5 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. Notwithstanding provisions related to processing of human biomonitoring data constituting personal data set out in Article 6, the Commission or Agency under whose authority chemicals data are included in the common data platform on chemicals shall remain the data controller with regard to the personal data it provided.

Amendment 65

Proposal for a regulation

Article 5 – paragraph 9 b (new)

Text proposed by the Commission	*Amendment*
	9b. Notwithstanding provisions related to processing of occupational human biomonitoring data constituting personal data set out in Article 6, the ECHA shall act as data processor for any personal data included in the common data platform falling under the Authority of another Agency or the Commission.

Amendment 66

Proposal for a regulation

Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries***, with the exception of occupational human biomonitoring data in accordance with Article 5(3)***.

Amendment 67

Proposal for a regulation

Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendment 68

Proposal for a regulation

Article 6 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. Human biomonitoring data constituting personal data ***may be processed by the EEA*** for the following purposes:	4. ***The EEA may process*** human biomonitoring data constituting personal data for the following purposes:

Amendment 69

Proposal for a regulation

Article 6 – paragraph 4 – point e

Text proposed by the Commission	*Amendment*
(e) supporting regulatory risk assessments.	(e) supporting regulatory risk assessments ***and management***.

Amendment 70

Proposal for a regulation

Article 6 – paragraph 4 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) supporting policy making and legislative processes at Union level;

Amendment 71

Proposal for a regulation

Article 6 – paragraph 4 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) the creation of a 'chemicals exposure index' for each region in the Union, to provide an overview of the population's exposure to chemical substances and facilitate comparisons between different regions, geographical areas and Member States;

Amendment 72

Proposal for a regulation

Article 6 – paragraph 4 – point e c (new)

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

Amendment 73

Proposal for a regulation

Article 6 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission may process human biomonitoring data constituting personal data for the following purposes only: ***(a) scientific research aimed at policy making;*** ***(b) assessing the impact of chemicals on human health and the environment;*** ***(c) monitoring time and spatial trends in exposure;*** ***(d) developing health risk and impact indicators;*** ***(e) monitoring the impact of regulatory intervention;*** ***(f) assessing the need for further regulatory action and prioritising such action;*** ***(g) supporting regulatory risk assessment and risk management.***

Amendment 74

Proposal for a regulation

Article 6 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The ECHA may process human biomonitoring data included in occurrence data related to workplace monitoring and which constitute personal data for the following purposes: ***(a) assessing the impact of chemicals on human health and the environment;*** ***(b) monitoring time and spatial trends in exposure;*** ***(c) developing health risk and impact indicators;***

Text proposed by the Commission	*Amendment*
	(d) monitoring the impact of regulatory intervention;
	(e) supporting regulatory risk assessment and management;
	(f) evaluating and prioritising required regulatory action;
	(g) performing assessments of chemicals;
	(h) as part of the commissioning of studies under the data generation mechanism referred to in Article 21.

Amendment 75

Proposal for a regulation

Article 6 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4c. The EFSA may process human biomonitoring data constituting personal data for the following purposes only:
	(a) evaluating and prioritising required regulatory action;
	(b) performing assessments of chemicals;
	(c) supporting regulatory risk management.

Amendment 76

Proposal for a regulation

Article 6 – paragraph 4 d (new)

Text proposed by the Commission	*Amendment*
	4d. The EMA may process human biomonitoring data constituting personal data for the following purposes only:
	(a) evaluating and prioritising required regulatory action;
	(b) performing assessments of chemicals;
	(c) supporting regulatory risk management.

Amendment 77

Proposal for a regulation

Article 6 – paragraph 4 e (new)

Text proposed by the Commission	*Amendment*
	4e. The EU-OSHA may process human biomonitoring data constituting personal data for the following purposes only:
	(a) scientific research aimed at policy making;
	(b) assessing the impact of chemicals on human health and the environment;
	(c) monitoring time and spatial trends in exposure;
	(d) monitoring the impact of regulatory intervention;
	(e) assessing the need for further regulatory action and prioritising such action;
	(f) supporting regulatory risk management.

Amendment 78

Proposal for a regulation

Article 6 – paragraph 5

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

Amendment 79

Proposal for a regulation

Article 6 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA, the EMA, the EU-OSHA, or the Commission for the purposes referred to in paragraphs 4, 4a, 4b, 4c, 4d, and 4e shall not entail the sharing of such data with third parties.

