European Parliament
2024-2029

Committee on the Environment, Public Health and Food Safety

2023/0453(COD)

5.12.2024

AMENDMENTS
91 - 314

Draft report
Dimitris Tsiodras
(PE763.255v01-00)

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

Proposal for a regulation
(COM(2023)0779 – C9-0449/2023 – 2023/0453(COD))

Amendment 91
Daniel Buda

Draft legislative resolution
Paragraph 2

Draft legislative resolution	*Amendment*
2. Calls on the Commission to refer the matter to Parliament again if it replaces, ***substantially*** amends or intends to substantially amend its proposal;	2. Calls on the Commission to refer the matter to Parliament again if it replaces, amends or intends to substantially amend its proposal;

Or. ro

Amendment 92
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Citation 1

Text proposed by the Commission	*Amendment*
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof.	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1)***, 168 and 191*** thereof.

Or. en

Amendment 93
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(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.

‘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. ***Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[3a] establishes measures for the protection of animals used for scientific or educational purposes, making full replacement of animal testing its ultimate goal. According to the Strategy, safety testing and chemical risk assessment need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.*** 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.

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions,

[1] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM (2019) 640 final.

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions,

Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM (2020) 667 final,	Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM (2020) 667 final,
	[3a] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p. 33–79

Or. en

Amendment 94
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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.

[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,

[1] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM (2019) 640 final.

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

Or. en

Amendment 95
Martin Hojsík

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	(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 their groupings*** to ensure that Union policies address

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.	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.
[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,

Or. en

Justification

Alignment with the CLP Regulation (2022/0432(COD)).

Amendment 96
Beatrice Timgren

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	(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 ***while ensuring proportionality and reducing unnecessary burdens on economic operators. By modernising the integration of information and establishing a cost-effective digital infrastructure, this***

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.

Regulation seeks to facilitate the internal market for chemicals ***and improve the predictability and transparency of regulatory processes***. 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.

Or. en

Amendment 97
Jutta Paulus

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	(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.

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***,*** 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 vertebrate 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 ***data of, and*** regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making. ***When reference is made to chemicals, this should be understood as including groups of chemicals.***

Or. en

Justification

The scope of the data platform goes beyond hazardous chemicals. This legislation also contributes to ensuring that testing on vertebrate animals only takes place as last resort, ín line with Article 25 of REACH. It should be specified that the notion of "chemicals" does not only mean individual substances, but also groups of chemical substances.

Amendment 98

Martin Hojsík

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 ***and improve integration of information from different sources resulting 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 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.

Or. en

Justification

The deletion reflects that the Common Data Platform is not limited to classified substances, but other dangerous chemicals and information on chemicals in general.

Amendment 99
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(2) The main ***objectives*** of this Regulation ***are*** to increase the level of protection of the environment and health from the risks arising from chemicals, ***to contribute to phasing out animal testing*** 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 ***and to contribute to ensuring animal testing takes place only 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

trust in the robustness of scientific decision-making.	predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making.

Or. en

Amendment 100
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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

Or. en

Amendment 101
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) People and other living organisms are exposed daily to a wide mix of chemicals originating and environmental stressors from various sources. However, the safety of chemicals in the EU is usually assessed through the evaluation of single chemicals without considering the combined exposure to multiple chemicals from different sources and over time. If some pieces of legislation require to assess the cumulative exposure to the same chemical from different sources, explicit requirements to take into account the impact of unintentional mixtures is generally lacking. The human exposome is a concept that provides a holistic view of human health and disease. It includes exposures from our diets, our lifestyles, and environmental factors, such as chemicals. This regulation should help gathering data on the impacts of the exposure to multiple chemicals and environmental factors to foster research on the human exposome and help to understand the causal pathways leading to common diseases such as cardiovascular disease, respiratory diseases, immunological disorders, mental health, and non-communicable diseases.

Or. en

Amendment 102
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 relevant Union agencies ***and Member States' authorities*** 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	[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.

European strategy for data, COM/2020/66 final.

Or. en

Amendment 103
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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

and the drivers and impact of chemical pollution.	and the drivers and impact of chemical pollution. ***Where multiple studies exist for the same chemical, potentially generated to meet requirements across different regulatory frameworks, data from each study should be published in a harmonised format which facilitates rapid comparison and review.***

Or. en

Amendment 104
Pietro Fiocchi

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 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	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence

base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.	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.***

Or. en

Amendment 105
Kristoffer Storm

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 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	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The

common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.	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.***

Or. en

Justification

Support for amendment 1 in the draft report.

Amendment 106
Martin Hojsík

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 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	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various

Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.	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 continue to take the necessary measures to protect the confidentiality of data, including, where relevant, by cybersecurity measures.***

Or. en

Amendment 107
Laurent Castillo

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 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	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information can be accessed and whether it can be used. This increases the likelihood of

inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.	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. ***Union agencies are required to make every effort to protect the data they hold, in particular where there is a cybersecurity risk.***

Or. fr

Amendment 108
Beatrice Timgren

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 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	(6) Business operators and Members States' competent authorities are required by various Union acts to submit data and information to a multitude of Union agencies, as well as to the Commission in specific cases. This generates a fragmentation of data and information on chemicals, which are held under various data sharing and use conditions and in different formats. Such fragmentation prevents public authorities, as well as the general public, from having a clear overview of what information is available on individual chemicals or groups of chemicals, of where and how information

can be accessed and whether it can be used. This increases the likelihood of inconsistency between various assessments of the same chemical required by various Union acts on chemicals and of damaging the general public's trust in the scientific grounds for Union decisions on chemicals. In order to ensure that data on chemicals is easily findable, accessible, interoperable and usable, the ECHA should establish a common data platform on chemicals. The common data platform on chemicals should serve as a single point of reference and as a broadened and shared evidence base to enable the efficient delivery of coherent hazard and risk assessments of chemicals across various Union acts on chemicals, as well as to enable the timely identification of emerging chemical risks and the drivers and impact of chemical pollution.	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 prioritise and protect the confidentiality of data and sensitive information while facilitating efficient data sharing.***

Or. en

Amendment 109
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(7) The common data platform should contain ***all*** chemicals-related data and information. 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 occurence of chemicals in articles***. The common data platform should also include chemicals data and information

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***.

generated as part of Union, national or international programmes***, enforcement actions*** or research activities related to chemicals***. For studies initiated after entry into force of this Regulation, the standard formats shall ensure publication of the date of commencement of studies and the name*** of the relevant ***GLP or equivalent compliance monitoring authority responsible for ensuring test facility compliance***.

Or. en

Amendment 110
Jutta Paulus

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 as part of the implementation of Union chemicals legislation listed in Annex I***, unless this Regulation specifies otherwise***. This includes, for instance, all 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.

Or. en

Justification

Alignment with proposals by the rapporteur to also include e.g. research funded by national programmes (AM 46). It is important to keep the references to "generated or submitted" so as not to exclude e.g. monitoring data held by Member States. It is also important to keep the specification to include all regulatory dossiers or applications - a qualifier of "relevant" would create major confusion. The default should be to include all data, except where there is specified differently.

Amendment 111
Beatrice Timgren

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 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 platform should ***focus on consolidating data directly related to regulatory purposes, excluding broader research*** or international ***program data unless explicitly required by Union legislation***

Or. en

Amendment 112
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 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***,*** ***exposure and fate*** 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.

Or. en

Amendment 113
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	(7) The common data platform should contain ***all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. 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.

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.

Or. en

Amendment 114
Martin Hojsík

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 ***all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. 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.

Or. en

Amendment 115
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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.	***deleted***

Or. en

Amendment 116
Pietro Fiocchi

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***	(8) ***While some medicinal products are also chemicals and could present an interest for the objectives of this Regulation, the application and use of*** hazard ***and risk*** assessments performed ***on them*** under Union acts on medicinal

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.

