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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	11275/24
Subject:	Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

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

2023/0453(COD)

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		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Formula				
G	1	2023/0453 (COD)	2023/0453 (COD)	2023/0453 (COD)	2023/0453 (COD) Text Origin: Commission Proposal
	Document Stage				
G	2	Proposal for a	Proposal for a	Proposal for a	Proposal for a Text Origin: Commission Proposal
	Document Type				
G	3	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Text Origin: Commission Proposal
	Document Purpose				
G	4	establishing a common data platform on chemicals, laying down rules to ensure that the data	establishing a common data platform on chemicals, laying down rules to ensure that the data	establishing a common data platform on chemicals, laying down rules to ensure that the data	establishing a common data platform on chemicals, laying down rules to ensure that the data

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	contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals	contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals	contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals	contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals Text Origin: Commission Proposal
EEA Relevance				
G 5	(Text with EEA relevance)	(Text with EEA relevance)	(Text with EEA relevance)	(Text with EEA relevance) Text Origin: Commission Proposal
Formula				
G 6	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN **UNION**,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN ***UNION***, Text Origin: Council Mandate
Citation 1				
G 7	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) thereof.	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) thereof. Text Origin: Commission Proposal
Citation 2				
G 8	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,

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				Text Origin: Commission Proposal
Citation 3				
9	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments, Text Origin: Commission Proposal
Citation 4				
10	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee, Text Origin: Commission Proposal
Citation 5				
11	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure, Text Origin: Commission Proposal
Formula				
12	Whereas:	Whereas:	Whereas:	Whereas: Text Origin: Commission Proposal
Recital 1				
13	(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero	(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero	(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution.	(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution.

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	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. _____	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.	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. _____	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. _____

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	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,	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, Text Origin: EP Mandate
Recital 2				
14	(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	(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***. Improving the integration of information from different sources, and establishing a cost-effective digital infrastructure will improve the predictability and transparency of regulatory processes and result in a reduction of the administrative burden and overlaps***. For that purpose, this Regulation should establish a common data platform	(2) The main objective of this Regulation is to increase the level of protection of the environment and human health from the risks arising from hazardous chemicals, as well as **to modernise the integration of information with a view to reducing the administrative burden and** to facilitate the functioning of the internal market for chemicals. For that purpose, this Regulation should establish a common data platform data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together	

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	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.	data on chemicals ('the common data platform'), to be managed by the European Chemicals Agency ('ECHA'). The common data platform is a digital infrastructure that brings together chemicals data and information generated under the Union chemicals acquis. This Regulation should also establish dedicated services within the common data platform and lay down rules on the ***transparency,*** accessibility and usability of the data contained in that platform. This Regulation aims to create a common knowledge base on chemicals available to authorities to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts and to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation ***and thereby contribute to ensuring that testing on animals only takes place as a last resort*** ~~*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	chemicals data and information generated under the Union chemicals ***acquis*** ~~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.	

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		predictability and the transparency of regulatory processes on chemicals, as well as to strengthen public trust in the robustness of scientific decision-making. ***By collecting and making available all data on chemicals that exist in the Union, the database will also foster innovation and support the development of advanced biologically-relevant tools, methods and models, and data analysis capacities.***		
Recital 3				
G	15	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[1], harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[1], harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[1], harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and	(3) Under Decision (EU) 2022/591 of the European Parliament and of the Council[1], harnessing the potential of digital and data technologies to support environmental policy, including by delivering real-time data where possible and information on the state of ecosystems, while increasing efforts to minimise the environmental footprint of these technologies and ensuring transparency, authenticity, interoperability and public accessibility of the data and information is a long-term priority objective. Data and information on chemicals are therefore essential for the proper development and

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	implementation of a Union environmental policy, and specifically of a chemicals policy. _____ 1. Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p. 22).	implementation of a Union environmental policy, and specifically of a chemicals policy. _____ 1. Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p. 22).	implementation of a Union environmental policy, and specifically of a chemicals policy. _____ 1. Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p. 22).	implementation of a Union environmental policy, and specifically of a chemicals policy. _____ 1. Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p. 22). Text Origin: Commission Proposal
Recital 4				
G 16	(4) In its communication of 19 February 2020 on a European strategy for data[1], 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	(4) In its communication of 19 February 2020 on a European strategy for data[1], 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	(4) In its communication of 19 February 2020 on a European strategy for data[1], 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	(4) In its communication of 19 February 2020 on a European strategy for data[1], 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 G

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	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. _____ 1. 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.	concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the ***Commission and the*** relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks. _____ 1. 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.	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. _____ 1. 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.	concerning the availability of data for the public good, including data availability, data infrastructures and governance, interoperability, as well as the lack of adequate sharing of data between public authorities. This Regulation aims to increase data availability on chemicals by requiring the ***Commission and the*** relevant Union agencies to make data available for integration in the common data platform on chemicals, to promote interoperability of that data by providing for the establishment of standard formats and controlled vocabularies, as well as to facilitate data exchange and use by public authorities to enable them to effectively carry out their regulatory and policy developing tasks. _____ 1. 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. Text Origin: EP Mandate
Recital 5				

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G 17	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act[1] by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications. _____ 1. Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) COM(2022) 720 final.	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act[1] by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications. _____ 1. Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) COM(2022) 720 final.	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act[1] by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications. _____ 1. Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) COM(2022) 720 final.	(5) This Regulation also aims to implement into the chemicals sector the principles laid out in the proposal for an Interoperable Europe Act[1] by strengthening the cross-border interoperability of network and information systems used to provide or manage public services on chemicals in the Union. This Regulation will contribute to increased cross-border data flows for truly European digital services and broaden the access to publicly available chemicals data for utilisation in other sectors' applications. _____ 1. Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) COM(2022) 720 final. Text Origin: Commission Proposal
Recital 6				
G 18	(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	(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	(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	(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

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	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	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	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	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

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	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.	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.***	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.**	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.*** Text Origin: Council Mandate
Recital 7				
G 19	(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	(7) The common data platform should contain***, but not be limited to, all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted ***to them*** as part of the implementation of Union chemicals legislation listed in Annex I***, unless this Regulation specifies otherwise***. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the	(7) The common data platform should contain **all** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I**, unless specified otherwise**. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the Commission in compliance with	(7) The common data platform should contain***, but not be limited to, all*** chemicals-related data and information held by relevant Union agencies or the Commission generated or submitted ***to them*** as part of the implementation of Union chemicals legislation listed in Annex I***, unless this Regulation specifies otherwise***. This includes, for instance, all regulatory dossiers or applications submitted to the relevant Union agencies, but also chemicals data on occurrence of chemicals submitted by Member States to Union agencies or the G

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	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.	Commission in compliance with their reporting obligations ***and enforcement activities***. The common data platform should also include chemicals data and information generated as part of Union, national or international programmes or research activities related to chemicals, where this data and information is held by the Commission or one of the relevant agencies.	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.	Commission ***as well as chemicals data resulting from Member States' implementation activities,*** 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. ***In addition, the common data platform should allow for the integration of chemicals data provided on a voluntary basis by Member States and other parties, including national agencies and research institutes, as well as chemicals data resulting from international collaboration with third countries' organization, and held by the Commission or one of the relevant agencies.***
Recital 8				
20	(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	(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	(8) ~~Due to the different nature of the risk and~~**While some medicinal products are also chemicals and could present an interest for the objectives of this Regulation, the application and**	

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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~medicines~~**Union** legislation **on medicinal products listed in Annex I, Part 2,** and also ~~used for other applications regulated by~~**subject to regulatory procedures under** other Union legislation **listed in Annex I, Part 1,** identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment. **The specific chemicals data to be included for those relevant active substances should cover chemicals data related to environmental risk assessments carried out under Union legislation on medicinal products for human and veterinary use, non-clinical studies carried out under Union legislation on medicinal products for human use and maximum residue limit values and the chemicals data underlying their derivation that the EMA holds, as well as specific reference values.**	
Recital 9				
21	(9) These data should also be limited to data submitted to the	(9) ~~*These data should also be limited*~~ ***Taking due account of the***	(9) ~~These data should also be limited to data~~**Considering the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***administrative work for EMA coming from the adaptation of such data*** to ***an appropriate format for inclusion in the common data platform, it is appropriate to adopt a stepwise approach, and to include during the first stage only chemical data for active substances which are*** ~~*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*~~***No*** later ~~*stage, it*~~***than eight years after the entry into force of this regulation, EMA*** should also ~~*be possible to*~~ include ~~*in the common data platform, where relevant, data the EMA holds*~~ ***the chemical data*** on ***active substances from*** procedures concluded before the entry into force of this Regulation.	**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 ~~or submitted~~ after the entry into force of this Regulation~~. At a later stage, it~~ should ~~also be possible to include~~**be included** in the common data platform~~, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation~~.	
Recital 9a				
21a			**(9a) Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data, data related to other**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			substances contained in medicinal products besides active substances and data that is submitted to the EMA in the context of the relevant procedures that are finalised before the entry into force of this Regulation. Moreover, a relevant part of the medicinal data is held by the National Competent Authorities. At a later stage and no later than 6 years after the entry into force of this Regulation, the Commission should therefore assess, in close cooperation with Member States and the Agencies, whether such additional data should be included in the common data platform. This assessment should take also into account the relevancy, the anticipated added value as well as the cost-benefit balance of incorporating the additional data.	
Recital 9a				
21b		***(9a) Active substances contained in medicinal products are covered by Annex II to this Regulation, but may also be regulated in legislation referred to in Annex I since active***		

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		substances in medicinal products may also be used in applications that fall under Union legislation listed under Annex I. In order to protect the confidentiality of certain data, the provisions on confidentiality under the originating Union act apply.		
Recital 9b				
21c			**(9b) In order to add, where relevant, data to be made available by the EMA through the common data platform to support the achievement of the objectives of this Regulation, especially to ensure coherence and the efficient delivery of hazard and risk assessments of chemicals, and to adapt to technical and scientific progress in the field of chemicals, the power to adopt acts in accordance with Article 290 of the Treaty of the Functioning of the European Union should be delegated to the Commission in respect of amending Article 3, paragraph 2a.**	
Recital 10				
G 22	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures	(10) Due to the sensitivity of the information on the exact chemical composition of mixtures G

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	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[1], 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[2] 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. _____ 1. 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).	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[1], 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[2] 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. _____ 1. 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).	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[1], 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[2] 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. _____ 1. 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).	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[1], 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[2] 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. _____ 1. 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).

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2. 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).	2. 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).	2. 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).	2. 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). Text Origin: Commission Proposal
Recital 11				
G 23	(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.	(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.	(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.	(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. Text Origin: Commission Proposal
Recital 12				
G 24	(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	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework, ***granting, as a general principle, the widest possible access to chemicals data and, where***	(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	(12) In order to respond to the needs of the digital economy and to ensure a high level of protection of the environment and human health, it is necessary to lay down a harmonised framework, ***granting, as a general principle, the widest possible access to chemicals data and, where***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***appropriate,*** specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies. ***Access to personal data should be limited to what is necessary in relation to the purposes for which those data are processed by the Authorities.***	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.**	***appropriate,*** specifying who is entitled to access and use the chemicals data contained in the common data platform, under which conditions, on what basis, and for which purposes. The Authorities that are entrusted with regulatory tasks related to chemicals should be allowed and encouraged to use the chemicals data and information contained in the common data platform to effectively fulfil their regulatory duties and tasks, in order to improve the effectiveness, efficiency, and coherence of chemicals-related assessments as well as the development of Union chemicals policies. ***Access to personal data should be limited to what is necessary in relation to the purposes for which those data are processed by the Authorities.*** Text Origin: EP Mandate
Recital 13				
G 25	(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	(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	(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	(13) Chemicals data and information generated as a result of obligations set by Union acts on chemicals may ***contain commercially sensitive information or*** be protected by confidentiality claims on G

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	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.	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.	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.	confidential business information ***under those Union acts***. The public dissemination of such data may affect the commercial ~~*interest*~~***interests*** of private parties. To ensure legal certainty ***and predictability*** 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*~~***all*** confidential information ***and information that has not been made available to the public. In contrast, other parties should not have access via the common data platform to confidential data, or data that is not made available to the public***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				as it may contain commercially sensitive information and its confidentiality has not been assessed. Nevertheless, all parties should maintain the right to request access to any data contained in the platform in accordance with Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.
Recital 14				
G 26	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks. ***The common data platform should also include terms and conditions, particularly regarding the respect of intellectual property rights and other related rights.***	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks.	(14) When using data contained in the common data platform, the Authorities should respect the originator principle. Under this principle, the confidentiality marking of chemicals data as done by the originator and as correspondingly indicated by the Agency when it provides that data to the common data platform should be respected by the Authorities using that data or information to perform their regulatory functions or fulfil their tasks. ***The common data platform should also include terms and conditions of use, including regarding intellectual property rights.*** G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 15				
27	(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[1], where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to	(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[1], where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to	(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[1], where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to	(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[1], where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the European Food Safety Authority ('EFSA') may disclose information previously considered confidential under that Regulation and the EFSA is required to make public information, previously considered confidential, that forms part of conclusions of scientific outputs of the EFSA and relates to

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	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[2] 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. _____ 1. 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). 2. 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).	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[2] 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. _____ 1. 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). 2. 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).	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[2] 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. _____ 1. 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). 2. 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).	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[2] 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. _____ 1. 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). 2. 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).

LIMITE

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Recital 15a				
27a			**(15a) When processing or disclosing personal data contained in the common data platform, the Agencies and the Commission should comply with Regulation (EU) 2018/1725 of the European Parliament and of the Council[1], and the Member State competent authorities should comply with Regulation (EU) 2016/679 of the European Parliament and of the Council[2].** _____ **1. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L, 295, 21.11.2018, p. 39 – 98).** **2. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). (OJ L 119, 4.5.2016, p. 1–88).**	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 16				
28	(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 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 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 access to confidential data is auditable. Text Origin: Commission Proposal
Recital 17				
29	(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	(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	(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	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies,– a database on environmental sustainability related data, ***a database on chemicals in articles, a database on safer alternatives to substances of concern,*** as well as a dashboard of indicators on chemicals.	Chemical Monitoring ('IPCHEM'), a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on applicable legal obligations, a repository of standard formats and controlled vocabularies,– a database on environmental sustainability related data, as well as a dashboard of indicators on chemicals.	
Recital 18				
G	30 (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[1]. 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,	(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[1]. 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	(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[1]. 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	(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[1]. 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

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	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. _____ 1. European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023.	and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets ***of chemicals data*** and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission. _____ 1. European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023.	and data providers, **and** required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets **of chemicals data** and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. **The Commission should ensure that all work areas in the scope of the present regulation are considered by the steering committee.** In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission. _____ 1. European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023.	and data providers, required rules, formats and vocabularies for data integration, and maintain a rolling implementation plan to ensure the progress in identification and integration of new datasets ***of chemicals data*** and services for inclusion. The governance scheme should be adopted and updated as necessary by the Commission, after consultation with a newly established platform steering committee composed of representatives from Union agencies and the Commission. ***The Commission should ensure that all work areas in the scope of the present regulation are considered by the steering committee.*** In order to ensure uniform conditions for the implementation of the obligations to establish an implementation plan and a governance scheme, implementing powers should be conferred on the Commission. _____ 1. European Union Common Data Platform on Chemicals Project Initiation Document, v1.1 endorsed by the One Substance One Assessment Interservice Group 27 February 2023. Text Origin: Council Mandate
Recital 18a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
30a			**(18a) When exercising implementing powers, and in the cases in which Regulation (EU) No. 182/2011 does not apply, the Commission should, as part of its preparatory work, take into account views of Member States.**	
Recital 19				
31	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets, develop new functionalities, and respond to developing tools and applications.	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets ***of chemicals data***, develop new functionalities, and respond to developing tools and applications.	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant **chemicals data** ~~datasets~~, develop new functionalities, and respond to developing tools and applications.	(19) The common data platform should serve the widest possible community, with the ability to address new use cases, incorporate new relevant datasets ***of chemicals data***, develop new functionalities, and respond to developing tools and applications. Text Origin: EP Mandate
Recital 20				
32	(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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.**	
Recital 21				
33	(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	(21) To ensure that an adequate knowledge base on chemicals is available through the common data platform, the Commission should be able to request the Agencies to host, maintain and make available, via the common data platform, ***chemicals*** data generated as part of Union, national or international programmes or research activities beyond the data already flowing to the Agencies as part of the obligations under the Union acts listed in Annex I ***or other***	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	requests to the Agencies in accordance with their mandates and allocated tasks.	***obligations laid down in this Regulation***. The Commission should make such requests to the Agencies in accordance with their mandates and allocated tasks. ***Other parties, such as Member States, national agencies, scientific bodies of Member States, national authorities or researchers or research consortia should be able to submit on a voluntary basis chemicals data to the Agencies or the Commission. Where such data are submitted, a standard format appropriate for the inclusion in the common data platform should be used, where available.***	requests to the Agencies in accordance with their mandates and allocated tasks. **Other parties, such as Member States, scientific bodies of Member States or national authorities, should be able to offer chemicals data to the Agencies or the Commission for hosting and maintenance. In such case, it should be for the Agencies or the Commission, as the case may be, to decide whether to respond positively to the offer.**	
Recital 22				
34	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, ***including occupational human***	(22) Some types of data are currently not within the mandate of any of the Agencies. In order to ensure clarity of responsibilities of the Agencies and efficient management of chemicals data, the Agencies should be required to host, maintain and provide specific data types to the common data platform. To this end, the ECHA should host and be a data provider to the common data platform for workplace monitoring data, and the EEA should host and be a data	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').	***biomonitoring data,*** and the EEA should host and be a data provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').	provider to the common data platform for data on indoor air quality and environment monitoring data, as well as data on concentrations of chemicals in human matrices such as blood or urine ('human biomonitoring data').	
Recital 23				
35	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA.	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by ***national or*** Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data**,** on chemicals or materials they collect or generate to the ECHA.	(23) To improve the uptake of academic data and to expand the knowledge base for chemicals safety assessments and environmental sustainability impacts of chemicals, researchers or research consortia funded by Union framework programmes should make available, in line with the 'as open as possible, as closed as necessary' principle, any human biomonitoring data they collect or generate resulting from research and development programmes to the EEA and any environmental sustainability data on chemicals or materials they collect or generate to the ECHA. **For human biomonitoring data constituting personal data, the EEA should specify which type of data should be made available to it (i.e. anonymised,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			pseudonymised, or identifiable data).	
Recital 24				
36	(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[1]. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory	(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~~**, with the exception of occupational** human biomonitoring data~~ constitutes a special category of personal data, namely, health data, the EEA~~**,** **which** 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[1]~~**be collected, hosted and maintained by the ECHA**. ~~This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in~~	(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[1]. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data: namely, where the EEA processes that data to assess the impact of chemicals on human health and the environment, to monitor time and spatial trends in exposure, to develop health risk and impact indicators, to monitor the impact of regulatory~~	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	intervention, and to support regulatory risk assessments. _____ 1. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).	~~*exposure, to develop health risk and impact indicators, to monitor the impact of regulatory intervention, and to support regulatory risk assessments.*~~ _____ ~~*1. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).*~~	~~intervention, and to support regulatory risk assessments.~~ _____ ~~1. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).~~	
Recital 24a				
36a		***(24a) The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitute a special category of personal data, namely, health data, the EEA, the Commission, the ECHA, the EFSA, the EU-OSHA and the EMA should process those data only where the processing is necessary for reasons of substantial public interest, as laid down in Article 10(2)(g) and for scientific***	**(24a) The EEA, ECHA, EFSA, EMA and the Commission should be able to process human biomonitoring data constituting personal data. Since human biomonitoring personal data constitutes a special category of personal data, namely, health data, the EEA, the Commission, the ECHA, the EFSA and the EMA should process that data only where the processing is necessary for reasons of substantial public interest, as laid out in Article 10(2)(g) and for scientific research as laid out in Article 10(2)(j) of the**	***(24a)***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		research as laid down in Article 10(2)(j) of 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.	**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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 24b				
36b		***(24b) The inclusion of human biomonitoring data collected prior to the entry into force of this Regulation in the common data platform is necessary to ensure the completeness and quality of the human biomonitoring datasets for the purposes of this Regulation.***	**(24b) 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.**	***(24b)***
Recital 24c				
36c			**(24c) 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**	***(24c)***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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	

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			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.	
Recital 25				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 37	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services.	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as– one of its main dedicated services.	(25) In order to ensure that appropriate safeguards are in place to secure the protection of this sensitive type of personal data, the EEA should only provide anonymised human biomonitoring data to the ECHA for integration in IPCHEM and the common data platform. IPCHEM, currently operated by the Commission, gathers occurrence data on chemicals in different media, including water, soil, indoor and outdoor air, biota, food and feed, humans, and products. In order to take advantage of the integration of various information systems and to ensure that occurrence data on chemicals is made available for use together with the other chemicals data, the ECHA should take over from the Commission the operation of IPCHEM and integrate it in the common data platform as one of its main dedicated services. Text Origin: Commission Proposal G
Recital 26				
G 38	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM,	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM,	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM,	(26) In order to prevent disruption to the existing operation and functioning of the IPCHEM, G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.	the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.	the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation.	the ECHA should integrate the IPCHEM in the common data platform together with the data present in IPCHEM at the moment of integration. At the same time, in order to enable optimal hosting and management of occurrence data on chemicals, the Commission should also transfer the data present in IPCHEM to the ECHA, the EEA or the EFSA for hosting and future updating in accordance with their respective mandates. In order to ensure that the ECHA takes over from the Commission the operation of the IPCHEM, integrates it into the common data platform and takes over the initial data sets and sets up adequate data flows, it is necessary to allow the ECHA an appropriate period of time to carry out these actions, of up to 3 years from the date of entry into force of this Regulation. Text Origin: Commission Proposal
Recital 27				
39	(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different	(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different	(27) In order to promote the use and harmonisation of reference values among risk assessors and risk managers across different	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	Union acts and to facilitate compliance with, and enforcement of, regulatory reference values, the ECHA should establish and maintain a repository of reference values established or adopted under the Union acts listed in Annexes I and II. The Agencies should provide the ECHA with reference values they hold or establish as part of their activities. In addition, the ECHA should regularly screen Union acts for reference values adopted under them. To facilitate automatic access of the general public to up-to-date reference values, the ECHA should integrate the repository of reference values in the common data platform as a dedicated service, include in that repository all reference values together with the relevant context data it has received or retrieved and ensure that those values and that context data are machine readable. ***The ECHA should also include in the repository of reference values reference values that are generated through other programmes or research activities and that are made available to it.***	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**	

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			risk associated with that reference value should also be specified, if available.	
Recital 28				
40	(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	(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. ***Scientific studies that are conducted only for research purposes*** ~~*For this purpose*~~, ***that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that are not part of a risk or safety assessment under Union acts listed in Annex I, do not need to be notified.*** The ECHA should establish and manage a database of study notifications~~, as a dedicated~~	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the information related to those studies. **The ECHA should also develop guidance for duty holders to facilitate the implementation of the notification obligation, including details as regards the type of studies requiring**	

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	two years after the date of entry into force of this Regulation.	~~*service of the common data platform,*~~ to store the information related to those studies. ***That database should be a separate database in which notification information is kept confidential. The ECHA, in cooperation with the relevant Agencies, should take the necessary measures to protect the safe transmission of chemicals data***. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply ~~*two years*~~***18 months*** after the date of entry into force of this Regulation. ***The ECHA should also set up a mechanism to cooperate with authorities in third countries in order to exchange information about studies that are notified or submitted for regulatory purposes.***	**notification.** In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.	
Recital 29				
G	41 (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	(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	(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	(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 G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	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. Text Origin: Commission Proposal
Recital 30				
42	(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	(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	(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	

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	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.	national institution ~~*and a decision on*~~***. In order to respect*** the confidentiality of ***relevant elements of study notifications when they are integrated in the common data platform, where the Commission or an Agency makes available to the ECHA the corresponding registration, application, notification or other relevant regulatory dossiers, it should also indicate which elements of the study notification are to be confidential when they will be included in the common data platform. Only those elements should be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant*** ~~*the data contained in that*~~ regulatory dossier ~~*was taken by that*~~***in accordance with the provisions on confidentiality under the originating*** Union ~~*or national institution*~~***act***. ~~*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	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.	