Amendment 80

Proposal for a regulation

Article 6 – paragraph 6

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

Amendment 81

Proposal for a regulation

Article 6 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission shall define the storage period, and carry out any review thereof, for the human biomonitoring data constituting personal data that they hold as well as the criteria used to define the storage period.

Amendment 82

Proposal for a regulation

Article 6 – paragraph 6 b (new)

Text proposed by the Commission	*Amendment*
	6b. The human biomonitoring data referred to in this Article include personal data lawfully collected before the entry into force of this Regulation.

Amendment 83

Proposal for a regulation

Article 8 – paragraph 4 – subparagraph 1 a (new)

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

Amendment 84

Proposal for a regulation

Article 9 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The ECHA shall establish and operate a mechanism for cooperation and exchange of information with relevant third countries' authorities for the exchange of studies notified or submitted by business operators to those authorities to support an application, notification or regulatory dossier for a chemical by... [OP please insert date: two years after the date of entry into force of this Regulation].

Amendment 85

Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22 ***and the data obtained through the mechanism referred to in paragraph 1a of this Article***.

Amendment 86

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
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***.	3. Data contained in the Database of Study Notifications ***shall be considered confidential and shall not be made public***.

Amendment 87

Proposal for a regulation

Article 9 – paragraph 4 a (new)

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

Amendment 88

Proposal for a regulation

Article 9 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. Upon receipt by the ECHA, in accordance with Article 5(2), of a registration, application, notification or other relevant regulatory dossier, in the context of which a notification was submitted under Article 22, the ECHA shall make the related notification information available through the common data platform, in accordance with the provisions on confidentiality under the originating Union act.

Amendment 89

Proposal for a regulation

Article 9 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4c. Authorities and national enforcement authorities shall have access to the data contained in the Database of Study Notifications before those data are integrated in the common data platform.

Amendment 90

Proposal for a regulation

Article 10 – paragraph 1

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

Amendment 91

Proposal for a regulation

Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay. ***For each regulatory process or activity, at least the following information shall be included:***

Amendment 92

Proposal for a regulation

Article 10 – paragraph 2 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) chemical identity;

Amendment 93

Proposal for a regulation

Article 10 – paragraph 2 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) the Union act and the regulatory process under which the activity takes place;

Amendment 94

Proposal for a regulation

Article 10 – paragraph 2 – point c (new)

Text proposed by the Commission	*Amendment*
	(c) the submitter or actor responsible for the regulatory process or activity;

Amendment 95

Proposal for a regulation

Article 10 – paragraph 2 – point d (new)

Text proposed by the Commission	*Amendment*
	(d) the status of the regulatory process or activity;

Amendment 96

Proposal for a regulation

Article 10 – paragraph 2 – point e (new)

Text proposed by the Commission	*Amendment*
	(e) the outcome of the regulatory process or activity, including, where applicable, the reports or opinions adopted;

Amendment 97

Proposal for a regulation

Article 10 – paragraph 2 – point f (new)

Text proposed by the Commission	*Amendment*
	(f) where applicable, the intended date for starting the regulatory process or activity, and the date of its completion and latest update;

Amendment 98

Proposal for a regulation

Article 10 – paragraph 2 – point g (new)

Text proposed by the Commission	*Amendment*
	(g) where applicable, whether the process or activity includes the use of animals in testing and for which endpoints.

Amendment 99

Proposal for a regulation

Article 10 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) ***substance*** identity***;***	(a) ***chemical*** identity;

Amendment 100

Proposal for a regulation

Article 10 – paragraph 3 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) where applicable, whether the process or activity includes the use of animals in testing and for which endpoints.

Amendment 101

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission	*Amendment*
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***.	4. The information referred to in paragraph 3, points (a) to ***(fa)***, on a specific regulatory process or activity shall be made available to the public ***without undue delay***.

Amendment 102

Proposal for a regulation

Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a ***Information on chemicals in articles*** ***1. The ECHA shall establish and manage, as part of the common data platform, a database containing information on chemicals in articles generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I.***

Text proposed by the Commission	*Amendment*
	That database shall integrate the information required under Article 9(1)(i) of Directive 2008/98/EC and to Article 14 of Regulation (EU) 2024/1781. ***The Commission shall design relevant related database functionalities.*** ***2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I 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 I without undue delay.*** ***3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment.***

Amendment 103

Proposal for a regulation

Article 10 b (new)

Text proposed by the Commission	*Amendment*
	Article 10b ***Information on safer alternatives to substances of concern*** ***1. The ECHA shall establish and manage, as part of the common data platform, a database containing information on safer alternatives to substances of concern as defined in Article 2(27) of Regulation (EU) 2024/1781 as well as substances that meet the criteria for classification in hazard classes referred to in Article 2(27)(b) of Regulation (EU) 2024/1781, including on materials not requiring such substances. The Commission shall design relevant related database functionalities.*** ***2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I 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 I without undue delay.***

Text proposed by the Commission	*Amendment*
	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.
	4. The ECHA shall encourage providers of safer alternatives to substances of concern, or of materials not requiring such substances, to identify them and to provide all relevant data.