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

Or. en

Amendment 117
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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,	(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.***	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.

Or. en

Amendment 118
Jutta Paulus

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***	(8) ***Despite*** 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, chemicals data related to ***human health and*** 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.

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.

Or. en

Justification

In order to have a true COMMON data platform, data for all active substances that are chemicals should be included in the platform, and not just for "relevant" ones. All data on pharmaceutical active substances are relevant for other policy areas and therefore, it is not appropriate to limit input to the data platform to dual use substances, PBT substances or active substances with known high level of residues. Data on medicines are rich, using many tests on animals as well as clinical studies. These data can contribute to the development and validation of predictive toxicological models, reducing the needs for animal tests in other policy areas (see references below to exchanges between EFPIA and ECHA as well as between the US FDA and ECHA. Data on all active substances are relevant for environmental legislation, because most if not all active substances or their metabolites will end up in the environment to a significant degree. Medicines may well have toxic properties and it is important to include such data in the platform, not only when they are also persistent and bioaccumulative. In addition, it is inappropriate to only include active substances with known high level of residues given combination effects and cumulative exposure, constant load into the environment and the need to be able to detect emerging risks in time.

The value of such data for developing predictive toxicology assessment - and thus for saving animal tests - has been officially recognised by ECHA.

https://echa.europa.eu/-/pharmaceutical-industry-provides-unpublished-data-on-chemical-substances

For latest situation of this data sharing , see

https://iuclid6.echa.europa.eu/data-contribution

A similar exchange exists between the US FDA and ECHA:

https://iuclid6.echa.europa.eu/us-fda-toxicity-data

Amendment 119
Beatrice Timgren

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 ***distinct*** nature of risk and hazard assessments under Union acts on medicinal products, ***the common data platform should include only essential*** chemicals data related to environmental risk assessments for human and veterinary medicines and ***specific*** maximum residue limit values ***held by*** the European Medicines Agency ('EMA'). For medicinal active substances, only data on substances ***with cross-sectoral relevance—those also*** regulated ***under*** other Union legislation identified in this ***Regulation—should be included. Data on*** other active substances ***should be limited to those with confirmed*** persistent, bio-accumulative***,*** and toxic properties or ***a significant impact on*** the environment.

Or. en

Amendment 120
Pietro Fiocchi

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) Chemicals contained in medicinal products are covered by Annex II of this Regulation, as well as Annex I since chemicals in medicinal products are also subject to regulatory procedures under the majority of other Union legislation listed under Annex I. In order to protect the confidentiality of certain data and to prevent any conflicts between legislative acts, the provisions from Directive 2001/83/EC of the European Parliament

and the Council and Regulation (EC) 726/2004 of the European Parliament and the Council should always take precedence over this Regulation. This covers future implementation through delegating and/or implementing acts.

Or. en

Amendment 121
Kristoffer Storm

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) Chemicals contained in medicinal products are covered by Annex II to this Regulation, as well as Annex I since chemicals in medicinal products are also subject to regulatory procedures under the majority of other Union legislation listed under Annex I. In order to protect the confidentiality of certain data and to prevent any conflicts between legislative acts, the provisions from Directive 2001/83/EC of the European Parliament and the Council and Regulation (EC) 726/2004 of the European Parliament and the Council should always take precedence over this Regulation. This covers future implementation through delegating and/or implementing acts.

Or. en

Justification

Support for amendment 4 in the draft report

Amendment 122
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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.	***deleted***

Or. en

Amendment 123
Jutta Paulus

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) ***Given the overall number of authorised medicines and the comparatively low number of annual new procedures,*** these data should ***not*** 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. ***Data to be submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation*** should ***be included by the date of establishment of*** the common data platform***. Data*** on procedures concluded before the entry into force of this Regulation ***should be included as part of the five-year implementation period after establishment of the database***.

Or. en

(Partially linked to the amendment on Article 3, paragraph 11 by the same author.)

Justification

According to information from EMA, there are currently 1,110 medicinal products containing chemically active substances authorised under the centralised procedure. On average, every year, the Agency assesses 61 such medicinal products. That amounts to just over 5% of the total. Limiting the inclusion to procedures finalised or submitted after the entry would mean that the very large majority of data held by EMA would not be included in the common data platform for many years to come (if at all). That is not appropriate. The fact that many data that EMA holds are not yet available in machine-readable format must not be used against inclusion of such data into the common data platform, as it would perpetuate outdated circumstances. The common data platform should be filled over a period of eight years after entry into force. This is more than enough time for EMA to digitalize the data it holds. There should be certainty as to when this data will be included. It is therefore appropriate to specify that existing data has to be included no later than eight years.

Amendment 124
Beatrice Timgren

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) These data should be limited to ***essential chemicals*** data submitted to the EMA in the context of relevant procedures finalised or submitted after the entry into force of this Regulation. ***The inclusion of data*** on ***earlier*** procedures ***finalised*** before the entry into force of this Regulation ***should be considered only for substances with persistent, bio-accumulative, and toxic properties or substances with significant environmental impact, where such inclusion is deemed necessary for coherence and interoperability within the common data platform***.

Or. en

Amendment 125
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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) 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, ***and no later than 4 years after the entry into force of this Regulation,*** 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.

Or. en

Amendment 126
Pietro Fiocchi

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

Or. en

Amendment 127
Laurent Castillo

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) These data should also be limited to	(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.	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. Data the EMA holds on procedures concluded before the entry into force of this Regulation ***will be entered as and when sufficient human and financial resources are available***.

Or. fr

Amendment 128
Martin Hojsík

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) 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. ***Progressively***, 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.

Or. en

Amendment 129
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9 a) Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances

contained in medicinal products, clinical data, data related to other substances contained in medicinal products besides active substances and data that is submitted to the EMA in the context of the relevant procedures that are finalised before the entry into force of this Regulation. Moreover, a relevant part of the medicinal data is held by the National Competent Authorities. At a later stage and no later than 5 years after the entry into force of this Regulation, the Commission should therefore assess, in close cooperation with Member States and the Agencies, whether such additional data should be included in the common data platform. This assessment should take also into account the relevancy, the anticipated added value as well as the cost-benefit balance of incorporating the additional data.

Or. en

Amendment 130
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council[6] , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products notified to the Cosmetic	***deleted***

Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[7] of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.

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

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

Or. en

Amendment 131
Radan Kanev

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council[6] , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, submitted to the bodies appointed by the Member States under Article 45 of Regulation (EC) No 1272/2008 of the European Parliament and the Council[6] , that information should not be included in the common data platform. Likewise, due to the commercial sensitiveness of data and information on final cosmetic products, the information related to cosmetic products

notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[7] of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform.

notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[7] of the European Parliament and of the Council should not be included in the common data platform either. However, chemicals data and information on individual chemical ingredients of cosmetic products should be included in the common data platform. ***To preserve innovation, this Regulation should not undermine the exemptions for Scientific Research and Development (SR&D) and Product and Process-Oriented Research and Development (PPORD) as established under REACH[8a] and CLP, ensuring that such data remains appropriately protected.***

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

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

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

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

[8a] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Or. en

Amendment 132
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 11

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

Or. en

Amendment 133
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and health ***and a high level of transparency***, it is necessary to lay down a harmonised framework***, granting as a general principle, the widest possible access to chemicals data and, where appropriate and justified,*** 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 ***all of*** the chemicals data and information contained in the common data platform to effectively fulfil their

development of Union chemicals policies.	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.