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		information in order to facilitate the traceability of studies notified to their respective databases. ***To avoid uncertainties for business operators resulting from the existence of two databases of study notifications, managed by ECHA and EFSA, respectively, the practical arrangements laid down by ECHA for implementing the provisions on notification of studies should as much as possible be aligned with the related practical arrangements of EFSA.***		
Recital 31				
43	(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	(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	(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	

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	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.	performed to support ***an application, notification or*** regulatory ***dossier intended to be notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, to ensure*** compliance under ***the*** 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.	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.	
Recital 32				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 44	(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) 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) 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) 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. Text Origin: Commission Proposal
Recital 33				
45	(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,	(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,	(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,	

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	where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.	where relevant, cooperate and exchange information with the Member State enforcement authorities ~~*on the*~~***to help them to verify*** compliance with the obligations laid out in Article 22. ***Information on enforcement should be made public to enhance public trust in the effective implementation of Union law.***	where relevant, cooperate and exchange information with the Member State enforcement authorities on the compliance with the obligations laid out in Article 22.	
Recital 34				
46	(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.	(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.	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that ~~is~~ **are** to be notified under this Regulation.	(34) While Regulation (EC) No 178/2002 of the European Parliament and of the Council also requires the consultation of stakeholders and the public following the notification to the EFSA of studies commissioned for the purposes of the renewal of an authorisation or approval, a similar requirement under this Regulation would lay a disproportionate administrative burden on the ECHA, given the wide scope of the studies that ~~*is*~~ ***are*** to be notified under this Regulation. Text Origin: Council Mandate
Recital 35				
47	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of	(35) A mechanism related to study notifications exists in Regulation (EC) No 1907/2006 of

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	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. Text Origin: Commission Proposal
Recital 36				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
48	(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.	(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, ***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	(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.	

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		publicly on the common data platform.		
Recital 36a				
48a		***(36a) There are data gaps on the occurrence of hazardous and other harmful chemicals in articles on the Union market. In order to enhance visibility on the availability of data, and to promote research and development activities as regards safer alternatives, as well as the uptake of such alternatives, ECHA should establish and manage a repository of information on chemicals in articles generated or submitted under Union acts listed in Annex I. This database should integrate the information required under Article 9(1)(i) of Directive 2008/98/EC and the web portal under Article 14 of Regulation (EU) 2024/178. In addition, ECHA should also establish and manage a database collecting available information from Agencies, Member States and business operators on safer alternatives to substances of concern, as defined in Article 2(27) of Regulation (EU) 2024/1781 as well as substances***		

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		that meet the criteria for classification in hazard classes referred to in Article 2(27)(b) of Regulation (EU) 2024/1781.		
Recital 37				
49	(37) The existing 'The EU Chemicals Legislation Finder'[1] project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service. _____ 1. EU Chemicals Legislation Finder - ECHA (europa.eu), database managed by ECHA and funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME).	(37) The existing 'The EU Chemicals Legislation Finder'[1] project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service. _____ 1. EU Chemicals Legislation Finder - ECHA (europa.eu), database managed by ECHA and funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME).	(37) The existing 'The EU Chemicals Legislation Finder'[1] project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service. _____ 1. EU Chemicals Legislation Finder - ECHA (europa.eu), database managed by ECHA and funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME).	(37) The existing 'The EU Chemicals Legislation Finder'[1] project managed by the ECHA makes it easier to find and identify legal obligations related to the use of a specific chemical. The project is especially helpful for small and medium sized enterprises in identifying their legal obligations. To reinforce the supportive function of the project for business operators, it should be established on a permanent basis and more Union acts should be included in its scope. For this purpose, the ECHA should collect information on the legal obligations deriving from the Union acts on chemicals listed in Annex I to this Regulation and incorporate that information into the common data platform as a dedicated service. _____ 1. EU Chemicals Legislation Finder - ECHA (europa.eu), database managed by ECHA and funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME).

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				Text Origin: Commission Proposal
Recital 38				
50	(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	(38) ***In order to ensure chemicals data are easily findable within the database and to avoid duplicates, each chemical contained in the common data platform should be identified by a unique chemical identifier and a chemical notation specifying its molecular structure.*** In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and	(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	

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	and ensuring interoperability with existing data submission approaches.	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.***	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.**	
Recital 39				
G	51 (39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform.	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform.	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform.	(39) Likewise, the Agencies and the Commission should specify appropriate controlled vocabularies for data they receive and store and, where relevant, integrate them in submission software or formats. Moreover, in order to facilitate a smooth electronic exchange of data through the common data platform, the Agencies and the Commission should agree on the required formats and controlled vocabularies for providing data to the common data platform. G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.	Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.	Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission.	Whenever the Agencies or the Commission set formats or controlled vocabularies, they should cooperate with each other to ensure their coherence, consistency and interoperability. In order to ensure uniform conditions for resolving divergences in data formats and controlled vocabularies, implementing powers should be conferred on the Commission. Text Origin: Commission Proposal
Recital 40				
G 52	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the general public.	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the ~~general~~ public.	(40) In order to promote the interoperability of database systems on chemicals beyond the common data platform, the ECHA should establish a repository of standard formats and controlled vocabularies as part of the common data platform. The Agencies and the Commission should make the formats and controlled vocabularies they set available to the repository and the ECHA should make them available free of charge in electronic formats for use by developers of database systems and the ~~*general*~~ public.

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				Text Origin: Council Mandate
Recital 41				
53	(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[1] and (EU) No 528/2012[2] 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	(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[1] and (EU) No 528/2012[2] 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	(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[1] and (EU) No 528/2012[2] 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	(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[1] and (EU) No 528/2012[2] 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

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 . _____ 1. 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). 2. 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).	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 . _____ 1. 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). 2. 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).	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 . _____ 1. 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). 2. 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).	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 . _____ 1. 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). 2. 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). Text Origin: Commission Proposal
Recital 41a				
53a		***(41a) Independent research studies are often given comparatively low weight as evidence in hazard and risk assessment of chemicals, thus creating a gap between independent research and chemicals regulation and policy. It is necessary to provide structure and transparency in the***		

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		evaluation of research data in order to increase their use in regulatory assessment of chemicals. The Commission should publish guidance setting minimum quality and reporting requirements to improve the uptake of research data.		
Recital 42				
54	(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-	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets ***of chemicals data*** on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on	(42) To increase the availability and facilitate the use of information on the environmental performance of chemicals throughout their lifecycle, and to enable a comprehensive assessment of the impacts of chemicals on the environment, the Commission should identify relevant data and information related to the environmental sustainability of chemicals, including, where available, information on their impact on climate change, for integration into the common data platform. Once the Commission has identified the relevant existing datasets **of chemicals data** on environmental sustainability related data and has designed the relevant related database functionalities, the ECHA should establish a database on	

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	related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.	environmental sustainability-related data, collect the data as made available by the Commission, the Agencies, ***national agencies,*** and, where relevant, by the researchers and research consortia funded by Union ***and national*** framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets, implementing powers should be conferred on the Commission.	environmental sustainability-related data, collect the data as made available by the Commission, the Agencies and, where relevant, by the researchers and research consortia funded by Union framework programmes, and integrate the content of that database into the common data platform as a dedicated service. In order to ensure uniform conditions for the implementation of the obligation to identify relevant environmental sustainability datasets **of chemicals data**, implementing powers should be conferred on the Commission.	
Recital 43				
G 55	(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	(43) To monitor the impacts on humans and the environment, including the climate, of exposure to chemicals and to establish a knowledge base to measure the effectiveness of chemicals legislation in protecting human health and the environment, the EEA, ***in collaboration with the Agencies,*** ~~*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,*~~	(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	(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, ***in collaboration with the EFSA, the EMA, the EU-OSHA and the Commission,*** develop and regularly, at least every two years, update a set of indicators and G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	~~*the EMA, the EU-OSHA*~~***In order to monitor the aggregated risk for territories associated with the impacts on humans and the environment, including on the climate, of exposure to chemicals and pollutants, the set of indicators should include an aggregated indicator for different territorial levels, developed in collaboration with the Joint Research Centre and drawing inspiration from its European wide vulnerability framework[1a]. The EEA should cross-reference the results of this indicator with other health and environment datasets, such as epidemiological data on occupational health, lifestyle factors, and socio-economic factors, in order to assess the impacts and risks of c cumulated risk factors on population at the territorial level. The Agencies*** and the Commission ~~*shall*~~***should*** regularly provide the EEA with any available data falling within their mandate and relevant for the establishment of the indicators. The EEA and the ECHA should integrate this dashboard of	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.	present it in the form of a dashboard***. The framework of indicators should, where meaningful and to the extent possible, include an aggregated territory-based risk indicator at appropriate geographical levels to monitor time and spatial trends in exposure of populations to chemicals and health risks associated with such exposure***. 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.

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		indicators into the common data platform.		
Recital 44				
56	(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	(44) ***This Regulation should establish an early warning and action system as regards existing and emerging chemical risks.*** To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory ***and policy*** follow-up actions ***by authorities***. In its work, the EEA should include its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant 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	(44) To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory follow-up actions. In its work, the EEA should ~~include~~ **use** its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting information on emerging risks under Regulation 178/2002. The EEA should make the summary report and the underlying data available through the common data platform, ensuring public access and its use for further action on existing and emerging risks. In order to allow the EEA sufficient time to organise the collection of early warning signals	(44) ***This Regulation should establish an early warning and action system as regards existing and emerging chemical risks in order to shorten the time between the identification of an emerging risk and the adoption of related regulatory action. It should not aim at providing rapid alerts or emergency signals on acute chemicals risks.*** To enable the identification and evaluation of emerging chemical risks, the EEA should develop and compile information on early warning signals and draw up an annual summary report to inform regulatory ***and policy*** follow-up actions ***by authorities***. In its work, the EEA should ~~include~~ ***use*** its own sources, targeted literature searches and make use of information from national early warning systems. It should also include relevant information made available by the related work of the ECHA, the EFSA, the EU-OSHA, the EMA and their networks, such as the EFSA's task of identifying and collecting

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	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.	action on existing and emerging risks ***concerning chemicals, groups of chemicals, and cumulative exposure to chemicals***. In order to allow the EEA sufficient time to organise the collection of early warning signals and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. this Regulation sets a deadline for the first report and associated data. ***For any risk and warning signal identified by the report, the Authorities should consider undertaking regulatory, policy or enforcement actions and provide justification when they decide not to proceed with any action. Emerging chemical risks identified in the early warning and action system should also be taken into account when setting priorities for the strategic planning of Horizon Europe.***	and to compile and analyse the initial information the EEA should only deliver the first report six months after the end of the first calendar year after entry into force of this Regulation. this Regulation sets a deadline for the first report and associated data.	information on emerging risks under Regulation 178/2002. The EEA should ***present the summary report to the Commission, relevant Union agencies and Member States competent authorities for consideration of the need for regulatory or policy action related to the early warning signals. The EEA should also*** 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. ***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***

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				action. Emerging chemical risks identified in the early warning and action system should also be taken into account when setting priorities for the strategic planning of Horizon Europe.
Recital 45				
G 57	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[1] ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market. _____ 1. Commission Staff Working Document – Impact assessment accompanying the document: Commission implementing decision on a delegation agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME program. SWD (2017) 138 final.	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[1] ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market. _____ 1. Commission Staff Working Document – Impact assessment accompanying the document: Commission implementing decision on a delegation agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME program. SWD (2017) 138 final.	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[1] ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market. _____ 1. Commission Staff Working Document – Impact assessment accompanying the document: Commission implementing decision on a delegation agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME program. SWD (2017) 138 final.	(45) In June 2017, at the Commission' request, the ECHA set up the European Observatory for Nanomaterials[1] ('EUON'), which collects existing data and information from databases, registries and studies and generates new data through studies and surveys on nanomaterials on the EU market. _____ 1. Commission Staff Working Document – Impact assessment accompanying the document: Commission implementing decision on a delegation agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME program. SWD (2017) 138 final. Text Origin: Commission Proposal G
Recital 46				
G 58	(46) The ECHA should continue operating the EUON and	(46) The ECHA should continue operating the EUON and	(46) The ECHA should continue operating the EUON and	(46) The ECHA should continue operating the EUON and G

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

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 47				
59	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission.	(47) The observatory should not be regarded as a substitute for required risk management action on any chemical in cases where a hazard or risk has been identified. In order to provide for an efficient and consistent approach for the generation and dissemination of all such additional information, the ECHA should oversee the work of the observatory and make the regularly updated data and information it collects available through the common data platform, or by means of other communication channels, as appropriate. In order to ensure uniform conditions for the implementation of the requirement to select chemicals to be included in the observatory, implementing powers should be conferred on the Commission. Text Origin: Commission Proposal
Recital 48				
60	(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	(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	(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	

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	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.	mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on ***chemicals and groups of*** chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy. ***When obtaining a sample of a substance is a precondition for conducting the scientific studies, ECHA should be given the necessary sample by the business operator, upon request, and provided that applicable confidentiality and data protection under Union law is ensured. Whenever possible, information generated through***	mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy. **Where relevant and whenever possible, information generated through studies commissioned by the ECHA should be generated by means other than vertebrate animal tests.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		studies commissioned by the ECHA should be generated by means other than animal tests.		
Recital 48a				
60a		***(48a) To support the effective implementation and evaluation of Union acts on chemicals and to contribute to the development of a comprehensive Union chemicals policy, it is essential to conduct Union-wide human biomonitoring studies that provide high-quality and representative data at regular intervals. To support a resource-efficient approach, the ECHA and EFSA should cooperate closely in pooling resources and expertise for such studies. The Member States should cooperate with the Agencies to organise the human bio-monitoring in their respective territories, in terms of planning, coordination, collection and transmission of samples.***		
Recital 48b				
60b		***(48b) In order to contribute to the overall objective of this Regulation to enable better, complete, coherent and robust scientific assessments of chemicals and their impacts, and***		

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		to ensure the best use of existing information for the purpose of the implementation and the development of Union legislation on chemicals, this Regulation should require the Commission to draw up a report analysing how adequate the resources of the agencies are in relation to their current tasks and their new tasks under this Regulation, and a prospective view of the resources needed to address key areas of regulatory challenge in the future.		
Recital 48c				
60c		***(48c) As this Regulation expands the tasks and workload of the European Chemicals Agency, it should be provided with appropriate and stable resources, and stable governance of the scientific committees should be ensured. In this respect, it is appropriate that the Commission takes account of any developments and reflects the needs of the Agency to allow fulfilment of its tasks and potential.***		
Recital 49				

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

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	2016[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. 1. OJ L 123, 12.5.2016, p. 1.	2016[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. 1. OJ L 123, 12.5.2016, p. 1.	~~principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts~~**to amend Annex I by adding new Union acts under which relevant chemicals data and information is generated or submitted, as soon as these Union acts enter into force or are revised, unless otherwise provided**. ~~1. OJ L 123, 12.5.2016, p. 1.~~	~~*2016[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.*~~ ~~*1. OJ L 123, 12.5.2016, p. 1.*~~
Recital 49a				
61a			**(49a) In order to adjust the content of Annex II, which should list relevant reference values resulting from the implementation of Union acts listed in Annex I, part 2, and held by the EMA, the power to adopt acts in accordance with Article 290 of the Treaty on the**	***(49a)***

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			Functioning of the European Union should be delegated to the Commission to amend Annex II when, taking into account the digitalisation and interoperability of the reference values held by the EMA as well as the values' usefulness for other policy areas and for the implementation of the Union acquis, there is a need to list additional reference values.	
Recital 49b				
61b			**(49b) In order to adjust the content of Annex III, which should list all Union acts under which chemicals data is generated or submitted to the Authorities it is appropriate to empower the Commission to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend Annex III by adding new Union acts under which relevant chemicals data and information is generated or submitted, as soon as these Union acts enter into force or are revised, unless otherwise provided.**	***(49b)***
Recital 49c				

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G 61c				***(49c) In order to adjust the content of Annex IIIb, which should list all Union acts in Annex I under which data on chemicals in articles or product is generated or submitted, it is appropriate to empower the Commission to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend Annex IIIb by adding Union acts under which relevant chemicals data and information is generated or submitted, as soon as these Union acts enter into force or are amended, unless otherwise provided, or Union acts which do not contain provisions on the generation or submission of data on chemicals in articles or products, but for which it has emerged that such data is generated or submitted under that Union act.*** G
Recital 49d				
61d			**(49c) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at**	***(49d)***

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			expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ **1. OJ L 123, 12.5.2016, p. 1.**	
Recital 50				
G	62	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the	(50) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as Member States do not hold the data within the scope of this Regulation and cannot establish a Union wide common data platform, but can rather, by reason of chemicals data and information being hosted at Union level by the	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	Agencies, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives. Text Origin: Commission Proposal
Recital 51				
G 63	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [OP: Please insert the date of the opinion of the EDPS].	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on ~~[OP: Please insert the date of the opinion of the EDPS]~~**29 January 2024** .	(51) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on ~~*[OP: Please insert the date of the opinion of the EDPS]*~~***29 January 2024*** . Text Origin: Council Mandate
Formula				
G 64	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION: Text Origin: Commission Proposal

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Chapter I						
G	65	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS	Chapter I SUBJECT MATTER, SCOPE AND DEFINITIONS Text Origin: Commission Proposal	G
Article 1						
G	66	Article 1 Subject matter and scope	Article 1 Subject matter and scope	Article 1 Subject matter and scope	Article 1 Subject matter and scope Text Origin: Commission Proposal	G
Article 1(1)						
G	67	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' trust in the scientific base for the decisions taken under Union legal acts on chemicals.	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of ***safe and*** sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' ***knowledge of, and*** trust in**,** the scientific base for the decisions taken under Union legal acts on chemicals**,** ***and to contribute to the goal of phasing***	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.	1. This Regulation aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of ***safe and*** sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the Union's citizens' ***knowledge of, and*** trust in**,** the scientific base for the decisions taken under Union legal acts on chemicals**,** ***and to contribute to the replacement and***	G

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		out animal testing wherever possible.		***reduction of the animal testing wherever possible***. Text Origin: EP Mandate
Article 1(2)				
68	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 measures to:	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 measures to: Text Origin: Commission Proposal
Article 1(2), point (a)				
69	(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;	(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; Text Origin: Commission Proposal
Article 1(2), point (b)				
70	(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 in the context of fulfilling their obligations set under Union chemicals legislation;	(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 in the context of fulfilling their obligations set under Union chemicals legislation; Text Origin: Commission Proposal
Article 1(2), point (ba)				
70a		***(ba) keep records of data on studies obtained from relevant***		*deleted*

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		third countries through the mechanism referred to in Article 9(1a);		
Article 1(2), point (c)				
71	*(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;	(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; Text Origin: Commission Proposal
Article 1(2), point (d)				
72	(d) establish an early warning and action system for emerging chemical risks.	(d) establish an early warning and action system for emerging chemical risks.	(d) establish an early warning and action system for emerging chemical risks.	(d) establish an early warning and action system for emerging chemical risks. Text Origin: Commission Proposal
Article 1(3)				
73	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 to chemicals data as laid out in Article 3(2).	3. The provisions laid down in this Regulation apply to chemicals data as laid out in Article ~~3(2)~~**3, paragraphs 2 and 2a.** ~~-~~	3. The provisions laid down in this Regulation apply to chemicals data as laid out in Article ~~*3(2)*~~***3, paragraphs 2 and 2a.*** ~~-~~ Text Origin: Council Mandate
Article 2				
74	Article 2 Definitions	Article 2 Definitions	Article 2 Definitions	Article 2 Definitions

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				Text Origin: Commission Proposal
Article 2, first paragraph				
75	For the purpose of this Regulation, the following definitions shall apply:	For the purpose of this Regulation, the following definitions shall apply:	For the purpose of this Regulation, the following definitions shall apply:	For the purpose of this Regulation, the following definitions shall apply: Text Origin: Commission Proposal
Article 2, first paragraph, point (1)				
76	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');	1. 'Agencies' means– the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA');	1. 'Agencies' means the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA') and the European Medicines Agency ('EMA') and the European Agency for Safety and Health at Work ('EU-OSHA'); Text Origin: Commission Proposal
Article 2, first paragraph, point (2)				
77	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;	2. 'Authorities' means, the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I, ***II*** and III, and the Agencies, excluding their management boards;	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;	2. 'Authorities' means the European Commission, the competent authorities of the Member States as referred to in any of the Union acts listed in Annexes I and III, and the Agencies, excluding their management boards;

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				Text Origin: Council Mandate
Article 2, first paragraph, point (3)				
78	3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;	3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I or II;	3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I ~~or II;~~**;**	3. ‘duty holder’ means a natural or legal person responsible for meeting obligations under the Union acts listed in Annex I ~~*or II;*~~**:** Text Origin: Council Mandate
Article 2, first paragraph, point (4)				
79	4. ‘business operators’ means duty holders which are private or public undertakings;	4. ‘business operators’ means duty holders which are private or public undertakings;	4. ‘business operators’ means duty holders which are private or public undertakings;	4. ‘business operators’ means duty holders which are private or public undertakings; Text Origin: Commission Proposal

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Article 2, first paragraph, point (5)				
80	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine;	5. ‘human biomonitoring data’ means concentrations of chemicals measured in human matrices such as blood or urine; Text Origin: Commission Proposal
Article 2, first paragraph, point (6)				
81	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable;	6. ‘reference value’ means an estimate of a maximum exposure to or emission level of a chemical below which no or only acceptable adverse effects on human health or the environment are expected, or below which risks related to the adverse effects on human health or the environment are considered acceptable or tolerable; Text Origin: Commission Proposal
Article 2, first paragraph, point (7)				
82	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I or Annex II;	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I ~~or Annex II~~;	7. ‘originator’ means the Commission, Agency, or Member State competent authority responsible for confidentiality assessments under any Union act listed in Annex I ~~*or Annex II*~~; Text Origin: Council Mandate

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Article 2, first paragraph, point (8)				
83	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted;	8. 'originating Union act' means the Union act under which chemicals data and information were generated or submitted; Text Origin: Commission Proposal
Article 2, first paragraph, point (9)				
84	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms;	9. 'controlled vocabularies' means standardised and organised arrangements of words and phrases presented as lists of terms or as thesaurus and taxonomies with a hierarchical structure of broader and narrower terms; Text Origin: Commission Proposal
Article 2, first paragraph, point (10)				
85	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	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	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	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

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	information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;	information, on those chemicals, regulatory process-related information on chemicals, ***information on the availability and suitability of alternatives,*** standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals ***and the enforcement thereof***;	information, on those chemicals, regulatory process-related information on chemicals, standard formats, controlled vocabularies, or any information on applicable legal obligations related to chemicals;	information, on those chemicals, regulatory process-related information on chemicals, ***data on alternatives to substances of concern,*** standard formats, controlled vocabularies, or any information on applicable legal obligations ***and information*** related to chemicals; Text Origin: EP Mandate
Article 2, first paragraph, point (11)				
86	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 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 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 or material throughout its entire life cycle, including: Text Origin: Commission Proposal
Article 2, first paragraph, point (11)(a)				
87	(a) data on resources, including raw materials, water, energy, fossil fuels and land;	(a) data on resources, including raw materials, water, energy, fossil fuels and land;	(a) data on resources, including raw materials, water, energy, fossil fuels and land;	(a) data on resources, including raw materials, water, energy, fossil fuels and land; Text Origin: Commission Proposal
Article 2, first paragraph, point (11)(b)				
88	(b) data on emissions, including greenhouse gases,	(b) data on emissions, including greenhouse gases,	(b) data on emissions, including greenhouse gases,	(b) data on emissions, including greenhouse gases,