Amendment 104

Proposal for a regulation

Article 11 – paragraph 2

Text proposed by the Commission	*Amendment*
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).	2. The ECHA shall update the information in the database on a regular basis***, and at least annually,*** and in accordance with the governance scheme referred to in Article 4(3).

Amendment 105

Proposal for a regulation

Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. At the latest within three years after the ***identification of datasets and design of database functionalities*** 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.

Amendment 106

Proposal for a regulation

Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
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	2. Where ***Authorities or national*** 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 Authority or national*** agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments.

Text proposed by the Commission	*Amendment*
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.	***Authorities and national*** agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data. ***The ECHA shall provide the necessary support to the Authorities and national agencies to facilitate the integration of those data.***

Amendment 107

Proposal for a regulation

Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. Where researchers or research consortia funded by Union framework ***and national*** 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.

Amendment 108

Proposal for a regulation

Article 13 – paragraph 4

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

Amendment 109

Proposal for a regulation

Article 14 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ***Commission and the*** Agencies shall exchange data contained in the common data platform in the relevant standard format.	4. The ***Authorities or national*** agencies shall exchange data contained in the common data platform in the relevant standard format.

Amendment 110

Proposal for a regulation

Article 14 – paragraph 5 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([1a]).
	([1a]) 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).

Amendment 111

Proposal for a regulation

Article 14 – paragraph 5 – point i b (new)

Text proposed by the Commission	*Amendment*
	(ib) Regulation (EC) No 396/2005 of the European Parliament and of the Council ([1b])
	([1b]) 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).

Amendment 112

Proposal for a regulation

Article 14 – paragraph 8

Text proposed by the Commission	*Amendment*
8. The Commission shall adopt an implementing ***decision*** to remedy the divergence**.**	8. The Commission shall adopt an implementing ***act*** to remedy the divergence

Amendment 113

Proposal for a regulation

Article 15 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(a) make them available free of charge through the common data platform ***and*** as open datasets;	(a) make them available free of charge through the common data platform as open datasets***, supporting their re-use***;

Amendment 114

Proposal for a regulation

Article 15 – paragraph 8

Text proposed by the Commission	*Amendment*
8. The Commission shall adopt an implementing ***decision*** to remedy the divergence**.**	8. The Commission shall adopt an implementing ***act*** to remedy the divergence

Amendment 115

Proposal for a regulation

Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	Uptake of research data
	1. Researchers shall be able to submit publicly available research data on chemicals related to an entry in the common data platform. Research data shall be submitted in a format prescribed by the ECHA.
	2. By... [OP: insert 18 months after the entry into force of this Regulation], the ECHA shall establish and maintain an online platform for the submission process referred to in paragraph 1.

Text proposed by the Commission	*Amendment*
	3. The ECHA shall assess the compliance of research data submitted through the portal referred to in paragraph 2 with the requirements set in the guidance referred to in paragraph 4. Where research data submitted are deemed to fulfil these requirements, the data shall be hosted on the common data platform together with the corresponding entry.
	4. By... [OP: insert 12 months after the entry into force of this Regulation], the Commission shall publish guidance setting minimum quality and reporting requirements to improve the uptake of research data.
	5. In order to ensure that the research data are submitted in a uniform format, the Commission shall, by means of implementing acts, adopt a standard format for the submission of research data.
	Those implementing acts shall be adopted by... [OP: please insert the date = 12 months after the entry into force of this Regulation], in accordance with the examination procedure referred to in Article 24a(2).

Amendment 116

Proposal for a regulation

Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is ***marked as*** confidential under Article 5(2), second sentence.

Amendment 117

Proposal for a regulation

Article 16 – paragraph 2

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

Amendment 118

Proposal for a regulation

Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
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***.	3. The public shall have access to all the chemicals data contained in the common data platform ***except data which are marked to be confidential*** under ***Article 5(2)***.