Or. en

Amendment 134
Pietro Fiocchi

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 specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies. ***Access to personal data should be limited to what is necessary in relation to the purposes for which this data is processed by the Authorities.***

Or. en

Amendment 135
Laurent Castillo

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 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. ***The Authorities should give limited access to personal data in accordance with the purposes for which the data is used.***

Or. fr

Amendment 136
Beatrice Timgren

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	(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 entrusted with regulatory tasks related to chemicals should use the

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***.

platform to fulfil their regulatory duties ***efficiently and cost-effectively. Provisions ensuring proportionality and minimised administrative burdens should guide the access and use framework, ensuring balance between robust regulatory oversight and economic competitiveness***. ***Access to personal data should be limited to what is necessary in relation to the purposes for which this data is processed by the Authorities.***

Or. en

Amendment 137
Radan Kanev

Proposal for a regulation
Recital 13

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

economic interest, that confidentiality should be safeguarded.

Or. en

Amendment 138
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 13

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

Or. en

Amendment 139
Beatrice Timgren

Proposal for a regulation
Recital 13

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

Or. en

Amendment 140
Jutta Paulus

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	(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.	functions or fulfil their tasks. ***Where relevant, a clear mention should be made on the common data platform, which indicates to the general public and business operators that data is owned by third parties and that any commercial use of the data without prior approval from the data owner might infringe its rights. The common data platform should also include relevant terms and conditions, including regarding intellectual property rights and other rights.***

Or. en

Justification

Amendment similar to AM 9 by the rapporteur with three main modifications: a) specify that mention of data ownership should only be made where relevant, b) respect for data ownership does not only apply to the general public but also to other business operators, and c) that potential infringement of rights only occur in case of commercial use of the data.

Amendment 141
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) To ensure the protection of ***legitimate expectations of duty holders when generating or submitting data or information under the Union acts listed in Annex I, as well as to protect the confidentiality of that information when used by the Authorities,*** exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I ***should apply only to the disclosure of the data and information submitted or generated in compliance with those acts***. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[8] , where urgent action is essential to protect human health, animal health or	(15) To ensure the protection of ***health and the environment, there may be*** exceptional grounds for disclosing confidential information laid down in the Union acts listed in Annex I. For example, under Article 39(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[8] , where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions

the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[9] provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations.

of scientific outputs of the EFSA and relates to foreseeable effects on human health, animal health or the environment. Likewise, Article 118 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[9] provides for the possibility for the ECHA to disclose confidential information submitted to it under that Regulation if urgent action is essential to protect human health, safety or the environment, such as in emergency situations. ***These emergency provisions should apply to all information held in the common data platform.***

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

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

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

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

Or. en

Amendment 142
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 16

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

Or. en

Amendment 143
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(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') ***which should rapidly be elaborated to include all data on chemical substances in articles and on their***

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.

alternatives, 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.

Or. en

Amendment 144
Martin Hojsík, Sigrid Friis

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 substances in articles and their available alternatives,*** as well as a dashboard of indicators on chemicals.

Or. en

Justification

We share the opinion of the Rapporteur that improving information on alternatives through the Common Data Platform would facilitate the transition to safe and sustainable chemicals and their uptake by the market. The database shall be user-friendly, reflecting the different technical functions and sectors of use. ECHA should be provided with the additional means necessary for this service.

Amendment 145
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 products and their alternatives,*** as well as a dashboard of indicators on chemicals.

Or. en

Amendment 146

Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 initial datasets ***of chemicals data*** to be made accessible via the platform and the timeline for their integration, informed by the preparatory work of the Commission and the Agencies[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, ***and*** required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets ***of chemicals data*** and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. 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.

Or. en

Amendment 147
Beatrice Timgren

Proposal for a regulation
Recital 18 a (new)

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

Or. en

Amendment 148
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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, develop new functionalities, and respond to developing tools and applications. ***Other parties, such as Member States, scientific bodies of Member States or national authorities, academia, and civil society should be able to submit chemicals data to the Agencies or the Commission for hosting and maintenance.***

Or. en

Amendment 149
Beatrice Timgren

Proposal for a regulation
Recital 19

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

Or. en

Amendment 150
Pietro Fiocchi

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such relevant data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available. ***The quality control of data and completeness checks of data submissions should be carried out by the originator in accordance with the originating Union act under which the data was submitted or generated.***

Or. en

Amendment 151
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding,

Catarina Martins

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such ***relevant*** data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.	(20) In order to bring together all relevant chemicals data and information in the common data platform, the Commission and Union agencies – notably the European Agency for Safety and Health at Work ('EU-OSHA'), the ECHA, the European Environment Agency ('EEA'), the EFSA, and the EMA ('the Agencies'), should act as data providers and make available any such ***chemical*** data they have or hold to the ECHA for integration in the common data platform. The Agencies, including the ECHA itself when making its own data available, should provide the necessary standard metadata, contextual information and relevant mapping to the platform's structure, and respect rules on standard formats and controlled vocabularies where available.

Or. en

Amendment 152
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(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***, including monitoring and enforcement,*** or research

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.

activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. ***Other parties, such as Member States, academic institutes, scientific bodies of Member States or national authorities, should be able to offer chemicals data to the Agencies or the Commission for hosting and maintenance. In such case, it should be for the Agencies or the Commission, as the case may be, to decide whether to respond positively to the offer, and give justification in case the offer is refused.***

Or. en

Amendment 153
Martin Hojsík

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, data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. ***Other parties, such as Member States, scientific bodies of Member States or national authorities, should be able to offer chemicals data to the Agencies or the Commission. In such case, it should be for the Agencies or the Commission, as the case may be, to decide whether to***

respond positively to the offer, taking into account the format appropriate for the inclusion in the common data platform.

Or. en

Justification

Member States posses relevant information that could fill data gaps and be useful for the policies.

Amendment 154
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 ***legislation,*** 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 subject to this Regulation***. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks.

Or. en

Amendment 155
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 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. ***Member States should require researchers or research consortia funded by national framework programmes to make their data that is relevant for regulatory purposes available to the EEA or to ECHA.***

Or. en

Amendment 156
Jutta Paulus

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, 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 ***other data on chemicals, including*** environmental sustainability data on chemicals or materials they collect or generate to the ECHA. ***Member States should require researchers or research consortia funded by national framework programmes to make their data available***

to the EEA or to ECHA, as appropriate.

Or. en

Justification

The scope of the data to be made available goes beyond chemicals safety assessment and environmental sustainability, as is evidenced e.g. by the explicit reference to human biomonitoring data. National research data should also be included.

Amendment 157
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 and ***their*** environmental sustainability impacts, researchers or research consortia***, notably those*** funded by Union framework programmes should ***be required to*** 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 ***other chemicals data, including*** environmental sustainability data on chemicals or materials they collect or generate to the ECHA.

Or. en

Amendment 158
Martin Hojsík

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 and*** 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.

Or. en

Amendment 159
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23 a) Independent research studies are often given comparatively low weight as evidence in hazard and risk assessment of chemicals creating a gap between independent research and chemicals regulation and policy. It is necessary to provide structure and transparency in the evaluation of research data in order to increase their use in regulatory assessment of chemicals. The Commission should publish a guidance setting minimum quality and reporting requirements to improve the uptake of research data.

Or. en

Amendment 160
Martin Hojsík

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23 a) To support a resource-efficient approach, the ECHA and EFSA, which were mandated to carry out scientific studies within the Regulation (EC) No 178/2002, should cooperate closely in pooling resources and expertise on EU-wide human biomonitoring studies. The Member States should cooperate with the Agencies to organise the monitoring in their respective territories, in terms of planning, coordination, collection and transmission of samples.

Or. en

Amendment 161
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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***	(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.

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.

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*[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).***

Or. en

Amendment 162
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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***	(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.

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.

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*[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).***

Or. en

Amendment 163
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24 a) 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 constitutes 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 that data only where the processing is necessary for reasons of substantial public interest, as laid out in Article 10(2)(g) and for scientific research as laid out in Article 10(2)(j) of the Regulation (EU) No 2018/1725. The present Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data constituting

personal data.