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	eutrophication-relevant substances, dust and all other polluting substances; and	eutrophication-relevant substances, dust and all other polluting substances; and	eutrophication-relevant substances, dust and all other polluting substances; and	eutrophication-relevant substances, dust and all other polluting substances; and Text Origin: Commission Proposal
Article 2, first paragraph, point (11)(c)				
89	(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.	(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.	(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.	(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. Text Origin: Commission Proposal
Article 2, first paragraph, point (11a)				
89a		***'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;***		***(11a) 'peer-reviewed published research data' means any chemicals data derived from scientific studies published in peer-reviewed literature that are not carried out specifically to inform regulatory assessments;***
Article 2, first paragraph, point (12)				
90	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (16), of Regulation (EU) 2018/175 of	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (16), of Regulation (EU) 2018/175 of	12. -'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 ~~of the European Parliament and of the Council~~ and as defined in Article 3, point ~~(16)~~ **(1)**, of Regulation (EU)	12. 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679 ~~*of the European Parliament and of the Council*~~ and as defined in Article 3, point ~~*(16)*~~ ***(1)***, of Regulation (EU) ~~*2018/175*~~

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	the European Parliament and of the Council;	the European Parliament and of the Council;	~~2018/175 of the European Parliament and of the Council~~**2018/ 1725** ;	~~*of the European Parliament and of the Council*~~***2018/ 1725*** ; Text Origin: Council Mandate
Article 2, first paragraph, point (13)				
91	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of Regulation (EU) 2018/175 of the European Parliament and of the Council;	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 of the European Parliament and of the Council and as defined in Article 3, point (3), of Regulation (EU) 2018/175 of the European Parliament and of the Council;	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 ~~of the European Parliament and of the Council~~ and as defined in Article 3, point (3), of Regulation (EU) ~~2018/175 of the European Parliament and of the Council~~**2018/ 1725** ;	13. 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679 ~~*of the European Parliament and of the Council*~~ and as defined in Article 3, point (3), of Regulation (EU) ~~*2018/175 of the European Parliament and of the Council*~~***2018/ 1725*** ; Text Origin: Council Mandate
Article 2, first paragraph, point (14)				
92	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of Regulation (EU) 2018/175 of the European Parliament and of the Council;	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of Regulation (EU) 2018/175 of the European Parliament and of the Council;	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of Regulation (EU) ~~2018/175 of the European Parliament and of the Council~~**2018/ 1725** ;	14. 'data controller' means controller as defined in Article 4, point (7), of Regulation (EU) 2016/679 and as defined in Article 3, point (8), of Regulation (EU) ~~*2018/175 of the European Parliament and of the Council*~~***2018/ 1725*** ; Text Origin: Council Mandate
Article 2, first paragraph, point (14a)				
92a		***(14a) 'data processor' means a processor as defined in Article 4, point (8), of Regulation (EU)***		***(14a) 'data processor' means a processor as defined in Article 4, point (8), of Regulation (EU) 2016/679 of the European***

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		2016/679 of the European Parliament and of the Council;		***Parliament and of the Council, and as defined in the Article 3, point 12, of the regulation 2018/1725;*** Text Origin: EP Mandate
Article 2, first paragraph, point (14b)				
G 92b			**(14a) 'third party' means third party as defined in Article 3, point (14) of Regulation (EU) 2018/1725;**	***(14b) 'third party' means third party as defined in Article 3, point (10) of Regulation (EU) 2016/679 and as defined in Article 3, point (14) of Regulation (EU) 2018/1725;*** Text Origin: Council Mandate
Article 2, first paragraph, point (15)				
G 93	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.	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. Text Origin: Commission Proposal
Article 2, first paragraph, point (16)				
G 93a			**(16) 'the public' means one or more natural or legal persons, and associations, organisations or groups of such persons.**	***(16) 'the public' means one or more natural or legal persons, and associations, organisations or groups of such persons.***

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				Text Origin: Council Mandate
Chapter II				
94	Chapter II INFORMATION SYSTEMS AND PLATFORMS	Chapter II INFORMATION SYSTEMS AND PLATFORMS	Chapter II INFORMATION SYSTEMS AND PLATFORMS	Chapter II INFORMATION SYSTEMS AND PLATFORMS Text Origin: Commission Proposal
Article 3				
95	Article 3 Common Data Platform on Chemicals	Article 3 Common Data Platform on Chemicals	Article 3 Common Data Platform on Chemicals	Article 3 Common Data Platform on Chemicals Text Origin: Commission Proposal
Article 3(1)				
96	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform'). Text Origin: Commission Proposal
Article 3(2)				
97	2. The common data platform shall provide access to all chemicals data:	2. The common data platform shall provide access to all chemicals data:	2. The common data platform shall provide access to all chemicals data:	2. The common data platform shall provide access to all chemicals data: Text Origin: Commission Proposal
Article 3(2), point (a)				

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98	(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 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 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 the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission; Text Origin: Commission Proposal
Article 3(2), point (b)				
99	(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 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 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 ECHA, the EEA, the EFSA, the EU-OSHA or the Commission; Text Origin: Commission Proposal
Article 3(2), point (ba)				
99a		***(ba) additional data provided on a voluntary basis by Member States, national agencies, research institutes or other parties;***		***(ba) additional data provided on a voluntary basis by Member States or other parties, including national agencies, research institutes and third countries' organisations, and held or accepted by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission;***
Article 3(2), point (bb)				
99b		***(bb) generated in the context of academic research activities in***		*deleted*

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		the sphere of chemicals not covered in point (b) and voluntarily submitted to ECHA by a third party;		*will be taken up in 99a*
Article 3(2), point (c)				
100	*(c)* listed in Annex II and held by the EMA;	(c) listed in Annex II and held by the EMA;	*deleted*	*deleted*
Article 3(2a)				
100a			**2a. By way of derogation from paragraph 2, the common data platform shall only provide access to chemicals data related to human and veterinary medicinal products as part of the implementation of the Union acts listed in Annex I, part 2, as far as:**	***2a. By way of derogation from paragraph 2, the common data platform shall only provide access to chemicals data related to human and veterinary medicinal products as part of the implementation of the Union acts listed in Annex I, part 2, as far as:*** Text Origin: Council Mandate
Article 3(2a), point (a)				
100b			**(a) it is held by the EMA and submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation; and**	***(a) it is held by the EMA and*** Text Origin: Council Mandate
Article 3(2a), point (b)				
100c			**(b) relates to active substances:**	***(b) it relates to active substances:***

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				Text Origin: Council Mandate

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Article 3(2a), point (b)(i)					
G	100d			**(i) subject to regulatory procedures under other Union acts listed in Annex I, part 1, to this Regulation; or**	***(i) subject to regulatory procedures under other Union acts listed in Annex I, part 1, to this Regulation; or*** Text Origin: Council Mandate	G
Article 3(2a), point (b)(ii)					
G	100e			**(ii) with particular persistent, bio-accumulative and toxic properties; or**	***(ii) with particular persistent, bio-accumulative and toxic properties; or*** Text Origin: Council Mandate	G
Article 3(2a), point (b)(iii)					
G	100f			**(iii) with a known high level of residues in the environment; and**	***(iii) with a known high level of residues in the environment; and*** Text Origin: Council Mandate	G
Article 3(2a), point (c)					
G	100g			**(c) it falls into at least one of the following categories:**	***(c) it falls into at least one of the following categories:*** Text Origin: Council Mandate	G
Article 3(2a), point (c)(-)					
G	100h			**(-) non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2011/83/EC of the European Parliament and of the Council[1]**	***(-) non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2011/83/EC of the European Parliament and of the Council[1]***	G

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			and Regulation (EC) No 726/2004 of the European Parliament and of the Council[2]; or **1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).** **2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).**	***and Regulation (EC) No 726/2004 of the European Parliament and of the Council[2]; or*** ***1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).*** ***2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).*** Text Origin: Council Mandate
Article 3(2a), point (c)(-)				
G	100i		**(-) data related to environmental risk assessments, compiled pursuant to Regulation (EU) No 470/2009 of the European Parliament and of the Coucil[1]; or** **1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).**	***(-) data related to environmental risk assessments, compiled pursuant to Regulation (EU) No 470/2009 of the European Parliament and of the Coucil[1]; or*** ***1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).*** Text Origin: Council Mandate

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Article 3(2a), point (c)(-)					
G	100j		**(-) maximum residue levels and the data used to derive them, compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council[1]** **1. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).**	***(-) maximum residue levels and the data used to derive them, compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council[1]*** ***1. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).*** Text Origin: Council Mandate	G
Article 3(3)					
G	100k		**3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend:**	***3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend:*** Text Origin: Council Mandate	G
Article 3(2b), point (-)					
G	100l		**(-) point a of Article 3(2a), by including, where necessary to ensure coherence and the efficient delivery of hazard and**	*deleted* Text Origin: Council Mandate	G

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			risk assessment of chemicals and to consider new scientific discoveries, in particular on the hazard or risk to the environment or human health, data that EMA holds on procedures concluded before the entry into force of this Regulation;	
Article 3(2b), point (-)				
G	*100m*		**(-) point b of Article 3(2a), by including, other data related to substances contained in medicinal products besides active substances or active substances with other properties when presenting an interest for the objectives of this Regulation or if, in view of developed scientific knowledge, there is new knowledge on the hazards or risks to the environment or human health;**	***(-) point b of Article 3(2a), by including, other data related to substances contained in medicinal products besides active substances or active substances with other properties when presenting an interest for the objectives of this Regulation or if, in view of developed scientific knowledge, there is new knowledge on the hazards or risks to the environment or human health;*** Text Origin: Council Mandate
Article 3(2b), point (-)				
G	100n		**(-) point c of Article 3(2a), by adding new categories of data types presenting an interest for the objectives of this Regulation or, in view of developed scientific knowledge, there is**	***(-) point c of Article 3(2a), by adding new categories of data types presenting an interest for the objectives of this Regulation or, in view of developed scientific knowledge, there is new data on***

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			new data on the hazard or risk to the environment or human health.	***the hazard or risk to the environment or human health.*** Text Origin: Council Mandate
Article 3(3)				
101	3. The following information shall not be included in the common data platform:	3. The following information shall not be included in the common data platform:	~~3~~**3a**. The following information shall not be included in the common data platform:	3. The following information shall not be included in the common data platform: Text Origin: Commission Proposal
Article 3(3), point (a)				
102	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[1]; 1. 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).	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[1]; 1. 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).	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[1]; 1. 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).	(a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[1]; 1. 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). Text Origin: Commission Proposal
Article 3(3), point (b)				
103	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[1] of	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[1] of	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[1] of	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[1] of

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	the European Parliament and of the Council. _____ 1. 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).	the European Parliament and of the Council. _____ 1. 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).	the European Parliament and of the Council. _____ 1. 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).	the European Parliament and of the Council. _____ 1. 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). Text Origin: Council Mandate
Article 3(4)				
G 104	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.	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.	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.	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. Text Origin: Commission Proposal
Article 3(4a)				
G 104a		***4a. Each chemical or material hosted on the common data platform shall be identified by a unique chemical identifier and a chemical notation specifying its molecular structure without prejudice to any confidentiality requirements in the original act or related legal obligations.***		***4a. The ECHA shall ensure that each chemical or material for which chemicals data is hosted on the common data platform is identified by a unique technical identifier used to link together all chemicals data on that chemical or material, and, where possible and available, a chemical notation specifying its molecular structure, without prejudice to any confidentiality***

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				requirements in the originating Union act.
Article 3(5)				
105	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 dedicated services identified in the governance scheme referred to in Article 4(3) including:	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 dedicated services identified in the governance scheme referred to in Article 4(3) including: Text Origin: Commission Proposal
Article 3(5), point (a)				
106	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7;	(a) the Information Platform for Chemical Monitoring ('IPCHEM') referred to in Article 7; Text Origin: Commission Proposal
Article 3(5), point (b)				
107	(b) the repository of reference values referred to in Article 8;	(b) the repository of reference values referred to in Article 8;	(b) the repository of reference values referred to in Article 8;	(b) the repository of reference values referred to in Article 8; Text Origin: Commission Proposal
Article 3(5), point (c)				
108	(c) the database of study notifications referred to in Article 9;	(c) the database of study notifications referred to in Article 9;	(c) the database of study notifications referred to in Article 9;	(c) the database of study notifications referred to in Article 9; Text Origin: Commission Proposal

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Article 3(5), point (d)				
109	(d) information on regulatory processes referred to in Article 10;	(d) information on regulatory processes referred to in Article 10;	(d) information on regulatory processes referred to in Article 10;	(d) information on regulatory processes referred to in Article 10; Text Origin: Commission Proposal
Article 3(5), point (da)				
109a		***(da) information on chemicals in articles as referred to in Article 10a;***		***(da) data on chemicals in articles or products as referred to in Article 10a;*** Text Origin: EP Mandate
Article 3(5), point (db)				
109b		***(db) information on safer alternatives to substances of concern as referred to in Article 10b;***		***(db) data on alternatives to substances of concern as referred to in Article 10b;*** Text Origin: EP Mandate
Article 3(5), point (e)				
110	(e) information on obligations under Union chemicals legislation referred to in Article 11;	(e) information on obligations under Union chemicals legislation referred to in Article 11;	(e) information on obligations under Union chemicals legislation referred to in Article 11;	(e) information on obligations under Union chemicals legislation referred to in Article 11; Text Origin: Commission Proposal
Article 3(5), point (f)				
111	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;	(f) the repository of standard formats and controlled vocabularies referred to in Article 12;

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Article 3(5), point (g)				
112	(g) the database on environmental sustainability-related data referred to in Article 13.	(g) the database on environmental sustainability-related data referred to in Article 13.	(g) the database on environmental sustainability-related data referred to in Article 13.	(g) the database on environmental sustainability-related data referred to in Article 13. Text Origin: Commission Proposal
Article 3(5), a				
112a			**The common data platform shall contain appropriate background and explanatory information in order to facilitate informed use of the data by the Authorities and the public.**	***The common data platform shall contain appropriate background and explanatory information in order to facilitate informed use of the data by the Authorities and the public.*** Text Origin: Council Mandate
Article 3(6)				
113	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.	6. The Authorities and the general public shall have access **free of charge, in accordance with Article 16,** to the data contained in the common data platform**, as well as any related context data as referred to in paragraph 5 of** ~~in accordance with~~ Article ~~16~~**4, point c), including, where relevant, an indication whether the data was generated by Authorities**.	6. The Authorities and the general public shall have ***easy*** access ***free of charge, in accordance with Article 16,*** to the data contained in the common data platform***, as well as any related context data as referred to in paragraph 5 of*** ~~*in accordance with*~~ Article ~~*16*~~***4, point c), including, where relevant, an indication whether the data was generated by Authorities***. Text Origin: Council Mandate

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Article 3(7)				
114	7. The data contained in the common data platform may be used in accordance with Article 17.	7. The data contained in the common data platform may be used in accordance with Article 17.	7. The data contained in the common data platform may be used in accordance with Article 17.	7. The data contained in the common data platform may be used in accordance with Article 17. Text Origin: Commission Proposal
Article 3(8)				
115	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available.	8. The data contained in the common data platform shall be made available in standard formats, where developed, and through controlled vocabularies where available. Text Origin: Commission Proposal
Article 3(9)				
116	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 ~~and~~***the common data platform. Security measures shall be adopted by the relevant Agencies in cooperation with the ECHA to ensure safe*** transmission of ~~chemicals~~***chemical*** data to the	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 ~~and~~***the common data platform. The relevant Agencies shall take measures in cooperation with the ECHA to ensure secure*** transmission of chemicals data to the common data platform. The

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		common data platform. The ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable.		ECHA shall design the common data platform in a way that guarantees that any access to confidential data is auditable. Text Origin: EP Mandate
Article 3(10)				
117	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001[1]. 1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).	10. The Commission or Agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001[1]. 1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).	10. The Commission or ~~Agency~~**agencies** under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001 **of the European Parliament and of the Council[1].** ~~[1].~~ 1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43).	10. The Commission or ~~*Agency*~~***Agencies*** under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001 ***of the European Parliament and of the Council[1].*** ~~[1].~~ 1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (. OJ L 145, 31.5.2001, p. 43). Text Origin: Council Mandate
Article 3(11)				
118	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	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	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***	11. The common data platform and its dedicated services shall be established by ***[OP: please insert date: three years after the***

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	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.	Regulation], unless specified otherwise~~. The~~***, and shall at least include the datasets set out in Annex IIIa. Further*** relevant datasets shall be integrated progressively into the common data platform by [OP please insert date: ~~ten~~***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~~***within a period of 30 days***.	***of this Regulation***~~OP: please insert date: three years after the date of entry into force of this Regulation~~], unless specified otherwise. The relevant datasets **of chemicals data, including chemicals data generated or submitted before the entry into force of this Regulation, unless specified otherwise,** shall be integrated progressively into the common data platform by [***OP please insert date: ten years from the date of entry into force of this Regulation***~~OP please insert date: ten years from the date of entry into force of this Regulation~~] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets **of chemicals data** in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	***date of entry into force of this Regulation]***~~[OP: please insert date: three years after the date of entry into force of this Regulation]~~, unless specified otherwise~~. The~~***, and shall at least include the datasets as set out in Annex IIIa by that date. Further*** relevant datasets ***of chemicals data, including chemicals data 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: [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. Chemicals data related to human and veterinary medicinal products, as specified in paragraphs 2a(a), (b) and (c) of this Article, in the context of procedures that were concluded before the entry into force of this Regulation, shall be progressively integrated from [the date six***~~[OP please insert date: ten~~ years from the date of entry into force of this

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				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*~~***receive s*** chemicals data in accordance with Article 5 ***belonging to a dataset which has already been integrated***, it shall make that data available through the common data platform ~~*without undue delay*~~***at the latest within 90 days***.
Article 4				
119	Article 4 Implementation plan and governance of the common data platform	Article 4 Implementation plan and governance of the common data platform	Article 4 Implementation plan and governance of the common data platform	Article 4 Implementation plan and governance of the common data platform Text Origin: Commission Proposal
Article 4(1)				
120	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.	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 ***of chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion by means of ~~*an*~~ implementing	1. By [***OP please insert date: 6 months after the date of entry into force of this Regulation***~~OP please insert date: 6 months after the date of entry into force of this Regulation~~] the Commission shall **by means of an implementing act** adopt ~~and publish~~ an implementation plan identifying **chemicals data** ~~datasets~~ for	1. By [***OP please insert date: 6 months after the date of entry into force of this Regulation***~~*OP please insert date: 6 months after the date of entry into force of this Regulation*~~] the Commission shall ***by means of implementing acts*** adopt ~~*and publish*~~ an implementation plan identifying datasets ***of chemicals data*** for

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	Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	~~decision~~***acts***. Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	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.	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. Text Origin: EP Mandate
Article 4(2)				
G 121	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~~***act***, establish and manage a platform steering committee, which shall include ~~*one representative from the ECHA,*~~***at least*** one representative from ~~*the EEA, one representative from the EFSA, one representative from the EMA*~~***each Union agency required to submit chemicals data to the Platform***, ~~*one representative from the EU-OSHA and five*~~ ***and as many*** representatives from the Commission ***as from all those Union agencies combined***.	2. The Commission shall, by means of an implementing ~~decision~~**act**, 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 **each of the Agencies and** the Commission.	2. The Commission shall, by means of an implementing ~~*decision*~~***act***, establish and manage a platform steering committee, which shall include ~~*one representative from the ECHA,*~~***at least*** one representative from ~~*the EEA, one representative from the EFSA, one representative from the EMA, one representative from the EU-OSHA and five*~~***each of the Agencies and as many*** representatives from the Commission ***as from all those Agencies combined***. Text Origin: EP Mandate G
Article 4(3)				
G 122	3. The platform steering committee shall advise the Commission in the preparation of	3. The platform steering committee shall advise the Commission in the preparation of	3. The platform steering committee shall advise the Commission in the preparation of	3. The platform steering committee shall advise the Commission in the preparation of G

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	the common data platform's governance scheme.	the common data platform's governance scheme.	the common data platform's governance scheme.	the common data platform's governance scheme. Text Origin: Commission Proposal
Article 4(4)				
123	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~~***acts.*** ***While setting up the governance scheme, the Commission shall consult the Agencies and shall take into account the different level of responsibilities of the Authorities in the management and operation of the common data platform.***	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing ~~decision~~ **act.**	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~~***acts.*** ***While setting up the governance scheme, the Commission shall take into account the different level of responsibilities of the Commission and the Agencies in the management and operation of the common data platform.*** Text Origin: EP Mandate
Article 4(5)				
124	5. That governance scheme shall describe:	5. That governance scheme shall describe:	5. That governance scheme shall describe:	5. That governance scheme shall describe: Text Origin: Commission Proposal
Article 4(5), point (a)				
125	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;	(a) the organisation of the main work structures supporting the development and implementation of the common data platform;

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				Text Origin: Commission Proposal

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Article 4(5), point (b)				
G 126	(b) the preparation and adoption of rolling implementation plans for the common data platform;	(b) the preparation and adoption of rolling implementation plans for the common data platform;	(b) the preparation and adoption of rolling implementation plans for the common data platform;	(b) the preparation and adoption of rolling implementation plans for the common data platform; Text Origin: Commission Proposal
Article 4(5), point (c)				
G 127	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform;	(c) the principles on data governance and the required standard formats, controlled vocabularies and further conditions for the provision of information and context data to the common data platform; Text Origin: Commission Proposal
Article 4(5), point (d)				
G 128	(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;	(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; Text Origin: Commission Proposal
Article 4(5), point (da)				
G 128a		***(da) the organisation and operation of the mechanisms for cooperation and information***		*deleted*

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		exchange with databases and similar platforms in third countries and internationally;		
Article 4(5), point (e)				
129	*(e)* any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;	(e) any other rules or requirements necessary for the operation of the common data platform such as the data update, archiving and deletion policy;	(e) any other rules or requirements necessary for the operation of the common data platform ***and the use of the data it contains*** such as the data update, archiving and deletion policy~~;~~ ***and the terms and conditions of use*** Text Origin: Commission Proposal
Article 4(5), point (f)				
130	(f) the operation of the steering committee itself.	(f) the operation, ***reporting requirements and transparency obligations*** of the steering committee itself.	(f) the operation of the steering committee itself.	(f) the operation ***and transparency obligations*** of the steering committee itself. Text Origin: EP Mandate
Article 5				
131	Article 5 Data flows for the purpose of the common data platform	Article 5 Data flows for the purpose of the common data platform	Article 5 Data flows for the purpose of the common data platform	Article 5 Data flows for the purpose of the common data platform Text Origin: Commission Proposal
Article 5(1)				
132	1. At the Commission's request, the Agencies shall host and maintain chemicals data	1. At the Commission's request, the Agencies shall host and maintain chemicals data	1. At the Commission's request, the Agencies shall host and maintain chemicals data	1. At the Commission's request, the Agencies shall host and maintain chemicals data