Amendment 119

Proposal for a regulation

Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. The Authorities may use the chemicals data contained in the common data platform ***or in the Database of Study Notifications*** in the performance of any of their activities, where those activities support the development***,*** implementation ***or enforcement*** of legislation and policy.

Amendment 120

Proposal for a regulation

Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, ***and to the possibility of identifying data gaps in the applications received from business operators,*** Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.

Amendment 121

Proposal for a regulation

Article 17 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The common data platform shall also include terms and conditions, particularly regarding the respect of intellectual property rights and other related rights.

Amendment 122

Proposal for a regulation

Article 18 – paragraph 1

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

Amendment 123

Proposal for a regulation

Article 18 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The framework of indicators referred to in paragraph 1 shall include an aggregated territory-based risk indicator at different administrative levels as defined in Regulation (EC) No 1059/2003 to monitor time and spatial trends in exposure of populations to individual and multiple chemicals and health risks associated with such exposure and co-exposure.

Amendment 124

Proposal for a regulation

Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The framework of indicators referred to in paragraph 1***, and the aggregated indicator referred to in paragraph 1a,*** 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.

Amendment 125

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***existing*** national early warning systems;	(b) national early warning systems;

Amendment 126

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) data that the EEA holds;	(c) data that the EEA holds***, including data from human biomonitoring as referred to in Article 6, and data from the framework of indicators and the aggregated indicator as referred to in Article 18***;

Amendment 127

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) relevant datasets from the EU Datasets Catalogue established by Article 57 of Regulation (EU) …/… of the European Parliament and of the Council on the European Health Data Space... [OP: please add number and publication reference];

Amendment 128

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) relevant information resulting from national enforcement programmes;

Amendment 129

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 1 – point e c (new)

Text proposed by the Commission	*Amendment*
	(ec) relevant data or information submitted by researchers.

Amendment 130

Proposal for a regulation

Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals ***obtained pursuant to this Regulation or*** from the field falling within their mandate and provide this data to the EEA.

Amendment 131

Proposal for a regulation

Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals.	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by **...** [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning

Text proposed by the Commission	*Amendment*
	signals. ***Within six months of the presentation of the report, the Authorities shall undertake regulatory, policy or enforcement actions accordingly or provide justification if they decide not to proceed with any action related to any of the early warning signals identified by the report, including an assessment of the possible consequences of non-action.***

Amendment 132

Proposal for a regulation

Article 19 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where the data analysis indicates there is a risk that warrants urgent action, the EEA shall inform the authorities without undue delay.

Amendment 133

Proposal for a regulation

Article 19 – paragraph 5

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

Amendment 134

Proposal for a regulation

Article 19 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Commission shall take into account, where relevant, the emerging chemical risks identified, in accordance with this Article, in the strategic planning of R&I activities of Regulation (EU) 2021/695 ([1a]).

Text proposed by the Commission	*Amendment*
	([1a]) Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013.

Amendment 135

Proposal for a regulation

Article 20 – paragraph 1

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

Amendment 136

Proposal for a regulation

Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing ***decision***. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.	2. By **...** [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing ***act***. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.

Amendment 137

Proposal for a regulation

Article 20 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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.	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate***, to facilitate the identification of potential further research needs or risk management measures***, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.

Amendment 138

Proposal for a regulation

Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Using the best independent resources available, the ECHA may commission scientific studies to**:** ***(a)*** support the implementation of Union acts on ***chemicals or groups of*** chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy**;** ***(b) investigate further emerging chemical risks identified in the report referred to in Article 19(4) of this Regulation;*** ***(c) conduct a Union-wide data sampling survey of human biomonitoring in collaboration with Member States***.

Amendment 139

Proposal for a regulation

Article 21 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1 ***and Article 20(4), point (b), of this Regulation. Member States may request the Commission to request the ECHA to commission such scientific studies.***

Amendment 140

Proposal for a regulation

Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***give priority to the use of non-animal methods, with animal testing on vertebrate animals used only as a last resort. It shall*** not commission studies with a predominant research objective. ***ECHA shall consult the chemical data platform in order to avoid unnecessary duplication of studies.***

Amendment 141

Proposal for a regulation

Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The ECHA may request from a business operator a sample of a substance, where such sample is indispensable to perform the scientific study referred to in paragraph 1. The request shall be duly justified and any handling of the substance shall be in accordance with applicable confidentiality and data protection rules under relevant Union law. The relevant business operator shall, upon a request from the ECHA, provide the requested sample to the ECHA or to any body commissioned by the ECHA to perform the scientific study.