Or. en

Amendment 164
Pietro Fiocchi

Proposal for a regulation
Recital 24 a (new)

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

Or. en

Amendment 165
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24 a) The EEA, ECHA, EFSA, EMA and the Commission should be able to process human biomonitoring data

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

Or. en

Amendment 166
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24 b) The EEA should be allowed to process human biomonitoring data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments, risk management and policy making. The Commission should be allowed to process human biomonitoring data constituting personal data, notably for scientific research, to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure of populations to chemicals, to develop indicators on health risks associated to such exposure, as well as to measure the efficiency and effectiveness of regulatory measures in preventing exposure by

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

Or. en

Amendment 167
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24 b) The EEA should be allowed to process that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments, risk management and policy making. The Commission should be allowed to process human biomonitoring data constituting personal data, notably for scientific research, to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure of populations to chemicals, to develop indicators on health risks associated to such exposure, as well as to measure the efficiency and effectiveness of regulatory measures in preventing exposure by analysing, for example, co-exposure to multiple chemicals for which data on co-occurrence of various chemicals per individual is necessary to observe common patterns and draw conclusions for populations, and supporting further risk assessments and risk management. The ECHA should also be allowed to act as a data processor for human biomonitoring data constituting personal data for the performance of assessments on chemicals, such as risk and safety assessments. Individual measurements of chemicals in human matrices may assist regulatory exposure and risk assessment, such as in the formulation of an opinion of the ECHA's Risk Assessment Committee, and lead to recommendations of risk management measures. The EFSA and the EMA should also be allowed to

act as a data processor for human biomonitoring data constituting personal data, notably to support the prioritisation of regulatory actions. Such data is also useful for EFSA when conducting assessments of chemicals in food and for understanding the effectiveness of existing measures in preventing human contamination through the food and feed chains. When processing human biomonitoring data constituting personal data, the EEA, the ECHA, the EFSA, the EMA and the Commission should pay particular attention to compliance with Article 13 of Regulation (EU) No 2018/1725.

Or. en

Amendment 168
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 24 c (new)

Text proposed by the Commission	*Amendment*
	(24 c) Human biomonitoring data collected prior to the coming into force of this Regulation is necessary to ensure the completeness, quality, and relevance of the human biomonitoring datasets for the purposes of guaranteeing the substantial public interests, and scientific research purposes as listed in this Regulation. Therefore, any such data gathered prior to the coming into force of this Regulation should be able to be processed by the EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission when this Regulation comes into force.

Or. en

Amendment 169
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding,

Catarina Martins

Proposal for a regulation
Recital 24 c (new)

Text proposed by the Commission	*Amendment*
	(24 c) Human biomonitoring data collected prior to the coming into force of this Regulation is necessary to ensure the completeness, quality, and relevance of the human biomonitoring datasets for the purposes of guaranteeing the substantial public interests, and scientific research purposes as listed in this Regulation. Therefore, any such data gathered prior to the coming into force of this Regulation should be able to be processed by the EEA, the ECHA, the EFSA, the EMA and the Commission when this Regulation comes into force.

Or. en

Amendment 170
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26 a) There are data gaps on the occurrence of hazardous and other harmful chemicals in products on the EU 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 maintain a repository of information on chemicals in products and their available alternatives generated under Union acts listed in Annex I. In addition, ECHA should integrate into the common data platform all chemicals data related to chemicals present in products or used in production processes and

which is accessible through the web portal under Article 14 of Regulation (EU) 2024/178.

Or. en

Amendment 171
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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. ***For a reference value for the carcinogenic effect of a chemical for which no maximum exposure level can be specified below which no harmful effects on human health are to be expected, the statistical cancer risk associated with that reference value should also be specified, if available.***

Or. en

Amendment 172
Beatrice Timgren

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27 a) Given the wide scope of Union acts listed in Annex I, when laying down the practical arrangements for implementing the study notification provisions, consideration should be given to proportionality to avoid the overburdening of business operators, laboratories and the ECHA.

Or. en

Justification

The proposed obligation for notification of studies commissioned by the industry will create a significant administrative burden. This burden on both the business operators and subsequently on the ECHA should not be underestimated, taking into account the large number and diversity of legislative acts included in Annex I, as well as the vast amount of studies, measurements and analyses performed on a daily basis by the industry. It must therefore be proportionately scoped and focused on studies with a specific added value to the risk or regulatory management of chemicals.

Amendment 173
Beatrice Timgren

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	***deleted***

chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.

Or. en

Justification

Both the Commission and the Parliament strive for efficient and effective regulation. For the new Commission President von der Leyen intends to task commissioners to reduce reporting obligations by at least 25 % - and for SME at least 35 %. Introducing a new reporting obligation of studies commissioned, mainly because of mistrust that existing obligations to include all relevant data in dossiers (e.g. Art 12 REACH) are not met, contradicts both. The effort to benefits ratio would be sub-optimal, particularly as no differentiation is made which studies really would be seen as relevant but missing in submissions. Enforcement by authorities would be challenging, companies fulfilling their duties would be unnecessarily burdened and bypassing can hardly be excluded. Instead, intelligent use of available knowledge/scientific data, especially from the upcoming common data platform, evaluation options of legislation concerned combined with targeted enforcement is expected to be a far more effective and efficient approach, reducing burden both on industry and authorities.

Amendment 174
Dennis Radtke

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	***deleted***

study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.

Or. en

Amendment 175
Martin Hojsík

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

start to apply two years after the date of entry into force of this Regulation.	start to apply two years after the date of entry into force of this Regulation. ***The ECHA should also develop guidance for duty holders to facilitate the implementation of the notification obligation, including information as regards the type of studies requiring notification.***

Or. en

Amendment 176
Pietro Fiocchi

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 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.	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA ***certain information related to*** the studies on chemicals they commission ***to support an application, notification or regulatory dossier intended to be notified or submitted to an authority*** for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.

Or. en

Amendment 177
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 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.	(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 their purpose, results or*** of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply ***one year*** after the date of entry into force of this Regulation.

Or. en

Amendment 178
Jutta Paulus

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28 a) 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 EFSA's practical arrangements.

Or. en

Justification

The requirement to notify studies already exists under Regulation (EC) No 178/2002 on food law. It therefore makes sense to align the practical arrangements for the study notifications to be done to ECHA with those done to EFSA.

Amendment 179
Dennis Radtke

Proposal for a regulation
Recital 29

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

Or. en

Amendment 180
Beatrice Timgren

Proposal for a regulation

Recital 29

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

Or. en

Amendment 181
Beatrice Timgren

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 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	***deleted***

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.

Or. en

Amendment 182
Dennis Radtke

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 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.	***deleted***

Or. en

Amendment 183

Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 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.	***deleted***

Or. en

Amendment 184
Beatrice Timgren

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 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.	***deleted***

Or. en

Amendment 185
Dennis Radtke

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 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.	***deleted***

Or. en

Amendment 186
Jutta Paulus

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) While the study notification	(31) While the study notification

obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

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

Or. en

Amendment 187
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	(31) While the study notification obligation established in this Regulation should apply in the context of all the Union acts on chemicals listed in Annex I, the various relevant data collection and safety

assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

assessment processes under those acts may vary widely procedurally. The overarching aim of the database of study notifications established under this Regulation should be to bring together information on studies on chemicals being commissioned by business operators, such as to enable a centralised and complete overview of the studies being performed to support regulatory compliance under Union acts on chemicals as listed in Annex I. On the basis of this objective and considering the fact that assessment procedures under Union acts on chemicals in Annex I may vary widely, it would be beyond the scope and aim of this Regulation to amend existing assessment processes set under those Union acts listed in Annex I by imposing additional conditions leading to potential market access consequences not foreseen in those Union acts. Consequently, it is not appropriate to introduce in this Regulation the consequences associated ***with*** non-compliance with the study notification obligation as laid out in Article 32b of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

Or. en

Amendment 188
Dennis Radtke

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those	***deleted***

penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.