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	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.	generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold. ***In addition, Agencies may host and maintain chemicals data in accordance with their mandate and chemicals data submitted to them by Member States, national agencies, research institutes or other parties.***	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.**	generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold. ***In addition, Agencies may host and maintain chemicals data in accordance with their mandate and chemicals data submitted to them by Member States, or other parties, including national agencies, research institutes and third countries' organisations.*** Text Origin: EP Mandate
Article 5(2)				
G 133	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)~~***4(5)***, point (c). The Commission and the Agencies shall indicate whether ~~that~~***the*** data or information ~~is~~***included in the common data platform can be*** made available to the public ***or whether it is or they are deemed confidential in accordance with***	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2) **or 3(2a)**, they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as referred to in Article 4(4) **(5)**, point (c). The Commission and the Agencies shall indicate whether that data or information is ~~made available to the public~~ **confidential in accordance with the provisions on confidentiality** under the originating Union act.	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2) ***or 3(2a)***, they shall make that data available to the ECHA, ***who shall integrate it in the common data platform. The Commission and the Agencies shall provide the data or information to the ECHA*** in a standard format, where available, together with the relevant context data as referred to in Article 4(4) ***(5)***, point (c). The Commission and the Agencies shall indicate whether that data or information is ***not*** made available G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the provisions on confidentiality under the originating Union act.		to the public under the originating Union act.
Article 5(3)				
G 134	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.	3. The ECHA shall host and maintain occurrence data related to workplace monitoring***, including occupational human biomonitoring data***.	3. The ECHA shall host and maintain occurrence data related to workplace monitoring.	3. The ECHA shall host and maintain occurrence data related to workplace monitoring***, including occupational human biomonitoring data***. Text Origin: EP Mandate
Article 5(4)				
G 135	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality.	4. The EEA shall host and maintain human biomonitoring data, occurrence data for the environment and occurrence data related to indoor air quality. Text Origin: Commission Proposal
Article 5(5)				
G 136	5. Researchers or research consortia funded by Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation].	5. Researchers or research consortia funded by ***national or*** Union framework programmes shall make available to the EEA any human biomonitoring data they collect or generate from [OP please insert: date of the entry into force of this Regulation]. ***For human biomonitoring data constituting personal data, the EEA shall specify which type of***	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***~~OP please insert: date of the entry into force of this Regulation~~]. **For human biomonitoring data constituting personal data, the**	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]***, researchers or research consortia funded by national or Union framework programmes shall make any human biomonitoring***

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		data are to be made available to it.	**EEA shall specify which type of data shall be made available to it.**	***data they collect or generate available to the EEA, who shall host the data. For human biomonitoring data constituting personal data, the EEA shall specify which type of data are to be made available to it.*** Text Origin: Council Mandate
Article 5(6)				
G 137	6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].	6. Researchers or research consortia funded by ***national or*** Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation ***+ 6 months***].	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*** ~~OP please insert: date of the entry into force of this Regulation~~].	6. ***From [OP please insert: date of the entry into force of this Regulation],*** researchers or research consortia funded by Union framework programmes shall make ~~*available to the ECHA*~~ any environmental sustainability ***related*** data ~~*on chemicals or materials*~~ they collect or generate ~~*from [OP please insert: date of the entry into force of this Regulation]*~~***available to the ECHA, who shall host the data***. 'National' dropped here but taken up in a recital that voluntary contributions from national programmes are encouraged. Text Origin: EP Mandate
Article 5(7)				
G 138	7. The Commission and the Agencies shall provide the	7. The ~~*Commission and the*~~***Authorities and national***	7. The Commission and the Agencies shall provide the	7. The Commission and the Agencies shall provide the

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	necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.	agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform. ***The ECHA shall provide support to the Authorities and national agencies to facilitate the integration of the chemicals data provided in accordance with paragraph 2.***	necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform.	necessary technical cooperation to the ECHA to enable the integration of the chemicals data provided in accordance with paragraph 2 in the common data platform as well as its publication through that platform. ***The ECHA shall provide support to the Authorities and national agencies to facilitate the integration of the chemicals data provided in accordance with paragraph 2.***
Article 5(8)				
G 139	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data ***that they have collected or received*** available to the ECHA without undue delay ~~*after collection or receipt of the data, after performance of*~~***once they have performed*** validity and confidentiality assessments ***of the data*** in accordance with applicable rules and once ***they have integrated*** the corresponding dataset ~~*has been integrated*~~ in the common data platform.	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data available to the ECHA without undue delay after collection or receipt of the data, after performance of validity and confidentiality assessments in accordance with applicable rules and once the corresponding dataset has been integrated in the common data platform.	8. For the purpose of paragraph 2, the Commission and the Agencies shall make chemicals data ***that they have collected or received*** available to the ECHA without undue delay ~~*after collection or receipt of the data, after performance of*~~***once they have performed*** validity and confidentiality assessments ***of the data*** in accordance with applicable rules and once ***they have integrated*** the corresponding dataset ~~*has been integrated*~~ in the common data platform. Text Origin: EP Mandate G
Article 5(9)				

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140	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.	9. The ~~*Commission and the*~~ ***Authorities and national*** agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing them to the ECHA.	9. The Commission and the Agencies shall ensure that data made available to the ECHA shall be downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing ~~them~~**it** to the ECHA.	9. ***9. The Authorities and national*** ~~*The Commission and the*~~ agencies shall ensure***, when making data*** ~~*that data made*~~ available to the ECHA ~~*shall be*~~***, that such data is*** downloadable, machine readable and interoperable. They shall appropriately curate and validate the data before providing ~~*them*~~***it*** to the ECHA.
Article 5(10)				
140a		***9a. Notwithstanding provisions related to processing of human biomonitoring data constituting personal data set out in Article 6, the Commission or Agency under whose authority chemicals data are included in the common data platform on chemicals shall remain the data controller with regard to the personal data it provided.***	**10. The Commission and the Agencies shall act as data controllers for any personal data stored in the platform.**	***9a. Without prejudice to Article 6([6]), the Commission and the Agencies shall act as data controller for any the personal data they provide to the ECHA for integration in the common data platform.***
Article 5(9b)				
140b		***9b. Notwithstanding provisions related to processing of occupational human biomonitoring data constituting personal data set out in Article 6, the ECHA shall act as data processor for any personal data included in the common data***		*deleted*

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		platform falling under the Authority of another Agency or the Commission.		
Article 6				
G *141*	Article 6 Human biomonitoring data	Article 6 Human biomonitoring data	Article 6 Human biomonitoring data	Article 6 Human biomonitoring data Text Origin: Commission Proposal G
Article 6(1)				
G 142	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries.	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries***, with the exception of occupational human biomonitoring data in accordance with Article 5(3)***.	1. The EEA shall collect, host, and maintain human biomonitoring data generated within the territory of the EEA's member and cooperating countries. **Where it concerns occupational human biomonitoring data, the EEA shall cooperate with the ECHA.**	1. The EEA shall collect~~,~~ ~~*host, and maintain*~~ human biomonitoring data generated within the territory of the EEA's member and cooperating countries. ***Where it concerns occupational human biomonitoring data, the EEA shall cooperate with the ECHA.*** G
Article 6(2)				
G 143	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.	2. At the latest by [OP please insert date: 3 years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.	2. At the latest by [***OP please insert date: 3 years after entry into force of this Regulation***~~OP please insert date: 3 years after entry into force of this Regulation~~] the Commission shall transfer any human biomonitoring data it holds to the EEA.	2. At the latest by [***OP please insert date: 3 years after entry into force of this Regulation***~~*OP please insert date: 3 years after entry into force of this Regulation*~~] the Commission shall transfer any human biomonitoring data it holds to the EEA. Text Origin: Council Mandate G
Article 6(3)				

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144	3. The EEA may process human biomonitoring data constituting personal data to support the Commission in its policy making or to support the Agencies in fulfilling their missions.	*deleted*	*deleted*	*deleted*
Article 6(4)				
145	*4.* Human biomonitoring data constituting personal data may be processed by the EEA for the following purposes:	~~*4*~~***3a***. ***The EEA may process*** human biomonitoring data constituting personal data ~~*may be processed by the EEA*~~ for the following purposes:	**43. The EEA may process** human biomonitoring data constituting personal data ~~may be processed by the EEA~~ for the following purposes **only**:	4. ***The EEA may process*** human biomonitoring data constituting personal data ~~*may be processed by the EEA*~~ for the following purposes ***only***: Text Origin: Council Mandate
Article 6(4), point (a)				
146	(a) assessing the impact of chemicals on human health and the environment;	(a) assessing the impact of chemicals on human health and the environment;	(a) assessing the impact of chemicals on human health and the environment;	(a) assessing the impact of chemicals on human health and the environment; Text Origin: Commission Proposal
Article 6(4), point (b)				
147	(b) monitoring time and spatial trends in exposure;	(b) monitoring time and spatial trends in exposure;	(b) monitoring time and spatial trends in exposure;	(b) monitoring time and spatial trends in exposure; Text Origin: Commission Proposal
Article 6(4), point (c)				
148	(c) developing health risk and impact indicators;	(c) developing health risk and impact indicators;	(c) developing health risk and impact indicators;	(c) developing health risk and impact indicators;

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Article 6(4), point (d)				
149	(d) monitoring the impact of regulatory intervention;	(d) monitoring the impact of regulatory intervention;	(d) monitoring the impact of regulatory intervention;	(d) monitoring the impact of regulatory intervention; Text Origin: Commission Proposal
Article 6(4), point (e)				
150	(e) supporting regulatory risk assessments.	(e) supporting regulatory risk assessments ***and management***.	(e) supporting regulatory risk assessments~~.~~**;**	(e) supporting regulatory risk assessments ***and regulatory risk management***. Text Origin: EP Mandate
Article 6(4), point (ea)				
150a			**(ea) supporting regulatory risk management;**	*deleted* *integrated in 150*
Article 6(4), point (eb)				
150b		***(ea) supporting policy making and legislative processes at Union level;***	**(eb)** ***supporting policy making and legislative developments at Union level;***	***(eb) supporting policy making and legislative developments at Union level;***
Article 6(4), point (ec)				
150c		***(eb) the creation of a 'chemicals exposure index' for each region in the Union, to provide an overview of the population's exposure to chemical substances and facilitate comparisons between different regions, geographical areas and Member States;***		*deleted*

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Article 6(4), point (ed)				
150d		***(ec) facilitating the processing by the Commission, the ECHA, the EFSA, the EMA, and the EU-OSHA in accordance with paragraphs 4a, 4b, 4c, 4d and 4e of this Article.***	**(ec) facilitating the processing by the Commission, the ECHA, the EFSA and the EMA in accordance with paragraphs 4, 5, 6 and 6a of this article.**	***(ed) facilitating the processing by the Commission, the ECHA, the EFSA, the EMA, and the EU-OSHA in accordance with paragraphs 4a, 4b, 4c, 4d and 4e of this Article.*** Text Origin: EP Mandate
Article 6(4)				
150e		***3b. The Commission may process human biomonitoring data constituting personal data for the following purposes only:***	**4. The Commission may process human biomonitoring data constituting personal data for the following purposes only:**	***4a. The Commission may process human biomonitoring data constituting personal data for the following purposes only:*** Text Origin: EP Mandate
Article 6(4), point (a)				
150f		***(a) scientific research aimed at policy making;***	**(a) scientific research aimed at policy making;**	*deleted* *moved to row 150m*
Article 6(4), point (b)				
150g		***(b) assessing the impact of chemicals on human health and the environment;***	**(b) assessing the impact of chemicals on human health and the environment;**	***(b) assessing the impact of chemicals on human health and the environment;*** Text Origin: EP Mandate
Article 6(4), point (c)				
150h		***(c) monitoring time and spatial trends in exposure;***	**(c) monitoring time and spatial trends in exposure;**	***(c) monitoring time and spatial trends in exposure;***

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				Text Origin: EP Mandate
Article 6(4), point (d)				
150i		***(d) developing health risk and impact indicators;***	**(d) developing health risk and impact indicators;**	***(d) developing health risk and impact indicators;*** Text Origin: EP Mandate
Article 6(4), point (e)				
150j		***(e) monitoring the impact of regulatory intervention;***	**(e) monitoring the impact of regulatory intervention;**	***(e) monitoring the impact of regulatory intervention;*** Text Origin: EP Mandate
Article 6(4), point (f)				
150k		***(f) assessing the need for further regulatory action and prioritising such action;***	**(f) assessing the need for further regulatory action and prioritising such actions;**	***(f) assessing the need for regulatory action and prioritising such action;***
Article 6(4), point (g)				
150l		***(g) supporting regulatory risk assessment and risk management.***	**(g) supporting regulatory risk assessment and risk management.**	***(g) performing regulatory risk assessment and regulatory risk management.***
Article 6(4a), point (h)				
150m				***(h) supporting policy making and legislation, including performing scientific research to that effect***
Article 6(4a), point (i)				
150n				***(i) in the context of studies under the data generation mechanism referred to in Article***

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				21 and the human biomonitoring study referred to in Article 21a.

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Article 6(5)				
150o		***3c. The ECHA may process human biomonitoring data included in occurrence data related to workplace monitoring and which constitute personal data for the following purposes:***	**5. The ECHA may process human biomonitoring data constituting personal data for the following purposes only:**	***5. The ECHA may process human biomonitoring data constituting personal data for the following purposes only:*** Text Origin: Council Mandate
Article 6(5), point (a)				
150p		***(a) evaluating and prioritising required regulatory action;***	**(a) evaluating and prioritising required regulatory action;**	*deleted* *taken up in 150x*
Article 6(4b), point (b)				
150q		***(b) assessing the impact of chemicals on human health and the environment;***		***(b) assessing the impact of chemicals on human health and the environment;*** Text Origin: EP Mandate
Article 6(4b), point (c)				
150r		***(c) monitoring time and spatial trends in exposure;***		***(c) monitoring time and spatial trends in exposure;*** Text Origin: EP Mandate
Article 6(4b), point (d)				
150s		***(d) developing health risk and impact indicators;***		***(d) developing health risk and impact indicators;*** Text Origin: EP Mandate

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 6(4b), point (e)				
150t		***(e) monitoring the impact of regulatory intervention;***		***(e) monitoring the impact of regulatory intervention;*** Text Origin: EP Mandate
Article 6(5), point (b)				
150u		***(f) performing assessments of chemicals;***	**(b) performing assessments of chemicals;**	***(f) performing regulatory risk assessment and regulatory risk management;***
Article 6(5), point (c)				
150v		***(g) supporting regulatory risk assessment and management;***	**(c) supporting regulatory risk management;**	*deleted* *taken up in 150u*
Article 6(5), point (d)				
150w		***(h) as part of the commissioning of studies under the data generation mechanism referred to in Article 21.***	**(d) as part of the commissioning of studies under the data generation mechanism referred to in Article 21.**	***(h) in the context of studies under the data generation mechanism referred to in Article 21 and the human biomonitoring study referred to in Article 21a.***
Article 6(4b), point (i)				
150x				***(i) assessing the need for regulatory action and prioritising such action***
Article 6(4b), point (j)				
150y				***(j) supporting policy making and legislation, including performing scientific research to that effect***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 6(4b), point (k)				
150z				***(k) facilitating the processing by the Commission, the EEA, the EFSA, the EMA, and the EU-OSHA in accordance with paragraphs 4a, 4b, 4c, 4d and 4e of this Article.***
Article 6(6)				
150aa		***3d. The EFSA may process human biomonitoring data constituting personal data for the following purposes only:***	**6. The EFSA may process human biomonitoring data constituting personal data for the following purposes only:**	***4c. The EFSA may process human biomonitoring data constituting personal data for the following purposes only:*** Text Origin: EP Mandate
Article 6(6), point (a)				
150ab		***(a) evaluating and prioritising required regulatory action;***	**(a) evaluating and prioritising required regulatory action;**	***(a) assessing the impact of chemicals on human health and the environment***
Article 6(6), point (b)				
150ac		***(b) performing assessments of chemicals;***	**(b) performing assessments of chemicals;**	***(b) monitoring time and spatial trends in exposure***
Article 6(6), point (c)				
150ad		***(c) supporting regulatory risk management.***	**(c) supporting regulatory risk management.**	***(c) developing health risk and impact indicators***
Article 6(4c), point (d)				
150ae				***(d) in the context of studies under the data generation mechanism referred to in Article***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				21 and the human biomonitoring study referred to in Article 21a.
Article 6(4c), point (e)				
150af				***(e) performing regulatory risk assessment and supporting regulatory risk management***
Article 6(4c), point (f)				
150ag				***(f) assessing the need for regulatory action and prioritising such action***
Article 6(4c), point (g)				
150ah				***(g) monitoring the impact of regulatory intervention***
Article 6(4c), point (h)				
150ai				***(h) supporting policy making and legislation, including performing scientific research to that effect***
Article 6(6a)				
150aj		***3e. The EMA may process human biomonitoring data constituting personal data for the following purposes only:***	**6a. The EMA may process human biomonitoring data constituting personal data for the following purposes only:**	***4d. The EMA may process human biomonitoring data constituting personal data for the following purposes only:*** Text Origin: EP Mandate
Article 6(6a), point (a)				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
150ak		***(a) evaluating and prioritising required regulatory action;***	**(a) evaluating and prioritising required regulatory action;**	***(a) assessing the impact of chemicals on human health and the environment*** Text Origin: EP Mandate
Article 6(6a), point (b)				
150al		***(b) performing assessments of chemicals;***	**(b) performing assessments of chemicals;**	***(b) monitoring time and spatial trends in exposure*** Text Origin: EP Mandate
Article 6(6a), point (c)				
150am		***(c) supporting regulatory risk management.***	**(c) supporting regulatory risk management.**	***(c) performing regulatory risk assessment and supporting regulatory risk management*** Text Origin: EP Mandate
Article 6(4d), point (d)				
150an				***(d) assessing the need for regulatory action and prioritising such action***
Article 6(4d), point (e)				
150ao				***(e) monitoring the impact of regulatory intervention***
Article 6(4d), point (f)				
150ap				***(f) supporting policy making and legislation, including performing scientific research to that effect***
Article 6(4e)				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
150aq		***3f. The EU-OSHA may process human biomonitoring data constituting personal data for the following purposes only:***		***4e. The EU-OSHA may process human biomonitoring data constituting personal data for the following purposes only:*** Text Origin: EP Mandate
Article 6(4e), point (a)				
150ar		***(a) scientific research aimed at policy making;***		*deleted* *taken up in 150ax*
Article 6(4e), point (b)				
150as		***(b) assessing the impact of chemicals on human health and the environment;***		***(b) assessing the impact of chemicals on human health and the environment;*** Text Origin: EP Mandate
Article 6(4e), point (c)				
150at		***(c) monitoring time and spatial trends in exposure;***		***(c) monitoring time and spatial trends in exposure;*** Text Origin: EP Mandate
Article 6(4e), point (d)				
150au		***(d) monitoring the impact of regulatory intervention;***		***(d) monitoring the impact of regulatory intervention;*** Text Origin: EP Mandate
Article 6(4e), point (e)				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
150av		***(e) assessing the need for further regulatory action and prioritising such action;***		***(e) assessing the need for regulatory action and prioritising such action;*** Text Origin: EP Mandate
Article 6(4e), point (f)				
150aw		***(f) supporting regulatory risk management.***		***(f) supporting regulatory risk assessment and regulatory risk management*** Text Origin: EP Mandate
Article 6(4e), point (g)				
150ax				***(g) supporting policy making and legislation, including performing scientific research to that effect***
Article 6(4e), point (h)				
150ay				***(h) developing health risk and impact indicators***
Article 6(7)				
150az		***5a. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA, the EMA, the EU-OSHA, or the Commission for the purposes referred to in paragraphs 4, 4a, 4b, 4c, 4d, and 4e shall not entail the sharing of such data with third parties.***	**7. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA, the EMA or the Commission for the abovementioned purposes shall not entail the sharing of such data with third parties.**	***5a. Any processing of human biomonitoring data constituting personal data by the EEA, the ECHA, the EFSA, the EMA, the EU-OSHA, or the Commission for the purposes referred to in paragraphs 4, 4a, 4b, 4c, 4d, and 4e shall not entail the sharing of such data with third parties.*** Text Origin: EP Mandate

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 6(5)				
151	5. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.	5. The EEA ***and ECHA*** shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.	~~5~~8. The EEA shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring.	5. The EEA ***and ECHA*** shall make human biomonitoring data they hold or host publicly available in anonymised form through the Information Platform for Chemical Monitoring. Text Origin: EP Mandate
Article 6(6)				
152	6. The EEA shall act as data controller for the human biomonitoring personal data it holds or hosts and processes for the purposes referred to in paragraph 2.	6. The EEA***, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission*** shall act as data controller for the human biomonitoring ***data constituting*** personal data ~~*it holds or hosts and processes*~~***they hold or host or process*** for the purposes referred to in ~~*paragraph 2*~~***paragraphs 4, 4a, 4b, 4c, 4d and 4e***.	~~6~~9. The EEA**, the ECHA, the EFSA, the EMA and the Commission** shall act as data controller for the human biomonitoring **data constituing** personal data ~~it holds or hosts and processes~~ **they hold or host or process** for the purposes referred to in ~~paragraph 2~~**paragraphs 2, 3, 4, 5, 6 and 8**.	6. The EEA***, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission*** shall act as data controller for the human biomonitoring ***data constituting*** personal data ~~*it holds or hosts and processes*~~***they hold or host or process*** for the purposes referred to in ~~*paragraph 2*~~***paragraphs 4, 4a, 4b, 4c, 4d and 4e***. Text Origin: EP Mandate
Article 6(10)				
152a		***6a. The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission shall define the storage period, and carry out any review thereof, for the human biomonitoring data constituting personal data that they hold as well as the criteria used to define the storage period.***	**10. The EEA, the ECHA, the EFSA, the EMA and the Commission shall define the storage period and any review thereof for the human biomonitoring data constituting personal data they hold as well as the criteria used to define the storage period.**	***6a. The EEA and the ECHA, shall define the storage period as well as the criteria used to define the storage period, and carry out any review thereof, for the human biomonitoring data constituting personal data that they hold.***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Article 6(11)					
152b		***6b. The human biomonitoring data referred to in this Article include personal data lawfully collected before the entry into force of this Regulation.***	**11. The human biomonitoring data referred to in this Article includes personal data lawfully collected before the entry into force of the present Regulation.**	***6b. The human biomonitoring data referred to in this Article includes personal data lawfully collected before the entry into force of this Regulation.***	
Article 7					
153	Article 7 Information Platform for Chemical Monitoring	Article 7 Information Platform for Chemical Monitoring	Article 7 Information Platform for Chemical Monitoring	Article 7 Information Platform for Chemical Monitoring Text Origin: Commission Proposal	
Article 7(1)					
154	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform.	1. The ECHA shall operate and maintain the Information Platform for Chemical Monitoring containing occurrence data on chemicals across different media, including water, soil, indoor air, outdoor air, biota, food and feed, humans, and products as part of the common data platform. Text Origin: Commission Proposal	
Article 7(2)					
155	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall	2. At the latest by [OP please insert date: 3 years after the date of entry into force of this Regulation], the Commission shall	2. At the latest by [***OP please insert date: 3 years after the date of entry into force of this Regulation***~~OP please insert date: 3~~	2. At the latest by [***OP please insert date: 3 years after the date of entry into force of this Regulation***~~OP please insert date:~~	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.	transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.	~~years after the date of entry into force of this Regulation~~], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.	~~*3 years after the date of entry into force of this Regulation*~~], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform. Text Origin: Council Mandate
Article 7(3)				
G 156	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5.	3. At the latest by [OP please insert date: 3 years after entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5.	3. At the latest by [***OP please insert date: 3 years after entry into force of this Regulation***~~OP please insert date: 3 years after entry into force of this Regulation~~], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5.	3. At the latest by [***OP please insert date: 3 years after entry into force of this Regulation***~~*OP please insert date: 3 years after entry into force of this Regulation*~~], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the ECHA, the EEA or the EFSA for hosting in accordance with the respective agencies' mandate and in accordance with Article 5. Text Origin: Council Mandate
Article 7(4)				
G 157	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host	4. After the completion of the transfer referred to in paragraph 3, where the Commission or the Agencies host

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.	or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.	or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring.	or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA without undue delay for integration in the Information Platform for Chemical Monitoring. Text Origin: Commission Proposal
Article 7(5)				
G 158	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform.	5. The Commission and Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration and publication of occurrence data and related chemicals data they host or hold through the common data platform. Text Origin: Commission Proposal
Article 7(6)				
G 159	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable.	6. The ECHA shall ensure that the data contained in the Information Platform for Chemical Monitoring is machine readable and downloadable. Text Origin: Commission Proposal
Article 8				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
G	160	Article 8 Repository of reference values	Article 8 Repository of reference values	Article 8 Repository of reference values	G
				Text Origin: Commission Proposal	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 8(1)				
161	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.	1. The ECHA shall establish and manage a repository of reference values as part of the common data platform. Text Origin: Commission Proposal
Article 8(2)				
162	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I or Annex II, Part 1, in the repository of reference values without undue delay.	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I ~~or Annex II, Part 1,~~ in the repository of reference values without undue delay.	2. The ECHA shall include any reference value adopted under Union acts listed in Annex I ~~*or Annex II, Part 1,*~~ in the repository of reference values without undue delay. Text Origin: Council Mandate
Article 8(3)				
163	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, or the reference values referred to in Annex II, Part 2, shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, **Part 1,** or the reference values referred to in Annex II, ~~Part 2,~~ shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.	3. For reference values not falling under paragraph 2, the Agencies holding or establishing reference values as part of their activities under Union acts listed in Annex I, ***Part 1,*** or the reference values referred to in Annex II, ~~*Part 2,*~~ shall make those reference values available to the ECHA, in the standard formats provided for in Article 14, where developed, and without undue delay, for integration in the repository of reference values.