Amendment 142

Proposal for a regulation

Article 21 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The ECHA shall commission these scientific studies in an open and transparent manner.	5. The ECHA shall commission these scientific studies in an open and transparent manner. ***The ECHA shall publish, on its website, the proposal for the study it intends to commission.***

Amendment 143

Proposal for a regulation

Article 21 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Without prejudice to the obligation on applicants to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances of serious controversies or conflicting results, may request the ECHA to commission scientific studies with the objective of verifying evidence used in its hazard and risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

Amendment 144

Proposal for a regulation

Article 21 – paragraph 6 b (new)

Text proposed by the Commission	*Amendment*
	6b. Every five years, the ECHA, in cooperation with the EFSA, shall commission a Union-wide human biomonitoring study that covers all Member States.

Amendment 145

Proposal for a regulation

Article 21 – paragraph 6 c (new)

Text proposed by the Commission	*Amendment*
	6c. Member States shall cooperate with and support the ECHA and EFSA in the organisation of any human biomonitoring study within their territories, to ensure sampling and collection of the data, and adequate representativeness and quality of the data. The human biomonitoring studies shall adhere to ethical and confidentiality standards.

Amendment 146

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without delay, ***any information referred to in paragraph 2 related to*** any studies ***that generate data*** on chemicals ***which*** they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, under the Union acts listed in Annex I. Business operators shall not notify to the Database of Study Notifications referred to in Article 9**:** ***(a) in the case of*** studies that are to be notified under Article 32b of Regulation (EC) No 178/2002**;** ***(b) scientific studies conducted only for research purposes that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that are not part of a risk or safety assessment under the Union acts listed in Annex I.*** ***Business operators shall provide a valid justification for the late notification of studies in accordance with this paragraph.***

Amendment 147

Proposal for a regulation

Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates***,*** and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.

Amendment 148

Proposal for a regulation

Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. Laboratories and testing facilities shall also, without delay, notify any ***information referred to in paragraph 2 related to studies*** commissioned by business operators to support ***an application, notification or*** regulatory dossier ***notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that they commission as part of a risk or safety assessment***, under the Union acts listed in Annex I. 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.

Amendment 149

Proposal for a regulation

Article 22 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.

Amendment 150

Proposal for a regulation

Article 22 – paragraph 6

Text proposed by the Commission	*Amendment*
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].	6. The obligations set under this article shall apply from [OP please insert date: ***18*** months after the date of entry into force of this Regulation].

Amendment 151

Proposal for a regulation

Article 22 – paragraph 7

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

Amendment 152

Proposal for a regulation

Chapter VIII – title

Text proposed by the Commission	*Amendment*
VIII DELEGATED POWERS	VIII DELEGATED POWERS ***AND COMMITTEE PROCEDURE***

Amendment 153

Proposal for a regulation

Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by ***extending it to additional active substances, and by*** adding new categories of data types***, subject to the outcome of the review in Article 26a(2)***.

Amendment 154

Proposal for a regulation

Article 24 a (new)

Text proposed by the Commission	*Amendment*
	Article 24a
	Committee procedure
	1. The Commission shall be assisted by a Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 ([1a]).
	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
	([1a]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment 155

Proposal for a regulation

Article 25 – title

Text proposed by the Commission	*Amendment*
Enforcement	Enforcement ***and cooperation on compliance***

Amendment 156

Proposal for a regulation

Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Reports and review
	1. No later than … [OP: please insert 18 months after the entry into force of this Regulation], the Commission shall assess the workload and further needs of the Agencies, stemming from the additional tasks related to the inclusion of information on substances in products and information on alternatives, and the inclusion of information on medicinal products resulting from procedures concluded before the entry into force of this Regulation, and where appropriate, provide it with adequate further resources.
	2. No later than... [OP: please insert the date: 4 years after the entry into force of this Regulation], the Commission shall assess the costs and benefits of extending the common data platform to additional medicinal active substances and of adding new categories of data types.
	3. No later than... [OP: please insert the date: 4 years after the entry into force of this Regulation], the Commission shall assess the feasibility, in collaboration with scientific and academic publishers, of harmonised reporting and of enabling the integration of relevant contents from scientific journals and publications into the common data platform, in order to increase further the uptake of research data into the hazard and risk assessment of chemicals.
	4. No later than … [OP: please insert 4 years after the entry into force of this Regulation], the Commission shall report on the resources needed to address key areas of regulatory challenge. The Commission shall present that report to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.
	5. By... [OP: please insert date: 5 years after the entry into force of this Regulation], the Commission shall draw up a report. That report shall assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has contributed sufficiently to achieve its objectives, in particular to allow a better reuse of data across the Union acts referred to in Annex I. The Commission shall present this report to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.