Or. en

Amendment 189
Beatrice Timgren

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Nevertheless, to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.	***deleted***

Or. en

Amendment 190
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) ***Nevertheless,*** to ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.	(32) To ensure compliance with the study notification obligation laid down in this Regulation, and to cater to the specificities of individual assessment processes, where existing, Member States should lay down rules on penalties applicable to the infringement of that obligation and take all necessary measures to ensure that those rules are complied with. Those penalties should be effective, proportionate, and dissuasive, since non-compliance with this Regulation could result in less robust chemicals risk assessments, creating potential risks and consequently adverse effects on human health and the environment.

Or. en

Amendment 191
Beatrice Timgren

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.	***deleted***

Or. en

Amendment 192
Dennis Radtke

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.	***deleted***

Or. en

Amendment 193
Jutta Paulus

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 on the 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.***

Or. en

Justification

Amendment complementing the amendment 27 by the rapporteur.

Amendment 194
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 on the compliance with the obligations laid out in Article 22 ***and ensure information on enforcement is made public***.

Or. en

Amendment 195
Martin Hojsík

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 verify*** the compliance with the obligations laid out in Article 22.

Or. en

Justification

It should be clarified, which bodies will be responsible for compliance verification.

Amendment 196
Dennis Radtke

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that is to be notified under this Regulation.	***deleted***

Or. en

Amendment 197
Beatrice Timgren

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide	***deleted***

scope of the studies that is to be notified under this Regulation.

Or. en

Amendment 198
Dennis Radtke

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.	***deleted***

Or. en

Amendment 199
Beatrice Timgren

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of the European Parliament and of the Council. Where registrants are required to perform studies to generate data in accordance with requirements in Annexes IX and X to that Regulation, they must first submit a testing proposal to the ECHA in order to receive a decision requiring them to perform a study. Such decision may also be issued as an outcome of compliance check or substance evaluation under that Regulation. In order to facilitate the transparency, traceability, and effective monitoring of studies commissioned or carried out pursuant to a decision of the ECHA in accordance with Articles 40, 41 or 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, business operators should specify in their notifications of studies under this Regulation that those studies are being commissioned or carried out in compliance with those decisions.	***deleted***

Or. en

Amendment 200
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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,	(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 ***and to promote the phasing out of animal tests***, the ECHA should establish and manage a database with information on

ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.

regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the outcome of the regulatory process or activity ***including any new requirement to conduct animal testing and the length of time each activity is expected to take***. 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.

Or. en

Amendment 201
Jutta Paulus

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, 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	(36) To strengthen the coordination and cooperation between the different bodies performing chemicals assessments in the Union, and to promote an increased transparency of chemicals assessments, the ECHA should establish and manage a database with information on regulatory processes or activities that are planned, ongoing or completed by Member States, the Commission and Agencies referred to in the Union acts listed in Annex III to this Regulation and integrate it into the common data platform for access by the authorities. The information on such regulatory processes or activities should include at least the substance identity and the identification, status and eventually the

outcome of the regulatory process or activity. That information should also be made available without undue delay and kept updated through the assessment process. Once the process or activity has formally started, that information should be shared also publicly on the common data platform.

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.

Or. en

Amendment 202
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 shall 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.

Or. en

Amendment 203
Beatrice Timgren

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 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.***

Or. en

Amendment 204
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 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. ***Such mutual coherence should be supported by the respective Agency's efforts to ensure alignment across full study data, study reports and study summaries.***

Or. en

Amendment 205
Jutta Paulus

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*

(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/2009[13] and (EU) No 528/2012[14] of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .

[13] 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).

[14] Regulation (EU) No 528/2012 of the

(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/2009[13] and (EU) No 528/2012[14] of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the Commission and the Agencies to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA . ***In light of its expertise and responsibility in IUCLID software, as well as the establishment and operation of the Common Data Platform, it is appropriate for ECHA to furnish precise guidelines and adequate technical and IT support to ensure that the competent authorities are able to comply with their obligation to submit the relevant sections of the dossiers.***

[13] 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).

[14] Regulation (EU) No 528/2012 of the

European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167 27.6.2012, p. 1).

European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167 27.6.2012, p. 1).

Or. en

Justification

Self-explanatory.

Amendment 206
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/2009[13] and (EU) No 528/2012[14] of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the ***Commission and the Agencies*** to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers	(41) The International Uniform Chemical Information Database ('IUCLID') is a software application designed to record, store, maintain and exchange data on chemicals. The ECHA develops and maintains the IUCLID software and the underlying format in collaboration with the Organisation for Economic Cooperation and Development ('OECD'). The IUCLID implements all OECD-harmonised templates, which are harmonised formats agreed at the OECD level to facilitate structured and consistent documentation of test outputs and similar chemicals data. Since chemicals data is being submitted to the ECHA in IUCLID under Union acts such as Regulations (EC) No 1907/2006, (EC) No 1107/2009[13] and (EU) No 528/2012[14] of the European Parliament and of the Council, the ECHA is closely involved in the continued development of IUCLID, and IUCLID implements the standard formats agreed at the OECD level, it is appropriate and necessary to require the ***Authorities*** to use IUCLID for the relevant parts of dossiers under specified Union acts listed in Annex I when they make the data contained in those dossiers available to the ECHA .

available to the ECHA .

[13] 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).

[14] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167 27.6.2012, p. 1).

[13] 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).

[14] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167 27.6.2012, p. 1).

Or. en

Amendment 207
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	(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 ***and health***, the Commission should identify relevant data and information related to the environmental sustainability ***and health impacts*** 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 ***and health*** related data and has designed the relevant related database functionalities, the ECHA should establish a database on environmental ***sustainability and health-related*** data, collect the data as made available by the Commission, the Agencies

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.	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 ***and health*** datasets ***of chemicals data***, implementing powers should be conferred on the Commission.

Or. en

Amendment 208
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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	(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 ***Member States and***, where relevant, by the researchers and research consortia***, in particular those*** funded by ***national and*** Union framework programmes, and integrate the content of that database into

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.

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.

Or. en

Amendment 209
Martin Hojsík

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	(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 ***national and*** 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

Commission.	on the Commission.

Or. en

Amendment 210
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 ***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 to the impacts on humans and the environment, including the climate, of exposure to chemicals and pollutants, the Agencies should jointly develop and regularly, at least every two years, update an aggregated indicator at different territorial level, in collaboration with the Joint Research Centre and drawing inspiration from its European wide vulnerability framework[1a]. The EEA should cross-reference the results of this indicator with other health and environment datasets, such as epidemiological data on occupational health, life-style factors, and socio-economic factors, in order to assess the impacts and risks of cumulated risk factors on population at the territorial level. The Agencies*** 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 ***Agencies*** should integrate this dashboard of indicators into the

common data platform.

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*[1a] **Eklund, L.G., Sibilia, A., Salvi, A., Antofie, T., Rodomonti, D., Salari, S., Poljansek, K., Marzi, S., Gyenes, Z. and Corban, C., Towards a European wide vulnerability framework, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/353889, JRC118850.***

Or. en

Amendment 211
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Recital 43 a (new)

Text proposed by the Commission	*Amendment*
	(43 a) In order to ensure the widest possible access to chemicals data and to improve trust in the implementation of this Regulation and Union policies and legislation on chemicals, and further acknowledging existing experience with citizen science approaches, individuals should be able to submit substantiated concerns regarding impacts of chemicals on humans and the environment, such as peer-reviewed research results, or biomonitoring data. The authorities should be obliged to assess submitted evidence and take action when they identify a concern. In line with commitments of the Union in relation to the Aarhus Convention, individuals submitting evidence should be equipped with procedural rights to ensure their concerns are appropriately taken into account.