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				Text Origin: Council Mandate
Article 8(4)				
G 164	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules.	4. For the purpose of paragraph 3, where reference values are included in a regulatory dossier submitted to the Agencies, the Agencies shall share those reference values in the standard formats with ECHA without undue delay and once relevant validity and confidentiality assessments have been completed by the originator in accordance with applicable rules. Text Origin: Commission Proposal
Article 8(4a)				
G 164a		***4a. The ECHA shall include in the repository of reference values, without undue delay, any reference value generated as part of Union, national or international programmes or research activities and made available to ECHA in the standard formats as referred to in Article 14, where such a standard format has been developed.***		***4a. The ECHA shall include in the repository of reference values, without undue delay, any reference value it considers relevant and that is generated as part of Union, national or international programmes or research activities and made available to the ECHA in the standard formats as referred to in Article 14, where such a standard format has been developed.***

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Article 8(5)				
165	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable.	5. The ECHA shall ensure that the data contained in the repository of reference values is machine readable. Text Origin: Commission Proposal
Article 9				
166	Article 9 Database of Study Notifications	Article 9 Database of Study Notifications	Article 9 Database of Study Notifications	Article 9 Database of Study Notifications Text Origin: Commission Proposal
Article 9(1)				
167	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].	1. The ECHA shall establish and operate a Database of Study Notifications by [OP please insert date: two years after the date of entry into force of this Regulation].	1. The ECHA shall establish and operate a Database of Study Notifications by [~~OP~~***OP please insert date: two years after the date of entry into force of this Regulation*** ~~please insert date: two years after the date of entry into force of this Regulation~~].	1. The ECHA shall establish and operate a Database of Study Notifications by [~~*OP*~~***OP please insert date: two years after the date of entry into force of this Regulation*** ~~*please insert date: two years after the date of entry into force of this Regulation*~~]. Text Origin: Council Mandate
Article 9(1a)				
167a		***1a. The ECHA shall establish and operate a mechanism for cooperation and exchange of information with relevant third countries' authorities for the exchange of studies notified or***		*deleted*

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		submitted by business operators to those authorities to support an application, notification or regulatory dossier for a chemical by ... [OP please insert date: two years after the date of entry into force of this Regulation].		
Article 9(2)				
168	*2.* The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22.	2. The ECHA shall store in the Database of Study Notifications the data notified to it in accordance with Article 22 ***and the data obtained through the mechanism referred to in paragraph 1a of this Article***.	2. The ECHA shall store in the Database of Study Notifications the **chemicals** data notified to it in accordance with Article 22.	2. The ECHA shall store in the Database of Study Notifications the ***chemicals*** data notified to it in accordance with Article 22. Text Origin: Council Mandate
Article 9(3)				
169	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in	3. ~~*The ECHA shall integrate the*~~ Data contained in the Database of Study Notifications ~~*in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable*~~	3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in	3. ~~*The ECHA shall integrate the*~~ Data contained in the Database of Study Notifications ~~*in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable*~~

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	accordance with the applicable rules on confidentiality.	~~*rules on confidentiality*~~***shall be considered confidential and shall not be made public***.	accordance with the applicable rules on confidentiality.	~~*rules on confidentiality*~~***shall be considered confidential and shall not be made public***. Text Origin: EP Mandate
Article 9(3a)				
G 169a			**3a. Authorities and national enforcement authorities shall have access to the data contained in the Database of Study Notifications before that data is integrated in the common data platform.**	*deleted*
Article 9(4)				
G *170*	*4.* The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.	4. The EFSA shall make the data contained in the database referred to in Article 32b of Regulation (EC) No 178/2002 available to the ECHA for integration in the common data platform once it has received a corresponding application and after it has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002. Text Origin: Commission Proposal

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Article 9(4a)					
G	170a		***4a. Without prejudice to paragraph 4, where the Commission or any of the Agencies makes available to the ECHA, in accordance with Article 5(2), a registration, application, notification or other relevant regulatory dossier in the context of which a notification was submitted under Article 22, it shall indicate which elements of the study notifications are confidential when included in the common data platform. Only those elements shall be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant regulatory dossier in accordance with the provisions on confidentiality under the originating Union act.***		***4a. Without prejudice to paragraph 4, where the Commission or any of the Agencies makes available to the ECHA, in accordance with Article 5(2), a registration, application, notification or other relevant regulatory dossier in the context of which a notification was submitted under Article 22, it shall indicate which elements of the study notifications are confidential when included in the common data platform. Only those elements shall be indicated as confidential where the same element is indicated as confidential in the corresponding application, notification or other relevant regulatory dossier in accordance with the provisions on confidentiality under the originating Union act.*** Text Origin: EP Mandate	G
Article 9(4b)					
G	170b		***4b. Upon receipt by the ECHA, in accordance with Article 5(2), of a registration, application, notification or other relevant regulatory dossier, in the context of which a notification***		***4b. Upon receipt by the ECHA, in accordance with Article 5(2), of a registration, application, notification or other relevant regulatory dossier, in the context of which a notification***	G

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		was submitted under Article 22, the ECHA shall make the related notification information available through the common data platform, in accordance with the provisions on confidentiality under the originating Union act.		***was submitted under Article 22, the ECHA shall make the related notification information available to the public through the common data platform, respecting the confidentiality indicated in accordance with paragraph 4a.*** Text Origin: EP Mandate
Article 9(4c)				
G 170c		***4c. Authorities and national enforcement authorities shall have access to the data contained in the Database of Study Notifications before those data are integrated in the common data platform.***		***4c. Authorities and national enforcement authorities shall have access to the data contained in the Database of Study Notifications before that data is integrated in the common data platform.*** Text Origin: EP Mandate
Article 9(5)				
G 171	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.	5. The ECHA and the EFSA shall cooperate to ensure a common approach for the identification of information notified to them in accordance with Article 22 of this Regulation and Article 32b of Regulation (EC) No 178/2002, respectively and facilitate the traceability of the studies notified to their respective databases.

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				Text Origin: Commission Proposal
Article 10				
172	Article 10 Information on regulatory processes on chemicals	Article 10 Information on regulatory processes on chemicals	Article 10 Information on regulatory processes on chemicals	Article 10 Information on regulatory processes on chemicals Text Origin: Commission Proposal
Article 10(1)				
173	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual ~~substances~~**chemicals** or groups of ~~substances~~**chemicals** that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual substances or groups of substances that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III.	1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on regulatory processes on individual ~~substances~~**chemicals** or groups of ~~substances~~**chemicals** that are planned, ongoing or have been completed since the entry into force of this Regulation by the Member States or the Union institutions, agencies or committees referred to in the Union acts listed in Annex III. Text Origin: EP Mandate
Article 10(2)				
174	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex III hold the information referred to in paragraph 1, they

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	shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay. ***For each regulatory process or activity, at least the following information shall be included:***	shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay.	shall make that information available to the Union agency responsible under the respective Union act listed in Annex III without undue delay. ***For each regulatory process or activity, at least the following information shall be included:*** Text Origin: EP Mandate
Article 10(1a), first subparagraph				
174a			**For each regulatory process or activity, the following information shall at least be transmitted:**	***1a. deleted***
Article 10(1a), first subparagraph, point (a)				
174b		***(a) chemical identity;***	**(a) the substance identity;**	***(a) chemical identity;*** Text Origin: EP Mandate
Article 10(1a), first subparagraph, point (b)				
174c		***(b) the Union act and the regulatory process under which the activity takes place;***	**(b) the Union act and the regulatory process under which the activity takes place;**	***(b) the Union act and the regulatory process under which the activity takes place;*** Text Origin: EP Mandate
Article 10(1a), first subparagraph, point (c)				
174d		***(c) the submitter or actor responsible for the regulatory process or activity;***	**(c) submitter or actor responsible for the regulatory process or activity;**	***(c) the submitter or actor responsible for the regulatory process or activity;*** Text Origin: EP Mandate

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Article 10(1a), first subparagraph, point (d)				
174e		***(d) the status of the regulatory process or activity;***	**(d) status of the regulatory process or activity;**	***(d) the status of the regulatory process or activity;*** Text Origin: EP Mandate
Article 10(1a), first subparagraph, point (e)				
174f		***(e) the outcome of the regulatory process or activity, including, where applicable, the reports or opinions adopted;***	**(e) where applicable, outcome of the regulatory process or activity, including reports or opinions adopted;**	***(e) the outcome of the regulatory process or activity, including, where applicable, the reports or opinions adopted;*** Text Origin: EP Mandate
Article 10(1a), first subparagraph, point (f)				
174g		***(f) where applicable, the intended date for starting the regulatory process or activity, and the date of its completion and latest update;***	**(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.**	***(f) where applicable, the intended date for starting the regulatory process or activity, and the date of its completion and latest update;*** Text Origin: EP Mandate
Article 10(2), point (a)				
174h		***(a) where applicable, whether the process or activity includes the use of animals in testing and for which endpoints.***		*deleted*
Article 10(3)				
175	*3.* Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information

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	available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included:	available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each regulatory process or activity, at least the following information shall be included: Text Origin: Commission Proposal
Article 10(3), point (a)				
176	(a) substance identity;	(a) ~~substance~~***chemical*** identity;	(a) substance identity;	(a) ~~substance~~***chemical*** identity; Text Origin: EP Mandate
Article 10(3), point (b)				
177	(b) the Union act and the regulatory process under which the activity takes place;	(b) the Union act and the regulatory process under which the activity takes place;	(b) the Union act and the regulatory process under which the activity takes place;	(b) the Union act and the regulatory process under which the activity takes place; Text Origin: Commission Proposal
Article 10(3), point (c)				
178	(c) submitter or actor responsible for the regulatory process or activity;	(c) submitter or actor responsible for the regulatory process or activity;	(c) submitter or actor responsible for the regulatory process or activity;	(c) submitter or actor responsible for the regulatory process or activity; Text Origin: Commission Proposal

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Article 10(3), point (d)				
179	(d) status of the regulatory process or activity;	(d) status of the regulatory process or activity;	(d) status of the regulatory process or activity;	(d) status of the regulatory process or activity; Text Origin: Commission Proposal
Article 10(3), point (e)				
180	(e) outcome of the regulatory process or activity, including, where applicable, reports or opinions adopted;	(e) outcome of the regulatory process or activity, including, where applicable, reports or opinions adopted;	(e) **where applicable,** outcome of the regulatory process or activity, including~~, where applicable,~~ reports or opinions adopted;	(e) outcome of the regulatory process or activity, including, where applicable, reports or opinions adopted; Text Origin: Commission Proposal
Article 10(3), point (f)				
181	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update. Text Origin: Commission Proposal
Article 10(3), point (fa)				
181a		***(fa) where applicable, whether the process or activity includes the use of animals in testing and for which endpoints.***		*deleted*
Article 10(4)				
182	*4.* The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or	4. The information referred to in paragraph 3, points (a) to ~~(f)~~***(fa)***, on a specific regulatory	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or	4. The information referred to in paragraph 3, points (a) to (f), on a specific regulatory process or

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	activity shall be made available to the public once that process or activity has formally started.	process or activity shall be made available to the public ~~*once that process or activity has formally started*~~***without undue delay***.	activity shall be made available to the public once that process or activity has formally started.	activity shall be made available to the public once that process or activity has formally started. Text Origin: Commission Proposal
Article 10a				
182a		***Article 10a*** ***Information on chemicals in articles***		***Article 10a*** ***Data on chemicals in articles or products***
Article 10a(1)				
182b		***1. The ECHA shall establish and manage, as part of the common data platform, a database containing information on chemicals in articles generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I.*** ***That database shall integrate the information required under Article 9(1)(i) of Directive 2008/98/EC and to Article 14 of Regulation (EU) 2024/1781.*** ***The Commission shall design relevant related database functionalities.***		***1. The ECHA shall establish and manage, as part of the common data platform, a database containing data on chemicals in articles or products generated or submitted as part of the implementation of Union chemicals legislation listed in Annex IIIb.*** ***The Commission shall design relevant related database functionalities.***
Article 10a(3)				
182c				***2. Where the Commission or the Agencies hold the***

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				information referred to in paragraph 1, they shall make that data available to the ECHA for integration in the common data platform in the standard formats as referred to in Article 14, where available, without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. Moved from EP proposal in row 182e and amended.
Article 10a(2)				
182d		***2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex I without undue delay.***		***3. Where Member State competent authorities hold the data referred to in paragraph 1, they may make that data available in the standard formats as referred to in Article 14, where available, to the Union agency responsible under the respective Union act listed in Annex IIIb, or to the ECHA in the absence of such agency, who may host the data.***
Article 10a(3)				
182e		***3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they***		*deleted* *Moved to row 182e and amended.*

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		shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment.		
Article 10a(5)				
182f				***4. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of data on chemicals in articles or products in the related database.***
Article 10b				
182g		***Article 10b*** ***Information on safer alternatives to substances of concern***		***Article 10b*** ***Data on alternatives to substances of concern***
Article 10b(1)				
182h		***1. The ECHA shall establish and manage, as part of the common data platform, a database containing information on safer alternatives to substances of concern as defined in Article 2(27) of Regulation (EU) 2024/1781 as well as substances that meet the criteria***		***1. The ECHA shall establish and manage, as part of the common data platform, a database containing data on alternatives to substances of concern as defined in Article 2(27) of Regulation (EU) 2024/1781 as well as substances that meet the criteria for***

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		for classification in hazard classes referred to in Article 2(27)(b) of Regulation (EU) 2024/1781, including on materials not requiring such substances. The Commission shall design relevant related database functionalities.		***classification in hazard classes referred to in Article 2(27)(b) of Regulation (EU) 2024/1781, including on alternative technologies or materials not requiring such substances. At a minimum, the ECHA shall include in the database data provided by applicants in accordance with Article 62, paragraph 4, point (e) of Regulation (EC) 1907/2006.***
Article 10b(2)				
G 182i				***2. Where the Commission or the Agencies hold the data referred to in the first subparagraph of paragraph 1, they shall make that data available to the ECHA for integration in the common data platform.*** G
Article 10b(3)				
G 182j		***2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex I without undue delay.***		***3. Where Member State competent authorities hold the data referred to in the first subparagraph of paragraph 1, they may make that data available in the standard formats as referred to in Article 14, where available, to the Union agency responsible under the respective Union act listed in Annex I , or to*** G

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				the ECHA in the absence of such agency, who may host the data.
Article 10b(4)				
182k		***3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment.***		*deleted* *Moved to 182i and amended*
Article 10b(5)				
182l		***4. The ECHA shall encourage providers of safer alternatives to substances of concern, or of materials not requiring such substances, to identify them and to provide all relevant data.***		***4. The ECHA shall facilitate the voluntary submission by interested parties of information on alternatives to substances of concern, including information on alternative technologies to substances of concern, or of materials not requiring such substances.***
Article 11				
183	Article 11 Information on the obligations under Union acts on chemicals	Article 11 Information on the obligations under Union acts on chemicals	Article 11 Information on the obligations under Union acts on chemicals	Article 11 Information on the obligations under Union acts on chemicals

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				Text Origin: Commission Proposal

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Article 11(1)				
184	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I.	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I**, Part 1.**	1. The ECHA shall establish and manage, as part of the common data platform, a database with information on the provisions and legal obligations applicable to chemicals under the Union acts listed in Annex I***, Part 1.*** Text Origin: Council Mandate
Article 11(2)				
185	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).	2. The ECHA shall update the information in the database on a regular basis***, and at least annually,*** and in accordance with the governance scheme referred to in Article 4(3).	2. The ECHA shall update the information in the database on a regular basis and in accordance with the governance scheme referred to in Article 4(3).	2. The ECHA shall update the information in the database on a regular basis***, and at least annually,*** and in accordance with the governance scheme referred to in Article 4(3). Text Origin: EP Mandate
Article 12				
186	Article 12 Repository of standard formats and controlled vocabularies	Article 12 Repository of standard formats and controlled vocabularies	Article 12 Repository of standard formats and controlled vocabularies	Article 12 Repository of standard formats and controlled vocabularies Text Origin: Commission Proposal
Article 12(1)				
187	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.	1. The ECHA shall establish and manage as part of the common data platform a repository of standard formats and controlled vocabularies.

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				Text Origin: Commission Proposal
Article 12(2)				
188	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.	2. Where standard data formats are established under the Union acts listed in Annexes I and II, the ECHA shall include them in the common data platform.	2. Where standard data formats are established under the Union acts listed in ~~Annexes I and II~~**Annex I**, the ECHA shall include them in the common data platform.	2. Where standard data formats are established under the Union acts listed in ~~*Annexes I and II*~~***Annex I***, the ECHA shall include them in the common data platform. Text Origin: Council Mandate
Article 12(3)				
189	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform.	3. Where the Commission or the Agencies specify a standard format or controlled vocabulary in accordance with Articles 14 or 15, the Commission or the Agency shall make it available to the ECHA without undue delay for integration in the common data platform. Text Origin: Commission Proposal
Article 13				
190	Article 13 Database on environmental sustainability related data	Article 13 Database on environmental sustainability related data	Article 13 Database on environmental sustainability related data	Article 13 Database on environmental sustainability related data Text Origin: Commission Proposal

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Article 13(1)				
191	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.	1. At the latest within three years after the ~~*publication of the decision*~~***identification of datasets and design of database functionalities*** referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.	1. At the latest within three years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.	1. At the latest ~~*within three*~~***by [OP please insert date: six*** years after the ~~*publication of the decision referred to in paragraph 4*~~***date of entry into force of this regulation]***, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data ***and providing the functionalities designed in accordance with paragraph 4***. Text Origin: EP Mandate
Article 13(2)				
192	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA	2. Where ~~*the Commission or the*~~***Authorities or national*** agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the ~~*Commission or the*~~***Authority or national*** agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. ~~*The Commission and the*~~***Authorities and national***	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA	2. Where the Commission or the Agencies- host or hold environmental sustainability related data ~~*in addition to the chemicals data already available in the common data platform*~~, they shall make that data available to the ECHA without undue delay ***for integration in the database on environmental sustainability related data*** once the Commission or the agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments.

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	to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.	agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data. ***The ECHA shall provide the necessary support to the Authorities and national agencies to facilitate the integration of those data.***	to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.	***In addition, in accordance with Article 5(1), Member States or other parties, including national agencies, research institutes, and third countries' organisations may submit environmental sustainability related data to the ECHA.*** -The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data. ***The ECHA shall provide the necessary support to the Commission and the Agencies to facilitate the integration of those data.*** Text Origin: EP Mandate
Article 13(3)				
G 193	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in	3. Where researchers or research consortia funded by Union framework ***and national*** programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in	3. Where researchers or research consortia funded by Union framework- programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in G

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	the database on environmental sustainability related data.	the database on environmental sustainability related data.	the database on environmental sustainability related data.	the database on environmental sustainability related data.
Article 13(4)				
194	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	4. By ... [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall ~~adopt an implementing decision identifying~~, ***in consultation with the Member States, identify*** existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform, ***request the ECHA to host and maintain them in accordance with Article 5(1)*** and shall design relevant related database functionalities.	4. By [***OP*** ~~OP~~ please ***insert date: three years after the date of entry into force of this Regulation*** ~~insert date: three years after the date of entry into force of this Regulation~~], the Commission shall ~~adopt an implementing decision identifying~~, **in consultation with Member States, identify** existing datasets **of chemicals data** on environmental sustainability related data, other than those referred to in ~~paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities~~**paragraphs 2 and 3, and request the ECHA to host and maintain them in accordance with Article 5(1)**.	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall ~~adopt an implementing decision identifying~~, ***in consultation with the Member States, design database functionalities and identify*** existing datasets ***of chemicals data*** on environmental sustainability related data, other than those referred to in paragraph 2, ~~for inclusion in the common data platform and~~***which*** shall ~~design relevant related database functionalities~~***be hosted and maintained by the ECHA***. Text Origin: Council Mandate
Chapter III				
195	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES	Chapter III DATA FORMATS AND CONTROLLED VOCABULARIES Text Origin: Commission Proposal

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Article 14				
196	Article 14 Standard formats	Article 14 Standard formats	Article 14 Standard formats	Article 14 Standard formats Text Origin: Commission Proposal
Article 14(1)				
197	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article ~~3 (2) and~~**3(2) and (2a)** falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and the Agencies shall specify, where relevant, for the data referred to in Article ~~*3 (2) and*~~***3(2) [and (2a)]*** falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform. Text Origin: Council Mandate
Article 14(2)				
198	2. The standard formats referred to in paragraph 1 shall, to the extent possible:	2. The standard formats referred to in paragraph 1 shall, to the extent possible:	2. The standard formats referred to in paragraph 1 shall, to the extent possible:	2. The standard formats referred to in paragraph 1 shall, to the extent possible: Text Origin: Commission Proposal
Article 14(2), point (a)				
199	(a) avoid the use of proprietary standards;	(a) avoid the use of proprietary standards;	(a) avoid the use of proprietary standards;	(a) avoid the use of proprietary standards;

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					Text Origin: Commission Proposal	
Article 14(2), point (b)						
G	200	(b) re-use existing data formats or parts of them;	(b) re-use existing data formats or parts of them;	(b) re-use existing data formats or parts of them;	(b) re-use existing data formats or parts of them; Text Origin: Commission Proposal	G
Article 14(2), point (c)						
G	201	(c) use OECD or other internationally agreed formats;	(c) use OECD or other internationally agreed formats;	(c) use OECD or other internationally agreed formats;	(c) use OECD or other internationally agreed formats; Text Origin: Commission Proposal	G
Article 14(2), point (d)						
G	202	(d) be coherent with other existing data formats;	(d) be coherent with other existing data formats;	(d) be coherent with other existing data formats;	(d) be coherent with other existing data formats; Text Origin: Commission Proposal	G
Article 14(2), point (e)						
G	203	(e) ensure interoperability with existing data submission approaches.	(e) ensure interoperability with existing data submission approaches.	(e) ensure interoperability with existing data submission approaches.	(e) ensure interoperability with existing data submission approaches. Text Origin: Commission Proposal	G
Article 14(3)						
G	204	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.	3. Those standard formats shall be interoperable with the common data platform and be user-friendly.	G

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				Text Origin: Commission Proposal
Article 14(4)				
205	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.	4. The ~~Commission and the~~**Authorities or national** agencies shall exchange data contained in the common data platform in the relevant standard format.	4. The Commission and the Agencies shall exchange data contained in the common data platform in the relevant standard format.	4. The ~~Commission and the~~**Authorities or national** agencies shall exchange data contained in the common data platform in the relevant standard format. Text Origin: EP Mandate
Article 14(5)				
206	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts:	5. The Commission and the Agencies shall use the International Uniform Chemical Information Database format (IUCLID) for making available to the ECHA for integration in the common data platform the relevant parts of dossiers under the following Union acts: Text Origin: Commission Proposal
Article 14(5), point (a)				
207	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in	(a) Regulation (EC) No 1831/2003 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in