Text proposed by the Commission	*Amendment*
	After the period of 5 years, the Commission shall report bi-annually to the European Parliament and to the Council on the progress made on the implementation and functioning of the common data platform.
	6. Based on the findings of the reports and assessments referred to in paragraphs 2 and 4, the Commission shall submit legislative proposals to the European Parliament and to the Council in this regard.

Amendment 157

Proposal for a regulation

Annex I – point 70 a (new)

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

Amendment 158

Proposal for a regulation

Annex II – Part 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. ***Where relevant***, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation ***may also be considered for inclusion*** into the common data platform.	These data shall be limited to data ***related to chemicals and materials used in medicinal products and*** submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. ***No later than... [OP please insert date: eight years after the date of entry into force of this Regulation]***, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation ***shall be included*** into the common data platform.

Amendment 159

Proposal for a regulation

Annex II – Part 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. ***Where relevant***, data held by the EMA resulting from procedures concluded before the ***date of*** entry into force of this Regulation shall ***also be considered for inclusion*** into the common data platform.	These data shall be limited to data ***related to chemicals and materials used in medicinal products and*** submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. ***No later than... [OP please insert date: eight years after the date of entry into force of this Regulation]***, ***the*** data held by the EMA resulting from procedures concluded before the entry into force of this Regulation shall ***be included*** into the common data platform.

Amendment 160

Proposal for a regulation

Annex III – point 34 a (new)

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

Amendment 161

Proposal for a regulation

Annex III a (new)

Text proposed by the Commission	*Amendment*
	ANNEX IIIa ***Datasets to be included at the date of establishment of the common data platform referred to in Article 3*** ***ECHA REACH: REACH registrations including Chemical Safety Reports (CSR).*** ***ECHA Classification, Labelling and Packaging (CLP): classification and labelling (C&L) inventory.*** ***ECHA Biocidal Products Regulation (BPR): biocidal active substance approval process data.***

Text proposed by the Commission	*Amendment*
	ECHA Prior Informed Consent (PIC): data on substances subject to PIC the Regulation.
	ECHA Persistent Organic Pollutants (POP): (1) List of POPs; (2) List of substances proposed to be included in the POP list of the Stockholm Convention.
	ECHA SCIP database: information on Substances of very high concern in articles as such or in complex objects (products) established under the Waste Framework Directive (WFD).
	Commission data from the Digital Product Passport Webportal: information on substances of concern present in products ·
	EFSA OpenFoodTox: summary of all EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs.
	EFSA Chemical Monitoring Data: chemical monitoring data for pesticides and veterinary medicinal product residues and contaminants data. The individual measurements of chemicals in food/feed and other materials sampled as part of official controls and enforcement activities. Measurements of chemicals in food and feed received from industry or other sources in response to a call for data.
	EFSA OpenEFSA: all information related to EFSA's scientific work. Tracking of the risk assessment process from receipt of the dossier to adoption of the opinion. Information available includes the status of assessments, dossiers and studies, meeting agendas and minutes, information on experts (DOIs), public consultations). ·
	EFSA EU_PPP Agency IUCLID: IUCLID dossiers submitted by applicants (industry) under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.
	EEA Air Quality: air quality data from a wide range of sources including the current status of Europe's air quality through five different air pollutants (European Air Quality Index), latest measurements from Europe's air quality monitoring network and statistics for air pollutants calculated from officially-verified country data for years until 'X-2'.
	EEA Waterbase Water Quality: time series of concentrations of nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters. Records reported under the Water Framework Directive Watch List for chemicals in surface waters.

Text proposed by the Commission	*Amendment*
	EEA Waterbase emissions: time series of emissions of nutrients and hazardous substances to water, reported by EEA member countries and cooperating countries. Data on yearly riverine input loads to transitional, coastal and marine waters.
	EEA Industrial emissions: data reported by Member States in the scope of the E-PRTR Regulation and Industrial Emissions Directive.
	EEA National Emission reductions Commitments (NEC) Directive emission inventory data: data on emissions of air pollutants.
	EMA human medicinal products data (environmental risk assessment and non-clinical safety data)
	EMA veterinary medicinal products (environmental risk assessment and maximum residue limit (MRL) values and MRL assessment data)