Or. en

Amendment 212
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 43 a (new)

Text proposed by the Commission	*Amendment*
	(43 a) In order to ensure the widest possible access to chemicals data and to improve trust in the implementation of this Regulation and Union policies on chemicals, and further acknowledging existing experience with citizen science approaches, natural or legal person should be able to submit substantiated concerns regarding impacts of chemicals on humans and the environment, such as peer-reviewed research results, or biomonitoring data. The authorities should assess submitted evidence and take action when they identify a concern. In line with commitments of the Union in relation to the Aarhus Convention, individuals submitting evidence should be equipped with procedural rights to ensure their concerns are appropriately taken into account.

Or. en

Amendment 213
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	(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 follow-up actions ***by***

early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. this Regulation sets a deadline for the first report and associated data.	***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 information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks ***of 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 chemicals 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.***

Or. en

Amendment 214
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. this Regulation sets a deadline for the first report and associated data.	(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. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks ***of chemicals and groups of 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 justify if they decide not to proceed with any action.***

Or. en

Amendment 215
Martin Hojsík

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

Or. en

Amendment 216
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	(46) The ECHA should continue operating the EUON and transform it into an observatory for specific ***chemicals, or groups of*** chemicals with potential

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

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

Or. en

Amendment 217
Martin Hojsík

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	(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.	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 a sample of a substance is precondition to conduct the scientific studies, ECHA should be given the necessary sample from 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 vertebrate animal tests***

Or. en

Amendment 218
Jutta Paulus

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	(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.	acts on chemicals within its mandate and contributing the development of a Union chemicals policy. ***If a sample of a substance is needed to conduct scientific studies, the ECHA should have the authority to request the business operator to provide the necessary sample.***

Or. en

Justification

In order to be able to conduct monitoring studies, a proper sample is needed. ECHA should therefore have the authority to request such a sample from a business operator.

Amendment 219
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy. ***Where relevant and whenever possible, information generated through studies commissioned by the***

ECHA should be generated by means of non animal testing methods.

Or. en

Amendment 220
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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***, groups of chemicals, and the risk of their cumulative exposure thereof,*** 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.

Or. en

Amendment 221
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48 a) 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 the adequacy between the resources of the agencies and their current tasks, their new tasks under this Regulation, and a prospective view of the ressources needed to address key areas of regulatory challenge in the future. The Commission should also draw up a report on the impacts of cumulative exposure to chemicals on health and the environment, and analysing the efficacy of the current risk assessment of chemicals across Union legislation to adequately address the combination effect of chemical mixtures and to ensure a high level of protection of health and the environment.

Or. en

Amendment 222
Martin Hojsík, Sigrid Friis

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48 a) As this Regulation expands the tasks and workload of the European Chemicals Agency, it shall 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 needs of the Agency to allow fullfillment of its tasks

and potential.

Or. en

Amendment 223
Jutta Paulus

Proposal for a regulation
Recital 49 a (new)

Text proposed by the Commission	*Amendment*
	(49 a) 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 EU-wide human biomonitoring studies that provide high-quality and representative data at regular intervals.

Or. en

Justification

Human biomonitoring studies are of crucial relevance to assess risks and to the effectiveness of Union legislation with regard to chemicals. EFSA has an annual budget of 15 mio € for verification studies pursuant to the General Food Law. ECHA will be given an annual budget of 5 mio € for data generation. A clear mandate should be given to conduct EU-wide human biomonitoring studies at regular intervals.

Amendment 224
Pietro Fiocchi

Proposal for a regulation
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51 a) By XXX/before implementation of this regulation, the Commission shall carry out an impact assessment on the "one substance one assessment" initiative to ensure that possible impacts on businesses are duly considered and that businesses are involved in the initiative

since its beginning.

Or. en

Amendment 225
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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***, to enable scrutiny by interested parties of data generated and used for regulatory purposes***, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.

Or. en

Amendment 226
Jutta Paulus

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	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

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.	proper functioning of the single market for chemicals, 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 help move away from animal testing wherever possible***.

Or. en

Justification

A comprehensive data base on hazard and risk assessments of chemicals can also help to reduce animal testing.

Amendment 227
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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 health and the environment, to enable the development and use of sustainable ***and safe*** chemicals, to ensure the proper functioning of the single market for chemicals, ***to contribute to the goal of phasing out animal testing*** and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.

Or. en

Amendment 228
Martin Hojsík

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

Or. en

Amendment 229
Beatrice Timgren

Proposal for a regulation
Article 1 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. To achieve the objectives referred to in paragraph 1, this Regulation contains measures to:	2. To achieve the objectives referred to in paragraph 1, this Regulation contains ***targeted*** measures to:

Or. en

Amendment 230
Daniel Buda

Proposal for a regulation
Article 1 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;	(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable ***for all categories of users***;

Or. ro

Amendment 231
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 1 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) bring together data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;	(a) bring together data and information on chemicals ***and their alternative*** and ensure that data and information are easily findable, accessible, interoperable and re-usable;

Or. en

Amendment 232
Beatrice Timgren

Proposal for a regulation
Article 1 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ***bring together*** data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;	(a) ***consolidate existing essential*** data and information on chemicals and ensure that data and information are easily findable, accessible, interoperable and re-usable;

Or. en

Amendment 233
Martin Hojsík

Proposal for a regulation
Article 1 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) bring together data and information on chemicals and ensure that data and	(a) bring together ***all*** data and information on chemicals and ensure that

information are easily findable, accessible, interoperable and re-usable;	data and information are easily findable, accessible, interoperable and re-usable;

Or. en

Amendment 234
Pietro Fiocchi

Proposal for a regulation
Article 1 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) keep records of studies commissioned ***or carried out*** by business operators in the context of fulfilling their obligations set under Union ***chemicals legislation***;	(b) keep records of studies commissioned by business operators in the context of fulfilling their obligations set under Union ***acts listed in Annex I, where those studies are commissioned to support an application, notification or regulatory dossier intended to be notified or submitted to an Authority to comply with regulatory requirements under the Union acts listed in Annex I***;

Or. en

Amendment 235
Beatrice Timgren

Proposal for a regulation
Article 1 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) keep records of studies commissioned or carried out by business operators ***in the context of fulfilling their obligations set*** under Union chemicals legislation;	(b) keep records of studies commissioned or carried out by business operators ***as required*** under ***existing*** Union chemicals legislation***, ensuring no additional obligations or market access conditions are imposed beyond those already set out in the relevant acts***;

Or. en

Amendment 236
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 1 – paragraph 2 – point b

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

Or. en

Amendment 237
Pietro Fiocchi

Proposal for a regulation
Article 1 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals;	(c) establish the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals ***taking into account the different sectorial risk assessment***;

Or. en

Amendment 238
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 1 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) foster innovations regarding advanced biologically-relevant tools, methods and models, and data analysis capacities.

Or. en

Amendment 239
Beatrice Timgren

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The provisions laid down in this Regulation apply to chemicals data ***as laid out in Article 3(2)***.	3. The provisions laid down in this Regulation apply ***only*** to chemicals data ***explicitly referenced under the Union acts listed in Annex I***.