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	animal nutrition (OJ L 268 18.20.2003, p. 29).	animal nutrition (OJ L 268 18.20.2003, p. 29).	animal nutrition (OJ L ~~268 18.20.2003~~**268 18.10.2003**, p. 29).	animal nutrition (OJ L ~~*268 18.20.2003*~~***268 18.10.2003***, p. 29). Text Origin: Council Mandate
Article 14(5), point (b)				
208	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4).	(b) Regulation (EC) No 1935/2004 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338 13.11.2004, p. 4). Text Origin: Commission Proposal
Article 14(5), point (c)				
209	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1).	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1).	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1).	(c) Regulation (EC) No 1331/2008 of the European Parliament and of the Council[1]; 1. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354 31.12.2008. p. 1). Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(5), point (d)				
210	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7).	(d) Regulation (EC) No 1332/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354 31.12.2008, p. 7). Text Origin: Commission Proposal
Article 14(5), point (e)				
211	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16).	(e) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354 31.12.2008, p. 16). Text Origin: Commission Proposal
Article 14(5), point (f)				
212	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of	(f) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[1]; _____ 1. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of

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	16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).	16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).	16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34).	16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354 31.12.2008, p. 34). Text Origin: Commission Proposal
Article 14(5), point (g)				
G 213	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [1]; 1. 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).	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [1]; 1. 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).	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [1]; 1. 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).	(g) Regulation (EC) No 1223/2009 of the European Parliament and of the Council [1]; 1. 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). Text Origin: Commission Proposal
Article 14(5), point (h)				
G 214	(h) Commission Regulation (EU) No 234/2011[1]; 1. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).	(h) Commission Regulation (EU) No 234/2011[1]; 1. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).	(h) Commission Regulation (EU) No 234/2011[1]; 1. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15).	(h) Commission Regulation (EU) No 234/2011[1]; 1. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 064 11.3.2011, p. 15). Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 14(5), point (i)				
215	(i) Directive 2009/48/EC of the European Parliament and of the Council.[1] 1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).	(i) Directive 2009/48/EC of the European Parliament and of the Council.[1] 1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).	(i) Directive 2009/48/EC of the European Parliament and of the Council~~.~~;[1] 1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1).	(i) Directive 2009/48/EC of the European Parliament and of the Council~~.~~;[1] 1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 30.6.2009, p. 1). Text Origin: Council Mandate
Article 14(5), point (j)				
215a		***(ia) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1].*** ***1. 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).***	**(j) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1];** **1. 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).**	***(j) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1];*** ***1. 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).*** Text Origin: Council Mandate
Article 14(5), point (k)				
215b		***(ib) Regulation (EC) No 396/2005 of the European Parliament and of the Council[1].*** ***1. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and***	**(k) Regulation (EC) No 396/2005 of the European Parliament and of the Council[1].** **1. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal**	***(k) Regulation (EC) No 396/2005 of the European Parliament and of the Council[1].*** ***1. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and***

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		amending Council Directive 91/414/EEC (OJ L70, 16.3.2005, p. 1).	**origin and amending Council Directive 91/414/EEC (OJ L 70 16.3.2005, p. 1).**	*amending Council Directive 91/414/EEC (OJ L 70 16.3.2005, p. 1).* Text Origin: Council Mandate
Article 14(6)				
G 216	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches. Text Origin: Commission Proposal
Article 14(7)				
G 217	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early stage any potential divergence between data formats that could cause interoperability problems. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report

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	shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.	shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.	shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.	shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence. Text Origin: Commission Proposal
Article 14(8)				
218	8. The Commission shall adopt an implementing decision to remedy the divergence.	8. The Commission shall adopt an implementing ~~*decision*~~***act*** to remedy the divergence~~.~~	8. The Commission shall adopt an implementing ~~decision~~ **act** to remedy the divergence.	8. The Commission shall adopt an implementing ~~*decision*~~***act*** to remedy the divergence~~.~~ Text Origin: EP Mandate
Article 15				
219	Article 15 Controlled vocabularies	Article 15 Controlled vocabularies	Article 15 Controlled vocabularies	Article 15 Controlled vocabularies Text Origin: Commission Proposal
Article 15(1)				
220	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2) **and 3(2a)**, where relevant.	1. The Commission and the Agencies shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2) ***and 3(2a)***, where relevant. Text Origin: Council Mandate
Article 15(2)				
221	2. The Commission and the Agencies shall prioritise	2. The Commission and the Agencies shall prioritise	2. The Commission and the Agencies shall prioritise	2. The Commission and the Agencies shall prioritise

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	specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.	specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.	specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms.	specifying controlled vocabularies for the identification of chemicals and the characterisation of their forms. Text Origin: Commission Proposal
Article 15(3)				
222	3. Those controlled vocabularies shall:	3. Those controlled vocabularies shall:	3. Those controlled vocabularies shall:	3. Those controlled vocabularies shall: Text Origin: Commission Proposal
Article 15(3), point (a)				
223	(a) avoid the use of proprietary controlled vocabularies to the extent possible;	(a) avoid the use of proprietary controlled vocabularies to the extent possible;	(a) avoid the use of proprietary controlled vocabularies to the extent possible;	(a) avoid the use of proprietary controlled vocabularies to the extent possible; Text Origin: Commission Proposal
Article 15(3), point (b)				
224	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible;	(b) re-use existing substance identifiers and controlled vocabularies or parts of them to the extent possible; Text Origin: Commission Proposal
Article 15(3), point (c)				
225	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;	(c) use OECD or other internationally agreed controlled vocabularies to the extent possible;

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				Text Origin: Commission Proposal
Article 15(3), point (d)				
226	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables.	(d) ensure coherence with other relevant controlled vocabularies including by preparing alignment tables. Text Origin: Commission Proposal
Article 15(4)				
227	4. Those controlled vocabularies shall be interoperable with the common data platform.	4. Those controlled vocabularies shall be interoperable with the common data platform.	4. Those controlled vocabularies shall be interoperable with the common data platform.	4. Those controlled vocabularies shall be interoperable with the common data platform. Text Origin: Commission Proposal
Article 15(5)				
228	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:	5. Where controlled vocabularies are specified, the Commission and the Agencies shall:	5. Where controlled vocabularies are specified, the Commission and the Agencies shall: Text Origin: Commission Proposal
Article 15(5), point (a)				
229	(a) make them available free of charge through the common data platform and as open datasets;	(a) make them available free of charge through the common data platform ~~and~~ as open datasets, ***supporting their re-use***;	(a) make them available free of charge through the common data platform and as open datasets;	(a) make them available free of charge through the common data platform ~~and~~ as open datasets, ***supporting their re-use***;

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				Text Origin: EP Mandate
Article 15(5), point (b)				
230	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I and referred to in Article 3(2); and	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I**, Part 1** and referred to in Article ~~3(2);~~ ~~and~~**3, paragraph 2; and**	(b) integrate them in any submission software or template to be used by duty holders under the Union acts listed in Annex I***, Part 1*** and referred to in Article ~~*3(2);*~~ ~~*and*~~***3, paragraph 2; and*** Text Origin: Council Mandate
Article 15(5), point (c)				
231	(c) use them when exchanging data between them through the common data platform.	(c) use them when exchanging data between them through the common data platform.	(c) use them when exchanging data between them through the common data platform.	(c) use them when exchanging data between them through the common data platform. Text Origin: Commission Proposal
Article 15(6)				
232	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.	6. The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies. Text Origin: Commission Proposal
Article 15(7)				
233	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early	7. The Commission and the Agencies shall take the necessary and appropriate measures to monitor and identify at an early

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.	stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.	stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence.	stage any potential divergence between controlled vocabularies. If a divergence is identified, the Agencies concerned shall cooperate to resolve it or, where the divergence is justified, explain the underlying reasons. Where the Agencies concerned are not able to resolve that divergence, they shall draw up a joint report and present it to the Commission. The report shall clearly outline the reasons for the divergence, clarify any underlying technical issue and make a proposal to remedy the divergence. Text Origin: Commission Proposal
Article 15(8)				
234	8. The Commission shall adopt an implementing decision to remedy the divergence.	8. The Commission shall adopt an implementing ~~*decision*~~***act*** to remedy the divergence~~.~~	8. The Commission shall adopt an implementing ~~decision~~ **act** to remedy the divergence.	8. The Commission shall adopt an implementing decision to remedy the divergence. Text Origin: Commission Proposal
Article 15a				
234a		***Article 15a*** ***Uptake of research data***		***Article 15a*** ***Uptake of peer-reviewed published research data*** See lines 234b-g.
Article 15a(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 234b		***1. Researchers shall be able to submit publicly available research data on chemicals related to an entry in the common data platform. Research data shall be submitted in a format prescribed by the ECHA.***		***1. The Commission and the Agencies shall promote the development and use of tools and practices facilitating the uptake of peer-reviewed published research data in regulatory chemicals assessments, including the development and use of reporting standards for such data and tools to search, screen and extract relevant peer-reviewed published research data.*** G
Article 15a(2)				
G 234c		***2. By ... [OP: insert 18 months after the entry into force of this Regulation], the ECHA shall establish and maintain an online platform for the submission process referred to in paragraph 1.***		*deleted* G
Article 15a(3)				
G *234d*		***3. The ECHA shall assess the compliance of research data submitted through the portal referred to in paragraph 2 with the requirements set in the guidance referred to in paragraph 4. Where research data submitted are deemed to fulfil these requirements, the data shall be hosted on the common***		*deleted* G

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		data platform together with the corresponding entry.		

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 15a(4)				
234e		***4. By ... [OP: insert 12 months after the entry into force of this Regulation], the Commission shall publish guidance setting minimum quality and reporting requirements to improve the uptake of research data.***		*deleted*
Article 15a(5)				
234f		***5. In order to ensure that the research data are submitted in a uniform format, the Commission shall, by means of implementing acts, adopt a standard format for the submission of research data. Those implementing acts shall be adopted by ... [OP: please insert the date = 12 months after the entry into force of this Regulation], in accordance with the examination procedure referred to in Article 24a(2).***		*deleted*
Article 15a(6)				
234g				***6. Where the Commission or one of the Agencies engages in the development of the tools and practices referred to in paragraph 1, the Commission and the Agencies shall closely cooperate***

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				and provide assistance as appropriate.
Chapter IV				
235	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE	Chapter IV CHEMICALS DATA CONFIDENTIALITY AND USE Text Origin: Commission Proposal
Article 16				
236	Article 16 Access rights and transparency	Article 16 Access rights and transparency	Article 16 Access rights and transparency	Article 16 Access rights and transparency Text Origin: Commission Proposal
Article 16(-1)				
236a			**-1. The public shall have access to all the chemicals data contained in the common data platform, except data which is deemed to be confidential under Article 5(2), second sentence.**	***-1. Without prejudice to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents the public shall have access to all the chemicals data contained in the common data platform, except data which is indicated in accordance with Article 5(2) as not being made available to the public under the originating Union act.***
Article 16(1)				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 237	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is ~~*deemed to be*~~***marked as*** confidential under Article 5(2), second sentence.	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is ~~*deemed to be confidential under*~~***indicated in accordance with*** Article 5(2)~~*, second sentence*~~ ***as not being made available to the public under the originating Union act***. G
Article 16(2)				
G 238	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	2. The Authorities shall take the necessary measures***, including security measures,*** to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2)***,*** is not made ***available to the*** public.	2. The Authorities shall take the necessary measures**, including security measures,** to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2)**, second sentence,** is not made **available to the** public.	2. The Authorities shall take the necessary measures***, including security measures,*** to ensure that information contained in the common data platform ~~*marked as confidential*~~ ***indicated*** in accordance with Article 5(2) ***as not being made available to the public under the originating Union act*** is not made ***available to the*** public. G
Article 16(3)				
G 239	3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.	3. The ~~*general*~~ public shall have access to all the chemicals data contained in the common data platform ~~*and considered as available to the public in accordance with the Union act*~~***except data which are marked to be confidential*** under ~~*which the*~~	*deleted*	*deleted* G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		~~*data was generated or submitted*~~***Article 5(2)***.		
Article 17				
240	Article 17 Use of chemicals data contained in the common data platform	Article 17 Use of chemicals data contained in the common data platform	Article 17 Use of chemicals data contained in the common data platform	Article 17 Use of chemicals data contained in the common data platform Text Origin: Commission Proposal
Article 17(1)				
241	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development or implementation of chemicals legislation and policy.	1. The Authorities may use the chemicals data contained in the common data platform ***or in the Database of Study Notifications*** in the performance of any of their activities, where those activities support the development ~~*or*~~***,*** implementation ***or enforcement*** of ~~*chemicals*~~ legislation and policy.	1. The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development ~~or~~ **,** implementation **or enforcement** of chemicals legislation and policy.	1. The Authorities may use the chemicals data contained in the common data platform ***or in the Database of Study Notifications*** in the performance of any of their activities, where those activities support the development ~~*or*~~***,*** implementation ***or enforcement*** of ~~*chemicals*~~ legislation and policy. Text Origin: EP Mandate
Article 17(2)				
242	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, ***and to the possibility of identifying data gaps in the applications received from business operators,*** Authorities shall not use chemicals data contained in the common data	2. Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II, Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders.	2. ~~*Without prejudice to existing provisions enabling the sharing and use of chemicals data under the Union acts listed in Annexes I and II,*~~ Authorities shall not use chemicals data contained in the common data platform to fulfil any legal obligations of duty holders ***except for the assessment of the completeness of chemicals***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		platform to fulfil any legal obligations of duty holders.		***data submitted by duty holders or where existing provisions enable the sharing and use of chemicals data under the Union acts listed in Annexes I and II***.
Article 17(3)				
243	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.	3. When using chemicals data contained in the common data platform that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator and shall not disclose that data to the public without the consent of the originator.	3. When using chemicals data ~~contained in the common data platform that is deemed confidential under Article 5(2), second sentence~~**as provided for in paragraph 1**, the Authorities shall respect the confidentiality of ~~information~~**that** data as marked by the originator ~~and shall not disclose that data to the public without the consent of the originator.~~**.**	3. When using chemicals data contained in the common data platform that is ~~*deemed confidential under*~~***indicated in accordance with*** Article 5(2)~~, second sentence,~~ ***as not being made available to the public,*** the Authorities shall respect ~~*the confidentiality of information data as marked*~~***that indication*** by the originator and shall not disclose that data to the public without the consent of the originator.
Article 17(3a)				
243a		***3a. The common data platform shall also include terms and conditions, particularly regarding the respect of intellectual property rights and other related rights.***		*deleted*
Chapter V				
244	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS	Chapter V MONITORING AND OUTLOOK FRAMEWORK FOR CHEMICALS

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 18				
245	Article 18 Framework of indicators	Article 18 Framework of indicators	Article 18 Framework of indicators	Article 18 Framework of indicators Text Origin: Commission Proposal
Article 18(1)				
246	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall***, in consultation with Member States,*** establish, operate, ~~*and*~~ maintain ***and update as appropriate*** a framework of indicators ***to monitor chemical pollution throughout the chemical's lifecycle, including emissions, occurrence and fate,*** to monitor the drivers and impacts of exposure to chemicals, ***and to*** measure the effectiveness of chemicals legislation and ~~*measure*~~ the transition towards the production of safe and sustainable chemicals.	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall**, in consultation with Member States,** establish, operate, ~~and~~ maintain **and update as appropriate** a framework of indicators **to monitor chemical pollution along the chemical's lifecycle, including emissions and occurrence,** to monitor the drivers and impacts of exposure to chemicals, **and to** measure the effectiveness of chemicals legislation and ~~measure~~ the transition towards the production of safe and sustainable chemicals.	1. The EEA ***and the ECHA shall***, in collaboration with ~~*the ECHA,*~~ the EFSA, the EMA, the EU-OSHA and the Commission, ***and in consultation with Member States,*** ~~*shall*~~ establish, operate, ~~*and*~~ maintain ***and update as appropriate*** a framework of indicators ***to monitor chemical pollution throughout a chemical's lifecycle, including emissions, occurrence and fate,*** to monitor the drivers and impacts of exposure to chemicals, ***and to*** measure the effectiveness of chemicals legislation and ~~*measure*~~ the transition towards the production of safe and sustainable chemicals. Text Origin: EP Mandate
Article 18(1a)				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 246a		***1a. The framework of indicators referred to in paragraph 1 shall include an aggregated territory-based risk indicator at different administrative levels as defined in Regulation (EC) No 1059/2003 to monitor time and spatial trends in exposure of populations to individual and multiple chemicals and health risks associated with such exposure and co-exposure.***		***1a. The framework of indicators referred to in paragraph 1 shall, where meaningful and to the extent possible, include an aggregated territory-based risk indicator to monitor time and spatial trends in exposure of populations to individual and multiple chemicals and health risks associated with such exposure.***
Article 18(2)				
G 247	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.	2. The framework of indicators referred to in paragraph 1***, and the aggregated indicator referred to in paragraph 1a,*** shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.	2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform. Text Origin: Commission Proposal
Article 19				
G 248	Article 19 Early warning and action system for emerging chemical risks	Article 19 Early warning and action system for emerging chemical risks	Article 19 Early warning and action system for emerging chemical risks	Article 19 Early warning and action system for emerging chemical risks Text Origin: Commission Proposal
Article 19(1)				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
249	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [OP please insert date: one year after the date of entry into force of this Regulation].	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [***OP please insert date: one year after the date of entry into force of this Regulation***~~OP please insert date: one year after the date of entry into force of this Regulation~~].	1. The EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks by [***OP please insert date: one year after the date of entry into force of this Regulation***~~*OP please insert date: one year after the date of entry into force of this Regulation*~~]. Text Origin: Council Mandate
Article 19(2), first subparagraph				
250	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from:	2. For the purpose of paragraph 1, the EEA shall compile early warning signals, which shall include at least signals from: Text Origin: Commission Proposal
Article 19(2), first subparagraph, point (a)				
251	(a) the EFSA's emerging risks exchange network;	(a) the EFSA's emerging risks exchange network;	(a) the EFSA's emerging risks exchange network;	(a) the EFSA's emerging risks exchange network; Text Origin: Commission Proposal
Article 19(2), first subparagraph, point (b)				
252	(b) existing national early warning systems;	(b) ~~*existing*~~ national early warning systems;	(b) ~~existing~~ national early warning systems;	(b) ~~*existing*~~ national early warning systems; Text Origin: EP Mandate
Article 19(2), first subparagraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
253	(c) data that the EEA holds;	(c) data that the EEA holds, ***including data from human biomonitoring as referred to in Article 6, and data from the framework of indicators and the aggregated indicator as referred to in Article 18***;	(c) data that the EEA holds**, including data from the framework of indicators as referred to in Article 18**;	(c) data that the EEA holds, ***including data from human biomonitoring as referred to in Article 6, and data from the framework of indicators as referred to in Article 18***; Text Origin: EP Mandate
Article 19(2), first subparagraph, point (d)				
254	(d) targeted literature searches performed by the EEA;	(d) targeted literature searches performed by the EEA;	(d) targeted literature searches performed by the EEA;	(d) targeted literature searches performed by the EEA; Text Origin: Commission Proposal
Article 19(2), first subparagraph, point (e)				
255	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3.	(e) data made available by the ECHA, the EFSA, the EU-OSHA and the EMA in accordance with paragraph 3. Text Origin: Commission Proposal
Article 19(2), first subparagraph, point (ea)				
255a		***(ea) relevant datasets from the EU Datasets Catalogue established by Article 57 of Regulation (EU) …/… of the European Parliament and of the Council on the European Health Data Space ... [OP: please add number and publication reference];***		***(ea) relevant datasets from the EU dataset catalogue established by Article 79 of Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space .***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 19(2), first subparagraph, point (eb)				
255b		***(eb) relevant information resulting from national enforcement programmes;***		***(eb) relevant information resulting from the implementation of Union legislation***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 19(2), first subparagraph, point (ec)				
255c		***(ec) relevant data or information submitted by researchers.***		*deleted*
Article 19(2), second subparagraph				
256	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk.	The early warning signals compiled by the EEA under the first subparagraph may be based on a positive identification of an emerging risk or on an uncertainty in the data leading to a potential positive identification of an emerging risk. Text Origin: Commission Proposal
Article 19(3)				
257	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals ***obtained pursuant to this Regulation or*** from the field falling within their mandate and provide this data to the EEA.	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate***, including data obtained pursuant to this Regulation,*** and provide this data to the EEA. Text Origin: EP Mandate
Article 19(4)				
258	4. The EEA shall draw up an annual report, compiling and analysing the data on early	4. The EEA shall draw up an annual report, compiling and analysing the data on early	4. The EEA shall draw up an annual report, compiling and analysing the data on early	4. The EEA shall draw up an annual report, compiling and analysing the data on early

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals.	warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by ... [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals. ***Within six months of the presentation of the report, the Authorities shall undertake regulatory, policy or enforcement actions accordingly or provide justification if they decide not to proceed with any action related to any of the early warning signals identified by the report, including an assessment of the possible consequences of non-action.***	warning signals gathered in accordance with paragraphs 2 and 3. ~~[~~The first report shall be prepared by [***OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation***~~OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation~~]. The EEA shall present this report to the ~~Commission, relevant Union agencies and Member State competent~~**Authorities. The** Authorities ~~for consideration of the need for~~**shall consider undertaking** regulatory or policy **actions accordingly and justify if they decide not to proceed with any** action related to the early warning signals.	warning signals gathered in accordance with paragraphs 2 and 3. ~~[~~The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation~~]~~. The EEA shall present this report to the ~~Commission, relevant Union agencies and Member State competent~~***Authorities. Within nine months of the presentation of the report, the*** Authorities ~~*for consideration of the need for*~~***shall considerundertaking*** regulatory ~~*or*~~**,** policy ***or enforcement actions accordingly or provide justification if they decide not to proceed with any*** action ~~*related to the early warning signals*~~.
Article 19(4a)				
258a		***4a. Where the data analysis indicates there is a risk that warrants urgent action, the EEA shall inform the authorities without undue delay.***		*deleted*

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Article 19(5)				
259	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.	5. The EEA shall make all ~~*relevant*~~ data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.	5. The EEA shall make all relevant data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.	5. The EEA shall make all ~~*relevant*~~ data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform. Text Origin: EP Mandate
Article 19(5a)				
259a		***5a. The Commission shall take into account, where relevant, the emerging chemical risks identified, in accordance with this Article, in the strategic planning of R&I activities of Regulation (EU) 2021/695[1a].***		*deleted*
Article 20				
260	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks	Article 20 Observatory for specific chemicals with potential contribution to emerging chemical risks Text Origin: Commission Proposal
Article 20(1)				
261	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The	1. The ECHA shall establish, operate and maintain an observatory for specific ***chemicals or groups of*** chemicals that the Commission considers as	1. The ECHA shall establish, operate and maintain an observatory for specific chemicals that the Commission considers as requiring additional scrutiny. The	1. The ECHA shall establish, operate and maintain an observatory for specific ***chemicals or groups of*** chemicals that the Commission considers as

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	observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.	requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.	observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence.	requiring additional scrutiny. The observatory shall include reliable information on the chemicals' properties, safety aspects, uses and market presence. Text Origin: EP Mandate
Article 20(2)				
G 262	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing decision. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.	2. By ... [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing ~~*decision*~~***act***. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.	2. By [***OP please insert date: 6 months after the date of entry into force of this Regulation***~~OP please insert date: 6 months after the date of entry into force of this Regulation~~] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing ~~decision~~ **act**. The Commission shall review the list of selected chemicals regularly **and** adopt any revision thereof by the same means. **Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.**	2. By [***OP please insert date: 6 months after the date of entry into force of this Regulation***~~OP please insert date: 6 months after the date of entry into force of this Regulation~~] the Commission shall adopt and publish a list of the selected chemicals by means of an implementing ~~*decision*~~ ***act***. The Commission shall review the list of selected chemicals regularly ***and*** adopt any revision thereof by the same means. ***Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.*** Text Origin: Council Mandate
Article 20(3)				
G 263	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using	3. The Commission shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using