Or. en

Amendment 240
Beatrice Timgren

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 referred to in ***Annex I, and the Agencies, only insofar as they perform tasks directly under*** the Union acts listed in ***Annex I***;

Or. en

Amendment 241
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
3. 'duty holder' means a natural or legal person responsible for ***meeting*** obligations under ***the*** Union acts ***listed in***	3. 'Duty holder' means a natural or legal person ***directly*** responsible for ***fulfilling specific*** obligations under ***Annex***

Annex I or II;	***I-listed*** Union acts;

Or. en

Amendment 242
Beatrice Timgren

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 ***factual or regulatory*** information ***submitted or generated under Union acts listed in Annex I, specifically concerning*** chemicals***'*** physico-chemical properties, hazard properties, exposure, ***and use***, as well as regulatory process-related information***. Environmental sustainability data is included only where explicitly required by Annex I-listed acts***;

Or. en

Amendment 243
Martin Hojsík, Sigrid Friis

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	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;	manufacturing process of the chemicals, ***information on availability of sustainable alternatives,*** 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***, including information related to enforcement activities***;

Or. en

Amendment 244
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 availability and suitability of alternatives,*** standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals ***and the enforcement thereof***;

Or. en

Amendment 245
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 11 – introductory part

Text proposed by the Commission	*Amendment*
11. ‘environmental sustainability related data’ means ***any data relevant*** for the environmental sustainability assessment of a chemical or material ***throughout its entire life cycle, including***:	11. ‘environmental sustainability related data’ means ***data explicitly generated or required under Annex I-listed Union acts*** for the environmental sustainability assessment of a chemical or material***, limited to***:

Or. en

Amendment 246
Pietro Fiocchi

Proposal for a regulation
Article 2 – paragraph 1 – point 11 – introductory part

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

Or. en

Amendment 247
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 11 – point a

Text proposed by the Commission	*Amendment*
(a) data on resources***, including raw materials, water, energy, fossil fuels and land***;	(a) data on resources ***and emissions relevant to the assessment of the chemical under applicable Union legislation***; ***and***

Or. en

Amendment 248
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 11 – point b

Text proposed by the Commission	*Amendment*
(b) ***data on emissions, including greenhouse gases, eutrophication-relevant substances, dust and all other polluting substances***; ***and***	(b) ***by-products explicitly identified in regulatory submissions***;

Or. en

Amendment 249
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 11 – point c

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

Or. en

Amendment 250
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 2 – paragraph 1 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	11 a. '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;

Or. en

Amendment 251
Martin Hojsík

Proposal for a regulation
Article 2 – paragraph 1 – point 14 a (new)

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

Or. en

Amendment 252
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 15

Text proposed by the Commission	*Amendment*
15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions**.**	15. 'interoperability' means the ability of two or more data spaces or communication networks, systems, products, applications or components to exchange and use data in order to perform their functions***;***

Or. en

Amendment 253
Beatrice Timgren

Proposal for a regulation
Article 2 – paragraph 1 – point 15 a (new)

Text proposed by the Commission	*Amendment*
	15 a. 'Study' means research conducted or commissioned by business operators for the purpose of preparing an

	application, notification, or regulatory dossier to be submitted to an Authority in compliance with the regulatory requirements of the Union acts specified in Annex I.

Or. en

Amendment 254
Martin Hojsík

Proposal for a regulation
Article 2 – paragraph 1 – point 15 a (new)

Text proposed by the Commission	*Amendment*
	15 a. 'the public' means one or more natural or legal persons, and associations, organisations or groups of such persons.

Or. en

Amendment 255
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The common data platform shall provide access to ***all*** chemicals data:	2. The common data platform shall provide access to ***essential*** chemicals data:

Or. en

Amendment 256
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) generated or submitted as part of	(a) generated or submitted as part of

the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies ***or*** the Commission;	the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies***,*** the Commission ***or Member States autorities ('the Authorities')***;

Or. en

Amendment 257
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) generated or submitted as part of the implementation of the Union acts listed in Annex I ***to this Regulation*** and held by the Agencies or the Commission;	(a) generated or submitted as part of the implementation of ***specific obligations under*** the Union acts listed in Annex I and held by the Agencies or the Commission;

Or. en

Amendment 258
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 3 – paragraph 2 – point b

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

Or. en

Amendment 259
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 2 – point b

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

Or. en

Amendment 260
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) listed in Annex II and held by the EMA;	***deleted***

Or. en

Amendment 261
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 3 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) ***listed in Annex II and*** held by the EMA;	(c) held by the EMA;

Or. en

Amendment 262
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 3 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) generated under Regulation (EU) 2024/1781 and accessible through the web portal under Article 14 of that regulation.

Or. en

Amendment 263
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) generated under Regulation (EU) 2024/1781 and accessible through the web portal under Article 14 of that regulation.

Or. en

Amendment 264
Martin Hojsík

Proposal for a regulation
Article 3 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) generated under Regulation (EU) 2024/1781 and accessible through the web portal under article 14 of that Regulation.

Or. en

Justification

We agree with the rapporteur that the proposal shall reflect the ESPR, which Digital Product Passport will include relevant information that will contribute to the goal of the OSOA.

Amendment 265
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The following information shall not be included in the common data platform:	***deleted***
(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[17] ;	
(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[18] of the European Parliament and of the Council.	

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

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

Or. en

Amendment 266
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) data not explicitly required for hazard or risk assessment purposes;

Or. en

Amendment 267
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 3 – point b b (new)

Text proposed by the Commission	*Amendment*
	(b b) information submitted to the Agencies or Commission prior to [a specific cutoff date].

Or. en

Amendment 268
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.	***deleted***

Or. en

Amendment 269
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Documents relating to Authorities' internal work or decision-making processes need not be included in the common data platform, unless required under Article 10.	***deleted***

Or. en

Amendment 270
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. 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.

Or. en

Amendment 271
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
5. The common data platform shall provide the ***dedicated*** services identified in the governance scheme referred to in Article 4(3) ***including***:	5. The common data platform shall provide the ***following essential*** services***, as*** identified in the governance scheme referred to in Article 4(3):

Or. en

Amendment 272
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 5 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) information on chemicals in products and their alternatives referred to in Article 10a;

Or. en

Amendment 273
Beatrice Timgren

Proposal for a regulation
Article 3 – paragraph 5 – point g

Text proposed by the Commission	*Amendment*
(g) the database on environmental sustainability-related data referred to in Article 13.	***deleted***

Or. en

Amendment 274
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 3 – paragraph 5 – point g

Text proposed by the Commission	*Amendment*
(g) the database on environmental ***sustainability-related*** data referred to in Article 13.	(g) the database on environmental ***sustainability and health-related*** data referred to in Article 13.

Or. en

Amendment 275
Martin Hojsík, Sigrid Friis

Proposal for a regulation
Article 3 – paragraph 5 – point g a (new)

Text proposed by the Commission	*Amendment*
	(g a) information on substances in products and their alternatives referred to in Article 10a.

Or. en

Amendment 276
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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

Or. en

Amendment 277
Martin Hojsík

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.

Or. en

Amendment 278
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 access ***free of charge*** to the data contained in the common data platform in accordance with Article 16.

Or. en

Amendment 279
Martin Hojsík

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. Safety measures shall be adopted by the relevant Agencies to ensure safe*** transmission of chemicals data to the platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.

Or. en

Justification

All involved agencies shall make sure that high standard of security is ensured also when it comes to the process of transmission of the data from one Agency to ECHA.

Amendment 280
Martin Hojsík

Proposal for a regulation
Article 3 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10 a. 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.

Or. en

Justification

Supporting the rapporteur´s view that it is important to clarify the role of ECHA and its responsibilities.

Amendment 281
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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: ***one year*** after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets ***of chemicals data, including those generated or submitted before the entry into force of this Regulation, unless specified otherwise*** shall be integrated progressively into the common data platform by [OP please insert date: ***six*** 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.

Or. en

Amendment 282
Jutta Paulus

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 as 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 without undue delay.

Or. en

Justification

There needs to be clarity from the outset of what should be integrated into the common data platform. The datasets to be included - as set out in the Staff Working Document SWD(2023) 850, p. 141 - 143) - should be included in an Annex. Another five years - eight years in total - should be more than enough to fill the common data platform with the remaining data.

Amendment 283
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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.	11. The common data platform and its dedicated services shall be established by [OP: please insert date: ***two*** years after the date of entry into force of this Regulation], unless specified otherwise. The relevant

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.	datasets shall be integrated progressively into the common data platform by [OP please insert date: ***five*** 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.

Or. en

Amendment 284
Beatrice Timgren

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: ***five*** 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: ***15*** 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.

Or. en

Amendment 285

Daniel Buda

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. 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 ***within a period of 30 days***.

Or. ro

Amendment 286
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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. ***Those implementing acts shall be adopted in accordance with the examination***

procedure referred to in Article 24a(2).

Or. en

Amendment 287
Beatrice Timgren

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 and publish an implementation plan identifying ***chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion by means of an implementing decision. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.

Or. en

Amendment 288
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 implementing ***acts***, 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. ***Those implementing acts shall be adopted in accordance with the examination***

procedure referred to in Article 24a(2).

Or. en

Amendment 289
Jutta Paulus

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 decision, 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 Union agencies combined***.

Or. en

Justification

The main parameters for the composition of the steeering committee should be laid down in the basic act and not be left to the discretion of the Commission via an implementing act (with no effective control rights by the European Parliament). For the good functioning of the common data platform, it is obvious that each agency should be represented in the steering committee with at least one representative. That still leaves flexibility, if needed, to add further representatives. There should be parity between the representatives of the agencies on the one hand and those of the Commission on the other hand.

Amendment 290
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	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***	means of ***implementing acts.***
	Those implementing ***acts shall be adopted in accordance with the examination procedure referred to in Article 24a(2).***

Or. en

Amendment 291
Beatrice Timgren

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 an implementing decision***. Stakeholders shall be consulted before decisions on implementation plans and governance are taken.***

Or. en

Justification

The establishment of the data platform is a complex undertaking, and e.g. as mentioned meta data are decisive to point out specific conditions, relevance and reliability of any information provided to allow proper re-use. Thus, also industry should be consulted before decisions on implementation plans, data collection or dissemination formats, vocabulary etc are taken.

Amendment 292
Dennis Radtke

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 an implementing decision ***after consulting stakeholders, when appropriate.***

Or. en

Amendment 293
Daniel Buda

Proposal for a regulation
Article 4 – paragraph 5 – point d

Text proposed by the Commission	*Amendment*
(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform;	(d) the decision-making procedures for the development of new dedicated services and the inclusion of new functionalities of the platform***, including mechanisms for cooperation and information exchange with databases and similar platforms in third countries and internationally***;

Or. ro

Amendment 294
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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.

Or. en

Amendment 295
Daniel Buda

Proposal for a regulation
Article 4 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*

	5a. The Commission shall report annually to the European Parliament and to the Council on the progress made on the implementation and functioning of the common data platform, including information on its use by different categories of users and its impact on environmental and public health policies.

Or. ro

Amendment 296
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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

Or. en

Amendment 297
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	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.	research activities, corresponding to their mandate and the type of data they already hold. ***The Agencies may host and maintain chemicals data corresponding to their mandate and submitted to them by Member States or other parties.***

Or. en

Amendment 298
Martin Hojsík

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

Or. en

Justification

Omitting information from the Member States authorities limits the ability to achieve political and technical objective of the proposal.

Amendment 299
Pietro Fiocchi

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	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.

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 ***confidential in accordance with the provisions on confidentiality*** under the originating Union act. ***Where the originating Union act does not contain confidentiality provisions, the Commission shall, by means of an implementing decision, establish interim confidentiality provisions under this Regulation. Such implementing decision shall be adopted, in consultation with stakeholders, within 12 months of the date of entry into force of this Regulation.***

Or. en

Amendment 300
Massimiliano Salini, Letizia Moratti, Flavio Tosi

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 that data or information is ***confidential in accordance with the provisions on confidentiality*** under the originating Union act. ***Where the originating Union act does not contain confidentiality provisions, the Commission shall, by means of an implementing decision, establish interim confidentiality provisions under this Regulation. Such implementing decision shall be adopted, in consultation with stakeholders, within 12 months of the date***

of entry into force of this Regulation.

Or. en

Amendment 301
Radan Kanev

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(4), point (c). The ***confidentiality provisions applicable under Union acts listed in Annex I*** shall ***remain in force and prevail over this Regulation in case of any conflict. All data deemed confidential under originating Union acts shall be treated accordingly in the common data platform.Confidential business*** information ***submitted by business operators, including trade secrets as defined*** under ***Directive (EU) 2016/943, shall not be disclosed unless explicitly required by*** the originating Union act.

Or. en

Justification

By ensuring that confidentiality provisions from existing legislation prevail in the event of conflicts, the amendment guards against unintended disclosure of sensitive data through the platform. This safeguard aligns with the principles of fairness and proportionality. Ambiguity about confidentiality protections could lead to disputes or non-compliance by stakeholders. The amendment ensures legal certainty, clarifying the hierarchy of protections in cases of overlapping legal requirements.

Amendment 302
Beatrice Timgren

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(4), point (c). The Commission and the Agencies shall indicate whether that data or information ***can be*** made available to the public ***or they are deemed confidential in accordance with the provisions on confidentiality*** under the originating Union act.

Or. en

Amendment 303
Kristoffer Storm

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(4), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public ***or they are deemed confidential in accordance with the provisions on confidentiality*** under the originating Union act.

Or. en

Justification

Support for amendment 42 in the draft report

Amendment 304
Martin Hojsík, Stine Bosse

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(4), point (c). The Commission and the Agencies shall indicate whether that data or information is made available to the public ***or confidential in accordance with the provisions on confidentiality*** under the originating Union act.

Or. en

Amendment 305
Jutta Paulus

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(4), point (c). The Commission and the Agencies shall indicate whether that data or information is ***confidential in accordance with the provisions on confidentiality*** under the originating Union act.

Or. en

Justification

As the default is access to the data, it is more appropriate to indicate when confidentiality applies under the originating act.

Amendment 306
Pietro Fiocchi

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(4), point (c). The Commission and the Agencies shall indicate whether that data or information is ***confidential in accordance with the provisions on confidentiality*** under the originating Union act.

Or. en

Amendment 307
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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	2. Where the ***Authorities*** 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 ***Authorities*** shall indicate whether that data or information is ***confidential in accordance with the provisions on confidentiality*** under the

act.	originating Union act.

Or. en

Amendment 308
Laurent Castillo

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(4), point (c). The Commission and the Agencies shall indicate whether that data or information is ***confidential or not*** under the originating Union act.

Or. fr

Amendment 309
Martin Hojsík

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 human biomonitoring data***. ***Human biomonitoring data constituting personal data may be processed by the ECHA 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;

(d) monitoring the impact of regulatory intervention;

(e) supporting regulatory risk assessments;

The ECHA shall make any human biomonitoring data they hold publicly available in anonymised form through the Common data platform.

Or. en

Justification

Supporting the rapporteur´s view related to the need to clarify the conditions for the processing of data on workplace monitoring.

Amendment 310
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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

Or. en

Amendment 311
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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***, in particular those*** funded by Union ***or national*** 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].

Or. en

Amendment 312
Martin Hojsík

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 and*** 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].

Or. en

Amendment 313
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 5 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. Member States shall require researchers or research consortia funded by national programmes to make available to the EEA any human biomonitoring data they collect or

generate from [OP please insert: date of the entry into force of this Regulation].

For human biomonitoring data constituting personal data, the EEA shall specify which type of data shall be made available to it.

Or. en

Amendment 314
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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 Union framework programmes shall make available to the ECHA any ***chemicals data other than biomonitoring data, including*** environmental sustainability ***and health-related*** data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].

Or. en