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	the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.	the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.	the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.	the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale. Text Origin: Commission Proposal
Article 20(4)				
G 264	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall:	4. For the purpose of operating the observatory referred to in paragraph 1, the ECHA shall: Text Origin: Commission Proposal
Article 20(4), point (a)				
G 265	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;	(a) make use of relevant datasets integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;	(a) make use of relevant ~~datasets~~**chemicals data** integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals;	(a) make use of relevant ~~*datasets*~~***chemicals data*** integrated in the common data platform, and compile, analyse and curate further available data on selected chemicals or classes of chemicals; Text Origin: Council Mandate
Article 20(4), point (b)				
G 266	(b) commission studies and, where relevant, use the data generation mechanism established	(b) commission studies and, where relevant, use the data generation mechanism established	(b) commission studies and, where relevant, use the data generation mechanism established	(b) commission studies and, where relevant, use the data generation mechanism established

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	under Article 21 to address knowledge gaps or significant uncertainties;	under Article 21 to address knowledge gaps or significant uncertainties;	under Article 21 to address knowledge gaps or significant uncertainties;	under Article 21 to address knowledge gaps or significant uncertainties; Text Origin: Commission Proposal
Article 20(4), point (c)				
267	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate***, to facilitate the identification of potential further research needs or risk management measures***, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate **the identification of potential further research needs or risk management measures, to facilitate** informed societal discussion and ~~increase~~ public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.	(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate***, to facilitate the identification of potential further research needs or risk management measures***, to facilitate informed societal discussion and increase public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information. Text Origin: EP Mandate
Chapter VI				
268	Chapter VI DATA GENERATION MECHANISM	Chapter VI DATA GENERATION MECHANISM	Chapter VI DATA GENERATION MECHANISM	Chapter VI DATA GENERATION MECHANISM Text Origin: Commission Proposal
Article 21				
269	Article 21	Article 21	Article 21	Article 21

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	Data generation mechanism	Data generation mechanism	Data generation mechanism	Data generation mechanism Text Origin: Commission Proposal
Article 21(1)				
270	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	1. Using the best independent resources available, the ECHA may commission scientific studies to ~~support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.~~ :	1. Using the best independent resources available, the ECHA may commission scientific studies to support the implementation of Union acts on chemicals listed in Annex I**, Part 1,** within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.	1. Using the best independent resources available, the ECHA may commission scientific studies to ~~support the implementation of Union acts on chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy.~~ :
Article 21(1), point (a)				
270a		***(a) support the implementation of Union acts on chemicals or groups of chemicals listed in Annex I within its mandate and to contribute to the support, evaluation or development of a Union chemicals policy;***		***a. support the implementation of Union acts on chemicals or groups of chemicals in Annex I [, Part 1,] within its mandate;*** [part 1]
Article 21(1), point (b)				
270b		***(b) investigate further emerging chemical risks identified in the report referred to in Article 19(4) of this Regulation;***		***b. contribute to the support, evaluation or development of a Union chemicals policy;***
Article 21(1), point (c)				

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270c		***(c) conduct a Union-wide data sampling survey of human biomonitoring in collaboration with Member States.***		***c. investigate further emerging chemical risks identified in the report referred to in Article 19(4) of this Regulation;***
Article 21(2)				
271	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1 ***and Article 20(4), point (b), of this Regulation***. ***Member States may request the Commission to request the ECHA to commission such scientific studies.***	2. The Commission may request the ECHA to commission the scientific studies referred to in paragraph 1.	2. ***Without prejudice to the obligations on duty holders under the Union acts listed in Annex I [, Part 1,]*** the Commission***, in exceptional circumstances of serious controversies or conflicting results,*** may request the ECHA to commission ~~*the*~~ scientific studies ~~*referred to in paragraph 1*~~***with the objective of verifying evidence used in its chemicals assessment process***. ***The studies commissioned may have a wider scope than the evidence subject to verification.*** [part 1]
Article 21(3)				
272	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall ***give priority to the use of non-animal methods, with animal***	3. The ECHA shall only commission scientific studies when results cannot be obtained through ~~existing legal provisions or processes under~~ **any of the** Union **acts on chemicals** ~~legislation~~ listed in Annex I**, *Part 1***. It shall not commission studies	3. ***Upon request by*** the ~~*ECHA shall only*~~ Commission***, the ECHA shall commission the*** scientific studies ~~*when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not*~~

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		testing on vertebrate animals used only as a last resort. It shall not commission studies with a predominant research objective. ***ECHA shall consult the chemical data platform in order to avoid unnecessary duplication of studies.***	with a predominant research objective.	~~*commission studies with a predominant research objective*~~***referred to in paragraph 1 and paragraph 2***.
Article 21(3a)				
272a		***3a. The ECHA may request from a business operator a sample of a substance, where such sample is indispensable to perform the scientific study referred to in paragraph 1. The request shall be duly justified and any handling of the substance shall be in accordance with applicable confidentiality and data protection rules under relevant Union law. The relevant business operator shall, upon a request from the ECHA, provide the requested sample to the ECHA or to any body commissioned by the ECHA to perform the scientific study.***		***3a. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall give priority to the use of validated non-animal methods, with animal testing on vertebrate animals used only as a last resort. It shall not commission studies with a predominant research objective.***
Article 21(4)				
273	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.	4. The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes.

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Article 21(5)				
G 274	5. The ECHA shall commission these scientific studies in an open and transparent manner.	5. The ECHA shall commission these scientific studies in an open and transparent manner. ***The ECHA shall publish, on its website, the proposal for the study it intends to commission.***	5. The ECHA shall commission these scientific studies in an open and transparent manner. **The ECHA shall consult Member States prior to commissioning those scientific studies.**	5. The ECHA shall commission these scientific studies in an open and transparent manner. ***The ECHA shall consult Member States prior to commissioning those scientific studies.*** G
Article 21(6)				
G 275	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002.	6. The ECHA and the EFSA shall closely cooperate with each other on the planning and commissioning of scientific studies undertaken by the ECHA in accordance with paragraph 1 and of studies undertaken by the EFSA in accordance with Article 32 of Regulation (EC) No 178/2002. Text Origin: Commission Proposal G
Article 21(6a)				
G 275a		***6a. Without prejudice to the obligation on applicants to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances of serious controversies or conflicting results, may request the ECHA to***		***6a. The ECHA may request a sample of a substance or mixture necessary for performing the scientific studies referred to in paragraph 1 from a business operator manufacturing, importing, formulating or placing such substance or mixture on the market. In order to request a*** G

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		commission scientific studies with the objective of verifying evidence used in its hazard and risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.		***sample, the ECHA shall send a draft request to the business operator explaining the request and specifying the quantity and form of the sample as well as the time within which the sample shall be provided. The ECHA may also ask the business operator to provide substance or mixture characterisation. The ECHA shall inform the business operator of its right to comment within 30 days of receipt of the request. Any such comment received shall be taken into account by the ECHA who shall confirm or amend the request. The business operator shall act upon receipt of the that request and shall, as the case may be, provide the requested sample free of charge to the ECHA or to anyone commissioned by the ECHA to perform the scientific study within the deadline set by ECHA. The business operator may request the ECHA not to disclose certain characterisation information of the provided sample if he demonstrates that the disclosure would undermine the protection of its commercial interests. If the ECHA deems the***

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				request is justified, that information shall be considered confidential and shall not be made available to the public.
Article 21(6b)				
275b		***6b. Every five years, the ECHA, in cooperation with the EFSA, shall commission a Union-wide human biomonitoring study that covers all Member States.***		*deleted* see new art 21a agreed
Article 21(6c)				
275c		***6c. Member States shall cooperate with and support the ECHA and EFSA in the organisation of any human biomonitoring study within their territories, to ensure sampling and collection of the data, and adequate representativeness and quality of the data. The human biomonitoring studies shall adhere to ethical and confidentiality standards.***		*deleted* see art 21a agreed
Article 21(7)				
276	*7.* The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.	7. The ECHA shall make the results of the scientific studies performed under this Article available through the common data platform.

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				Text Origin: Commission Proposal
Article 21a				
276a				***Article 21a*** ***Human biomonitoring study***
Article 21a(1)				
276b				***1. At the latest by [OP: please insert 4 years after entry into force], the ECHA and EFSA, in cooperation with the EEA, shall, in the context of the data generation mechanism referred to in Article 21, commission a Union-wide human biomonitoring study covering all Member States.***
Article 21a(2)				
276c				***2. Member States shall cooperate with the ECHA, the EFSA and the EEA in the planning and organisation of the human biomonitoring study and provide the necessary technical assistance and administrative support to the parties contracted by the ECHA or EFSA and performing the sampling in order to enable sampling in their territories and to ensure adequate representativeness of the samples. The human biomonitoring studies***

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				shall adhere to ethical and confidentiality standards.

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Chapter VII				
277	Chapter VII NOTIFICATION OF STUDIES	Chapter VII NOTIFICATION OF STUDIES	Chapter VII NOTIFICATION OF STUDIES	Chapter VII NOTIFICATION OF STUDIES Text Origin: Commission Proposal
Article 22				
278	Article 22 Notification of studies	Article 22 Notification of studies	Article 22 Notification of studies	Article 22 Notification of studies Text Origin: Commission Proposal
Article 22(1)				
279	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without ~~*undue*~~ delay, any ***information referred to in paragraph 2 related to any*** studies ***that generate data*** on chemicals ***which*** they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment~~*, prior to placing on the market*~~, under the Union acts listed in Annex I. ~~*However, business operators shall not notify to the Database of Study Notifications referred to in Article*~~	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9,~~, without undue delay, any~~ **within one month from the date of the commissioning, any** studies **that generate**~~on~~ chemicals **data which** they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment ~~, prior to placing on the market,~~ under the Union acts listed in Annex I**, part 1**. However, business operators shall not notify to the Database of Study	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9,~~,~~ without~~*undue*~~ delay, any studies ***that generate***~~*on*~~ chemicals ***data which*** they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment ~~*, prior to placing on the market,*~~ under the Union acts listed in Annex I**, *part 1***. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be

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	under Article 32b of Regulation (EC) No 178/2002.	~~*9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.*~~	Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002, **study falls under the notification obligation of paragraph 3. At the time of the commissioning of a study, business operators shall inform the laboratory or testing facility in which the study is carried out that this study falls under the notification obligation of paragraph 3.**	notified under Article 32b of Regulation (EC) No 178/2002. ***At the time of the commissioning of a study, business operators shall inform the laboratory or testing facility in which the study is carried out that this study falls under the notification obligation of paragraph 3.*** Text Origin: Council Mandate
Article 22(1a)				
G	279a	***Business operators shall not notify to the Database of Study Notifications referred to in Article 9:***		*deleted*
Article 22(1a), point (a)				
G	*279b*	***(a) in the case of studies that are to be notified under Article 32b of Regulation (EC) No 178/2002;***		*deleted*
Article 22(1a), point (b)				
G	*279c*	***(b) scientific studies conducted only for research purposes that are not commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, or that***		*deleted*

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		are not part of a risk or safety assessment under the Union acts listed in Annex I.		
Article 22(1a), a				
G	*279d*	***Business operators shall provide a valid justification for the late notification of studies in accordance with this paragraph.***		*deleted* Text Origin: EP Mandate
Article 22(2)				
G	*280*	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates, and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the **identity of the chemical(s) concerned,** title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates, and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006. Text Origin: EP Mandate
Article 22(3)				
G	281	3. Laboratories and testing facilities shall also, without undue delay, notify any study	3. Laboratories and testing facilities shall also, without ~~*undue*~~ delay, notify any	3. Laboratories and testing facilities shall also, without undue delay, notify any study	3. Laboratories and testing facilities shall also, without ~~*undue*~~ delay, notify any ~~*study*~~***information***

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	commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	~~study~~***information referred to in paragraph 2 related to studies*** commissioned by business operators to support ~~a~~***an application, notification or*** regulatory dossier ~~on which an Agency is required to provide a scientific output, including a scientific opinion~~***notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that they commission as part of a risk or safety assessment***, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	commissioned by business operators to support ~~a~~**an application, notification or** regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I**, part 1**. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	***referred to in paragraph 2 related to studies*** commissioned by business operators to support ~~a~~***an application, notification or*** regulatory dossier ~~on which an Agency is required to provide a scientific output, including a scientific opinion~~***notified or submitted to an Authority, as well as any studies on chemicals on their own or in products that they commission as part of a risk or safety assessment***, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. Text Origin: EP Mandate
Article 22(4)				
G 282	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** title, scope, intended starting and planned completion	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the **identity of the chemical(s) concerned,** title, scope, intended starting and planned completion dates of any test they carry out, as well as the	4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the ***following information: the identity of the chemicals concerned,*** title, scope, intended starting and planned completion G

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	name of the business operator who commissioned the test.	dates of any test they carry out, as well as the name of the business operator who commissioned the test.	name of the business operator who commissioned the test.	dates of any test they carry out, as well as the name of the business operator who commissioned the test. Text Origin: EP Mandate
Article 22(5)				
283	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.	5. Paragraphs 3 and 4 shall apply, mutatis mutandis, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.	5. Paragraphs 3 and 4 shall apply, ***mutatis mutandis***~~mutatis mutandis~~, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries.	5. Paragraphs 3 and 4 shall apply, ***mutatis mutandis***~~*mutatis mutandis*~~, to laboratories and testing facilities located in third countries insofar as set out in relevant agreements with those third countries. Text Origin: Council Mandate
Article 22(6)				
284	6. The obligations set under this article shall apply from [OP please insert date: 24 months after the date of entry into force of this Regulation].	6. The obligations set under this article shall apply from [OP please insert date: ~~24~~***18*** months after the date of entry into force of this Regulation].	6. The obligations set under this article shall apply from [***OP please insert date: 24 months after the date of entry into force of this Regulation***~~OP please insert date: 24 months after the date of entry into force of this Regulation~~].	6. The obligations set under this article shall apply from [OP please insert date: ~~24~~***22*** months after the date of entry into force of this Regulation]. Text Origin: Commission Proposal
Article 22(6a)				
284a			**6a. Member States may allow for exemptions from the obligations set out under paragraphs 1 to 5 of this Article for studies conducted in the**	***6a. Member States may allow for exemptions from the obligations set out under paragraphs 1 to 5 of this Article***

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			interest of national security and defence.	***for studies conducted in the interest of defence.*** ***Where the Union legislation listed in Annex I provides that Member States may allow for exemptions from the obligations of one of these acts in the interests of national security, Member States may allow for exemptions from the obligations set out under paragraphs 1 to 5 of this Article.***
Article 22(7)				
285	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.	7. The ECHA***, in close cooperation with the EFSA and in consultation with stakeholders,*** shall lay down the practical arrangements for implementing the provisions of this Article.	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.	7. The ECHA***, in close cooperation with the EFSA and in consultation with stakeholders,*** shall lay down the practical arrangements for implementing the provisions of this Article. Text Origin: EP Mandate
Chapter VIII				
286	Chapter VIII DELEGATED POWERS	Chapter VIII DELEGATED POWERS ***AND COMMITTEE PROCEDURE***	Chapter VIII DELEGATED POWERS	Chapter VIII DELEGATED POWERS ***AND COMMITTEE PROCEDURE*** Text Origin: EP Mandate
Article 23				
287	Article 23 Amendment of Annexes I, II and III	Article 23 Amendment of Annexes I, II and III	Article 23 Amendment of Annexes I, II and III	Article 23 Amendment of Annexes I, II and III

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Article 23(1)				
288	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.	1. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex I in order to adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it new Union acts under which relevant chemicals data is generated or submitted.	1. **In order to keep Annex I complete, since it lists all the Union acts under which chemicals data is generated or submitted to the Agencies or to the Commission, and in order to keep the common data platform up to date, as soon as new Union acts under which chemicals data is generated or submitted enter into force or an existing Union act is amended to the extent of introducing provisions on the generation or submission of data,** the Commission ~~is empowered to~~**shall** adopt delegated acts in accordance with Article 24 to amend Annex I in order to ~~adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it~~**list those** new Union acts ~~under which relevant chemicals data is generated or submitted~~**, if the new Union act did not amend Annex I**.	1. ***In order to keep Annex I complete, since it lists all the Union acts under which chemicals data is generated or submitted to the Agencies or to the Commission, and in order to keep the common data platform up to date, as soon as new Union acts under which chemicals data is generated or submitted enter into force or an existing Union act is amended to the extent of introducing provisions on the generation or submission of data,*** the Commission ~~*is empowered to*~~***shall*** adopt delegated acts in accordance with Article 24 to amend Annex I in order to ~~*adjust the content of that Annex to technical and scientific progress in the field of chemicals or, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it*~~***list those*** new Union acts ~~*under which relevant chemicals data is generated or submitted*~~***, if the new Union act did not amend Annex I***. Text Origin: Council Mandate

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Article 23(2)				
G 289	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by adding, where relevant, new categories of data types.	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II by ***extending it to additional active substances, and by*** adding ~~*, where relevant,*~~ new categories of data types***, subject to the outcome of the review in Article 26a(2)***.	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II **to this Regulation** by adding~~, where relevant, new categories of data types~~ **new reference values derived under Union legislation on medicinal products, taking into account advances in digitalisation and interoperability as well as the values' relevance for other chemicals policy and regulatory areas**.	2. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II ***to this Regulation*** by adding~~, where relevant, new categories of data types~~ ***new reference values derived under Union legislation on medicinal products, taking into account advances in digitalisation and interoperability as well as the values' relevance for other chemicals policy and regulatory areas***. Text Origin: Council Mandate
Article 23(3)				
G 290	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.	3. The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Annex III in order to adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it Union acts relevant for data on new regulatory processes on chemicals.	3. **In order to keep Annex III complete, since it lists all the Union acts under which regulatory processes on chemicals or groups of chemicals are undertaken by Member States' competent authorities, the ECHA, the EEA, the EFSA, the EU-OSHA, and the Commission, and in order to keep the common data platform up to date, as soon as new Union acts under which new regulatory processes are established enter into force or an existing Union	3. ***In order to keep Annex III complete, since it lists all the Union acts under which regulatory processes on chemicals or groups of chemicals are undertaken by Member States' competent authorities, the ECHA, the EEA, the EFSA, the EU-OSHA, and the Commission, and in order to keep the common data platform up to date, as soon as new Union acts under which new regulatory processes are established enter into force or an existing Union act is amended to***

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			act is amended to the extent of establishing new regulatory procedures, the Commission ~~is empowered to~~**shall** adopt delegated acts in accordance with Article 24 to amend Annex III in order to ~~adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it~~**list those new** Union acts ~~relevant for data on new regulatory processes on chemicals~~**, if the new Union act did not amend Annex III**.	***the extent of establishing new regulatory procedures,*** the Commission ~~*is empowered to*~~***shall*** adopt delegated acts in accordance with Article 24 to amend Annex III in order to ~~*adjust the content of that Annex to technical and scientific and technical progress in the field of chemicals and, where the development of Union chemicals legislation so requires, to supplement that Annex by adding to it*~~***list those new*** Union acts ~~*relevant for data on new regulatory processes on chemicals*~~***, if the new Union act did not amend Annex III***. Text Origin: Council Mandate
Article 23(3a)				
290a				***3a. The Commission shall adopt delegated acts in accordance with Article 24, where necessary to keep Annex IIIb as complete as possible, and to keep the common data platform up to date, to amend Annex IIIb by adding***
Article 23(3a), point (a)				
290b				***(a) any new Union act under which data on chemicals in articles or products is generated***

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				or submitted, as soon as it enters into force, unless it contains a provision adding that act to Annex IIIb;
Article 23(3a), point (b)				
290c				***(b) any existing Union act listed in Annex I which is amended in such a way that data on chemicals in articles or products is generated or submitted, as soon as the respective amending act enters into force, unless the amending act contains a provision adding that act to Annex IIIb; or***
Article 23(3a), point (c)				
290d				***(c) any existing Union act listed in Annex I for which it has become apparent from further verification that data on chemicals in articles or products is generated or submitted under it.***
Article 24				
291	Article 24 Exercise of the delegation	Article 24 Exercise of the delegation	Article 24 Exercise of the delegation	Article 24 Exercise of the delegation Text Origin: Commission Proposal

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Article 24(1)				
292	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. Text Origin: Commission Proposal
Article 24(2)				
293	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.	2. The power to adopt delegated acts referred to in Article 23 shall be conferred on the Commission for a period of five years from [OP please insert: the date of the entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.	2. The power to adopt delegated acts referred to in **Article 3(3) and** Article 23 shall be conferred on the Commission for a period of five years from [***OP please insert: the date of the entry into force of this Regulation***~~OP please insert: the date of the entry into force of this Regulation~~]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.	2. The power to adopt delegated acts referred to in ***Article 3(3) and*** Article 23 shall be conferred on the Commission for a period of five years from [***OP please insert: the date of the entry into force of this Regulation***~~*OP please insert: the date of the entry into force of this Regulation*~~]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.

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Article 24(3)				
294	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in **Article 3(3) and** Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the ***Official Journal of the European Union*** ~~Official Journal of the European Union~~ or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in ***Article 3(3) and*** Article 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the ***Official Journal of the European Union*** ~~*Official Journal of the European Union*~~ or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. Text Origin: Council Mandate
Article 24(4)				
295	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. Text Origin: Commission Proposal
Article 24(5)				

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296	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. Text Origin: Commission Proposal
Article 24(6)				
297	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to **Article 3(3) and** Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to ***Article 3(3) and*** Article 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council. Text Origin: Council Mandate
Article 24a				
297a		***Article 24a*** ***Committee procedure***	**Article 24a** **Committee procedure**	***Article 24a*** ***Committee procedure***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: EP Mandate

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 24a(1)				
297b		***1. The Commission shall be assisted by a Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011[1].*** ***1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementaing powers (OJ L 55, 28.2.2011, p. 13).***	**1. The Commission shall be assisted by a committee . This committee shall be a committee within the meaning of Regulation (EU) No 182/2011.**	***1. The Commission shall be assisted by a Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011[1].*** ***1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementaing powers (OJ L 55, 28.2.2011, p. 13).*** Text Origin: EP Mandate
Article 24a(2)				
297c		***2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***	**2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.**	***2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.*** Text Origin: EP Mandate
Chapter IX				
298	Chapter IX ENFORCEMENT AND PENALTIES	Chapter IX ENFORCEMENT AND PENALTIES	Chapter IX ENFORCEMENT AND PENALTIES	Chapter IX ENFORCEMENT AND PENALTIES Text Origin: Commission Proposal
Article 25				
299	Article 25	Article 25	Article 25	Article 25

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Enforcement	Enforcement ***and cooperation on compliance***	~~Enforcement~~ **Cooperation on compliance**	~~*Enforcement*~~ ***Cooperation on compliance*** Text Origin: Council Mandate
Article 25, first paragraph				
300	The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.	The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.	The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22.	The Agencies shall cooperate with Member States' enforcement authorities and exchange information on the compliance, by business operators and laboratories, with the obligation to notify studies in accordance with Article 22. Text Origin: Commission Proposal
Article 26				
301	Article 26 Penalties for non-compliance	Article 26 Penalties for non-compliance	Article 26 Penalties for non-compliance	Article 26 Penalties for non-compliance Text Origin: Commission Proposal
Article 26(1)				
302	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations ~~laid out in~~ **to inform and notify in accordance with** Article 22 and shall take all necessary measures to ensure that they are implemented. The	1. Member States shall introduce penalties for non-compliance, by business operators and laboratories, with the obligations laid out in Article 22 and shall take all necessary measures to ensure that they are implemented. The penalties

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	provided for shall be effective, proportionate, and dissuasive.	provided for shall be effective, proportionate, and dissuasive.	penalties provided for shall be effective, proportionate, and dissuasive.	provided for shall be effective, proportionate, and dissuasive. Text Origin: Commission Proposal
Article 26(2)				
303	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them.	2. Member States shall notify the Commission of those rules and of those measures by 30 June 2025 and shall notify to the Commission without delay any subsequent amendment affecting them. Text Origin: Commission Proposal
Chapter X				
303a			**Chapter X** **REVIEW AND ENTRY INTO FORCE**	***Chapter X*** ***REVIEW AND ENTRY INTO FORCE*** Text Origin: Council Mandate
Article 26a				
303b		***Article 26a*** ***Reports and review***	**Article 26a** **Review**	***Article 26a*** ***Reports and review*** Text Origin: EP Mandate
Article 26a(1)				
303c		***1. No later than … [OP: please insert 18 months after the entry into force of this Regulation], the Commission***		*deleted*

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		shall assess the workload and further needs of the Agencies, stemming from the additional tasks related to the inclusion of information on substances in products and information on alternatives, and the inclusion of information on medicinal products resulting from procedures concluded before the entry into force of this Regulation, and where appropriate, provide it with adequate further resources.		
Article 26a(2), first subparagraph				
G	*303d*		**1. No later than … [OP: please insert six years after the entry into force of this Regulation], the Commission shall assess and adopt a report whether it is appropriate to include in the common data platform the following chemicals data relating to medicinal products pursuant to Article 3(2a) of this Regulation:**	***1. No later than … [OP: please insert six years after the entry into force of this Regulation], the Commission shall assess and adopt a report on the appropriateness and cost-benefit balance of including in the common data platform the following chemicals data relating to medicinal products pursuant to Article 3(2a) of this Regulation:***
Article 26a(2), first subparagraph, point (a)				
G	303e		**(a) chemicals data that the EMA holds resulting from procedures concluded before the entry into force of this**	***(a) (a) new categories of data types;*** Text Origin: Council Mandate

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Regulation and new categories of data types;	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 26a(2), first subparagraph, point (b)				
303f			**(b) chemicals data on substances other than active substances;**	***(b) chemicals data on substances other than active substances;*** Text Origin: Council Mandate
Article 26a(2), first subparagraph, point (c)				
303g			**(c) chemicals data on active substances not meeting the criteria referred to in Article 3(2a)(b);**	***(c) chemicals data on active substances not meeting the criteria referred to in Article 3(2a)(b);*** Text Origin: Council Mandate
Article 26a(2), first subparagraph, point (d)				
303h			**(d) chemicals data collected and submitted in the context of Union acts listed in Annex I and held by national competent authorities and not by the Agencies;**	***(d) chemicals data collected and submitted in the context of Union acts listed in Annex I, part 2, and held by national competent authorities and not by the Agencies.*** Text Origin: Council Mandate
Article 26a(2), second subparagraph				
303i		***2. No later than ... [OP: please insert the date: 4 years after the entry into force of this Regulation], the Commission shall assess the costs and benefits of extending the common data platform to additional medicinal active substances and of adding new categories of data types.***	**The cost-benefit balance of incorporating additional data in the common data platform shall be assessed.**	*deleted* Text Origin: Council Mandate

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Article 26a(3)					
G	*303j*		***3. No later than ... [OP: please insert the date: 4 years after the entry into force of this Regulation], the Commission shall assess the feasibility, in collaboration with scientific and academic publishers, of harmonised reporting and of enabling the integration of relevant contents from scientific journals and publications into the common data platform, in order to increase further the uptake of research data into the hazard and risk assessment of chemicals.***		***2. No later than ... [OP: please insert the date: 4 years after the entry into force of this Regulation], and taking into account the work done by the Organisation for Economic Co-operation and Development on the generation, reporting, and use of peer-reviewed published research data for regulatory assessments, the Commission shall assess whether to initiate collaboration with scientific and academic publishers and operators of databases containing contents of peer-reviewed journals on:***	G
Article 26a(3), point (a)					
G	303k			***(a) harmonised reporting of peer-reviewed published research data to scientific peer-reviewed journals; and***	G
Article 26a(3), point (b)					
G	303l			***(b) the use of tools to search, screen and extract peer-reviewed published research data relevant for chemicals assessments from databases containing contents of peer-reviewed journals.***	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 26a(4)				
303m		***4. No later than … [OP: please insert 4 years after the entry into force of this Regulation], the Commission shall report on the resources needed to address key areas of regulatory challenge. The Commission shall present that report to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.***		*deleted*
Article 26a(5), first subparagraph				
303n				***3. Within two years after the finalisation of the human biomonitoring study referred to in Article 21a, the Commission shall assess the appropriateness of requiring the ECHA and the EFSA, in cooperation with the EEA, to commission regular human biomonitoring studies, as well as the resource needs for and modalities to involve Member States in such studies.***
Article 26a(5), second subparagraph				
303o				***On the basis of the assessment carried out in accordance with the first subparagraph, the***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Commission may present a legislative proposal.
Article 26a(4)				
303p		***5. By ... [OP: please insert date: 5 years after the entry into force of this Regulation], the Commission shall draw up a report. That report shall assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has contributed sufficiently to achieve its objectives, in particular to allow a better reuse of data across the Union acts referred to in Annex I. The Commission shall present this report to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions.***	**2. By … [OP: please insert ten years after the entry into force of this Regulation], the Commission shall carry out a general review of this Regulation, and present a report to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal. The report shall assess whether this Regulation has contributed sufficiently to achieve its objectives, in particular to allow a better reuse of data across the Union acts referred to in Annex I.**	***4. By … [OP: please insert 6 years after the entry into force of this Regulation], the Commission shall carry out a general review of this Regulation, and present a report to the European Parliament and the Council, accompanied, if appropriate, by a legislative proposal. The report shall assess the progress made on the implementation and functioning of the common data platform, whether this Regulation has contributed sufficiently to achieve its objectives, in particular to allow a better reuse of data across the Union acts referred to in Annex I, and the appropriateness of resource allocation to the Agencies and the Commission.***
Article 26a(4)				
303q		***6. Based on the findings of the reports and assessments referred to in paragraphs 2 and 4, the Commission shall submit legislative proposals to the European Parliament and to the Council in this regard.***		*deleted*

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Article 27				
304	Article 27 Entry into force and application in time	Article 27 Entry into force and application in time	Article 27 Entry into force and application in time	Article 27 Entry into force and application in time Text Origin: Commission Proposal
Article 27, first paragraph				
305	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Regulation shall enter into force on the twentieth day following that of its publication in the ***Official Journal of the European Union*** ~~Official Journal of the European Union~~.	This Regulation shall enter into force on the twentieth day following that of its publication in the ***Official Journal of the European Union*** ~~*Official Journal of the European Union*~~. Text Origin: Council Mandate
Article 27, second paragraph				
306	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States. Text Origin: Commission Proposal
Formula				
307	Done at Brussels,	Done at Brussels,	Done at Brussels,	Done at Brussels, Text Origin: Commission Proposal
Formula				
308	For the European Parliament	For the European Parliament	For the European Parliament	For the European Parliament

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Formula				
309	The President	The President	The President	The President Text Origin: Commission Proposal
Formula				
310	For the Council	For the Council	For the Council	For the Council Text Origin: Commission Proposal
Formula				
311	The President	The President	The President	The President Text Origin: Commission Proposal
Annex I				
312	Annex I	Annex I	Annex I	Annex I Text Origin: Commission Proposal
Annex I, first paragraph				
313	Union acts referred to in articles 2, 3, 8, 11, 12, 15, 17, 21, 22 and 23	Union acts referred to in articles 2, 3, 8, 11, 12, 15, 17, 21, 22 and 23	~~Union acts referred to in articles~~**Part 1 UNION ACTS REFERRED TO IN ARTICLES** 2, 3, 8, 11, 12, 15, 17, 21, 22 ~~and~~**AND** 23	~~*Union acts referred to in articles*~~***Part 1 - UNION ACTS REFERRED TO IN ARTICLES*** 2, 3, 8, 11, 12, 15, 17, 21, 22 ~~*and*~~***AND*** 23
Annex I, second paragraph				
314	Reference to each Union act listed herein should be understood also	Reference to each Union act listed herein should be understood also	Reference to each Union act listed herein should be understood also	Reference to each Union act listed herein should be understood also

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	as reference to all implementing and delegated acts adopted under that Union act, where relevant.	as reference to all implementing and delegated acts adopted under that Union act, where relevant.	as reference to all implementing and delegated acts adopted under that Union act, where relevant.	as reference to all implementing and delegated acts adopted under that Union act, where relevant. Text Origin: Commission Proposal
Annex I, point 1.				
G 315	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40)	1. Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (OJ L 135, 30.5.1991, p. 40) Text Origin: Commission Proposal
Annex I, point 2.				
G 316	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1)	2. Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p.1) Text Origin: Commission Proposal
Annex I, point 3.				
G 317	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)	3. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)

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				Text Origin: Commission Proposal
Annex I, point 4.				
318	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	4. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste Text Origin: Commission Proposal
Annex I, point 5.				
319	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)	5. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11) Text Origin: Commission Proposal
Annex I, point 6.				
320	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of	6. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)	Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)	Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)	Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50) Text Origin: Commission Proposal
Annex I, point 7.				
321	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)	7. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34) Text Origin: Commission Proposal
Annex I, point 8.				
322	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1)	8. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for the Community action in the field of water policy (OJ L 327, 22.12.2000, p.1) Text Origin: Commission Proposal
Annex I, point 9.				
323	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing	9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)	Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)	Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)	Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1) Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Annex I, point 10.					
G	324	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)	10. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1) Text Origin: Commission Proposal	G
Annex I, point 11.					
G	325	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	11. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) Text Origin: Commission Proposal	G
Annex I, point 12.					
G	326	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51)	12. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51) Text Origin: Commission Proposal	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, point 13.				
327	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)	13. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1) Text Origin: Commission Proposal
Annex I, point 14.				
328	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	14. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29) Text Origin: Commission Proposal
Annex I, point 15.				
329	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1)	15. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1) Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, point 16.				
330	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)	16. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) Text Origin: Commission Proposal
Annex I, point 17.				
331	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)	17. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1) Text Origin: Commission Proposal
Annex I, point 18.				
332	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)	18. Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) Text Origin: Commission Proposal
Annex I, point 19.				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 333	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	19. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4) Text Origin: Commission Proposal
Annex I, point 20.				
G 334	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	20. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3) Text Origin: Commission Proposal
Annex I, point 21.				
G 335	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)	21. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 070, 16.3.2005, p. 1)

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex I, point 22.				
G	336	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1)	22. Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 033, 4.2.2006, p. 1) Text Origin: Commission Proposal
Annex I, point 23.				
G	337	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)	23. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19) Text Origin: Commission Proposal
Annex I, point 24.				
G	338	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the	24. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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)	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)	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)	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) Text Origin: Commission Proposal
Annex I, point 25.				
G 339	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9)	25. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9) Text Origin: Commission Proposal
Annex I, point 26.				
G 340	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of	26. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	certain other substances to foods (OJ L 404, 30.12.2006, p. 26)	certain other substances to foods (OJ L 404, 30.12.2006, p. 26)	certain other substances to foods (OJ L 404, 30.12.2006, p. 26)	certain other substances to foods (OJ L 404, 30.12.2006, p. 26) Text Origin: Commission Proposal
Annex I, point 27.				
341	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)	27. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1) Text Origin: Commission Proposal
Annex I, point 28.				
342	28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)	28. Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 39, 13.2.2008, p. 11)	*deleted*	*deleted*
Annex I, point 29.				
343	*29.* Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of	29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of

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	marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)	marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)	marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)	marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19) Text Origin: Commission Proposal
Annex I, point 30.				
344	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1)	30. Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1) Text Origin: Commission Proposal
Annex I, point 31.				
345	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3)	31. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3) Text Origin: Commission Proposal
Annex I, point 32.				
346	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality	32. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality

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	standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84) Text Origin: Commission Proposal	
Annex I, point 33.					
G	347	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	33. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1) Text Origin: Commission Proposal	G
Annex I, point 34.					
G	348	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of	34. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1) Text Origin: Commission Proposal
Annex I, point 35.				
349	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	35. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7) Text Origin: Commission Proposal
Annex I, point 36.				
350	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	36. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16) Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, point 37.				
G	351	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)	37. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34) Text Origin: Commission Proposal	G
Annex I, point 38.				
G	352	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products	38. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products Text Origin: Commission Proposal	G
Annex I, point 39.				
G	353	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment	39. Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment	G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Information and Observation Network (OJ L 126, 21.5.2009, p. 13)	Information and Observation Network (OJ L 126, 21.5.2009, p. 13)	Information and Observation Network (OJ L 126, 21.5.2009, p. 13)	Information and Observation Network (OJ L 126, 21.5.2009, p. 13) Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, point 40.				
354	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	40. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3) Text Origin: Commission Proposal
Annex I, point 41.				
355	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	41. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1) Text Origin: Commission Proposal
Annex I, point 42.				
356	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)	42. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1)

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex I, point 43.				
G	357	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)	43. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1) Text Origin: Commission Proposal
Annex I, point 44.				
G	358	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71)	44. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71) Text Origin: Commission Proposal
Annex I, point 45.				
G	359	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to	45. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to

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	asbestos at work (OJ L 330, 16.12.2009, p. 28)	asbestos at work (OJ L 330, 16.12.2009, p. 28)	asbestos at work (OJ L 330, 16.12.2009, p. 28)	asbestos at work (OJ L 330, 16.12.2009, p. 28) Text Origin: Commission Proposal
Annex I, point 46.				
G 360	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1)	46. Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1) Text Origin: Commission Proposal
Annex I, point 47.				
G 361	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	47. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59) Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, point 48.				
G 362	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17)	48. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17) Text Origin: Commission Proposal
Annex I, point 49.				
G 363	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1)	49. Regulation (EC) No 66/210 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 027, 30.1.2010, p. 1) Text Origin: Commission Proposal
Annex I, point 50.				
G 364	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)	50. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88) Text Origin: Commission Proposal
Annex I, point 51.				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 365	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)	51. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18) Text Origin: Commission Proposal
Annex I, point 52.				
G 366	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	52. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1) Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Annex I, point 53.					
G	367	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1)	53. Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1) Text Origin: Commission Proposal	G
Annex I, point 54.					
G	368	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)	54. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38) Text Origin: Commission Proposal	G
Annex I, point 55.					
G	369	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60)	55. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the import and export of hazardous chemicals (OJ L 201, 27.7.2012, p. 60) Text Origin: Commission Proposal	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Annex I, point 56.					
G 370	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35)	56. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35) Text Origin: Commission Proposal	G
Annex I, point 57.					
G 371	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1)	57. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1) Text Origin: Commission Proposal	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Annex I, point 58.					
G	372	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1)	58. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1) Text Origin: Commission Proposal	G
Annex I, point 59.					
G	373	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195)	59. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195) Text Origin: Commission Proposal	G
Annex I, point 60.					
G	374	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European	60. Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)	Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)	Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1)	Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1) Text Origin: Commission Proposal
Annex I, point 61.				
G 375	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1)	61. Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1) Text Origin: Commission Proposal
Annex I, point 62.				
G 376	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations	62. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations

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	(EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)	(EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)	(EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1)	(EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095, 7.4.2017, p. 1) Text Origin: Commission Proposal
Annex I, point 63.				
377	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009	63. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

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	and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)	and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)	and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)	and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1) Text Origin: Commission Proposal
Annex I, point 64.				
G 378	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1)	64. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1) Text Origin: Commission Proposal
Annex I, point 65.				
G 379	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).	65. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1). Text Origin: Commission Proposal
Annex I, point 66.				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
G	380	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1)	66. Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1) Text Origin: Commission Proposal	G
Annex I, point 67.					
G	381	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)	67. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45) Text Origin: Commission Proposal	G
Annex I, point 68.					
G	382	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	68. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	G

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Annex I, point 69.				
383	69. Regulation (EU) …/… of the European Parliament and of the Council on nature restoration (OJ …/ELI: … [OP: please add number and publication reference].	69. Regulation (EU) …/… of the European Parliament and of the Council on nature restoration (OJ …/ELI: … [OP: please add number and publication reference].	69. Regulation (EU) …/… of the European Parliament and of the Council on nature restoration (OJ …/ELI: … [OP: please add number and publication reference].	69. Regulation (EU) …/… of the European Parliament and of the Council on nature restoration (OJ …/ELI: … [OP: please add number and publication reference]. Text Origin: Commission Proposal
Annex I, point 70.				
384	70. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].	70. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].	70. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].	70. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference]. Text Origin: Commission Proposal
Annex I, point 70a.				
384a		***70a. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and***		***70a. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)		*repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)* Text Origin: EP Mandate
Annex I, third paragraph				
384b			**Part 2 UNION ACTS REFERRED TO IN ARTICLE 3(2a)**	
Annex I, fourth paragraph				
384c			**Reference each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.**	*Reference each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.* Text Origin: Council Mandate
Annex I, point 71.				
384d			**71. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).**	*71. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).* Text Origin: Council Mandate
Annex I, point 72.				
384e			**72. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the**	*72. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the*

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	***authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).*** Text Origin: Council Mandate
Annex I, point 73.				
G	384f		**73. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).**	***73. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).*** Text Origin: Council Mandate
Annex I, point 74.				
G	384g		**74. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No**	***74. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No***

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).	***726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).*** Text Origin: Council Mandate
Annex II				
385	Annex II	Annex II	Annex II	Annex II Text Origin: Commission Proposal
Annex II, first paragraph				
386	Union acts referred to in Articles 2, 3, 12, 17 and 23 and reference values referred to in Article 8	Union acts referred to in Articles 2, 3, 12, 17 and 23 and reference values referred to in Article 8	~~Union acts referred to in Articles 2, 3, 12, 17 and 23 and reference values referred to in Article~~ **REFERENCE VALUES REFERRED TO IN ARTICLE** 8	~~*Union acts referred to in Articles 2, 3, 12, 17 and 23 and reference values referred to in Article*~~ ***REFERENCE VALUES REFERRED TO IN ARTICLE*** 8 Text Origin: Council Mandate
Annex II, Part I				
387	Part I Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products	Part I Part 1 - Specific data on relevant active substances to be identified in accordance with Article 4(5)(b) falling under the scope of this Regulation for the purposes of Article 3 for human and veterinary medicinal products	*deleted*	
Annex II, point 1.				
388	*1.* Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive	1. Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive	*deleted*	

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2001/83/EC of the European Parliament and of the Council[1] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[2]; _____ 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). 2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	2001/83/EC of the European Parliament and of the Council[1] and Regulation (EC) No 726/2004 of the European Parliament and of the Council[2]; _____ 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). 2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).		
Annex II, point 2.				
G	*389*	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council[1]; and _____ 1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).	2. Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council[1]; and _____ 1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).	*deleted*	G
Annex II, point 3.				

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	*390*	*3.* Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council[1]. _____ 1. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).	3. Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council[1]. _____ 1. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).	*deleted*	G
Annex II, second paragraph				
G	*391*	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.	These data shall be limited to data ***related to chemicals and materials used in medicinal products and*** submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. ~~*Where relevant*~~***No later than ... [OP please insert date: eight years after the date of entry into force of this Regulation]***, the data held by the EMA resulting from procedures concluded before the entry into force of this Regulation ~~*may also*~~	*deleted*	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		~~*be considered for inclusion*~~***shall be included*** into the common data platform.		
Annex II, Part II				
G	*392*	*Part II* Part 2 - Reference values to be included in the repository of reference values following Article 8(3)	Part II Part 2 - Reference values to be included in the repository of reference values following Article 8(3)	~~*Part II*~~ ~~*Part 2 -*~~ Reference values to be included in the repository of reference values following Article 8(3) Text Origin: Council Mandate
Annex II, point 4.				
G	393	4. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.	~~*4.*~~***1*** Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.	**41**. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council.	4. Predicted no effect concentrations derived as part of the environmental risk assessment under Directive 2001/83/EC of the European Parliament and of the Council, Regulation (EC) No 726/2004 of the European Parliament and of the Council and Regulation (EU) 2019/6 of the European Parliament and of the Council. Text Origin: Commission Proposal
Annex II, third paragraph				
G	394	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the	These data shall be limited to data ***related to chemicals and materials used in medicinal products and*** submitted to the EMA in the context of the relevant procedures that are concluded after	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the	These data shall be limited to data submitted to the EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation. Where relevant, data held by the

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.	the date of entry into force of this Regulation. ~~*Where relevant*~~***No later than ... [OP please insert date: eight years after the date of entry into force of this Regulation], the*** data held by the EMA resulting from procedures concluded before the ~~*date of*~~ entry into force of this Regulation shall ~~*also be considered for inclusion*~~***be included*** into the common data platform~~.~~	EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform.	EMA resulting from procedures concluded before the date of entry into force of this Regulation shall also be considered for inclusion into the common data platform. Text Origin: Council Mandate
Annex III				
395	Annex III	Annex III	Annex III	Annex III Text Origin: Commission Proposal
Annex III, first paragraph				
396	Union acts referred to in Articles 2, 10 and 23	Union acts referred to in Articles 2, 10 and 23	~~Union acts referred to in Articles 2, 10 and~~**UNION ACTS REFERRED TO IN ARTICLES 2, 10 AND** 23	Union acts referred to in Articles 2, 10 and 23 Text Origin: Commission Proposal
Annex III, second paragraph				
397	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.	Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant. Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
Annex III, point 1.					
G	398	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1)	1. Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.2.1993, p.1) Text Origin: Commission Proposal	G
Annex III, point 2.					
G	399	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	2. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste Text Origin: Commission Proposal	G
Annex III, point 3.					
G	400	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50)	3. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50) Text Origin: Commission Proposal	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, point 4.				
G	401	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11)	4. Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11) Text Origin: Commission Proposal
Annex III, point 5.				
G	402	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)	5. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34) Text Origin: Commission Proposal
Annex III, point 6.				
G	403	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)	6. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p. 1)

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex III, point 7.				
404	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10)	7. Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) Text Origin: Commission Proposal
Annex III, point 8.				
405	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)	8. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29) Text Origin: Commission Proposal
Annex III, point 9.				
406	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)	9. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex III, point 10.				
407	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3)	10. Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 023, 26.1.2005, p. 3) Text Origin: Commission Proposal
Annex III, point 11.				
408	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)	11. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) Text Origin: Commission Proposal
Annex III, point 12.				
409	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater	12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater

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	against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)	against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)	against pollution and deterioration (OJ L 372, 27.12.2006, p. 19)	against pollution and deterioration (OJ L 372, 27.12.2006, p. 19) Text Origin: Commission Proposal
Annex III, point 13.				
G 410	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)	13. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC (OJ L 396, 30.12.2006, p. 1) Text Origin: Commission Proposal G
Annex III, point 14.				
G 411	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic	14. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)	equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)	equipment (WEEE) (OJ L 197, 24.7.2012, p. 38)	equipment (WEEE) (OJ L 197, 24.7.2012, p. 38) Text Origin: Commission Proposal
Annex III, point 15.				
G 412	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84)	15. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84) Text Origin: Commission Proposal
Annex III, point 16.				
G 413	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and	16. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemicals of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)	amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1) Text Origin: Commission Proposal
Annex III, point 17.				
G 414	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	17. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1) Text Origin: Commission Proposal
Annex III, point 18.				
G 415	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7)	18. Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC, and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p.7) Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, point 19.				
416	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16)	19. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16) Text Origin: Commission Proposal
Annex III, point 20.				
417	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)	20. Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34) Text Origin: Commission Proposal
Annex III, point 21.				
418	21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes	21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes	*deleted*	*deleted*

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and food flavourings (OJ L 354, 31.12.2008, p. 1)	and food flavourings (OJ L 354, 31.12.2008, p. 1)		

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, point 22.				
419	*22.* Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3)	22. Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3) Text Origin: Commission Proposal
Annex III, point 23.				
420	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products	23. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products Text Origin: Commission Proposal
Annex III, point 24.				
421	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1)	24. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1) Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, point 25.				
G	422	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1)	25. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1) Text Origin: Commission Proposal
Annex III, point 26.				
G	423	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)	26. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1) Text Origin: Commission Proposal
Annex III, point 27.				
G	424	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)	27. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28)

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex III, point 28.				
425	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)	28. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59) Text Origin: Commission Proposal
Annex III, point 29.				
426	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)	29. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88) Text Origin: Commission Proposal
Annex III, point 30.				
427	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)	30. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, point 31.				
428	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1).	31. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.1.2019, p. 1). Text Origin: Commission Proposal
Annex III, point 32.				
429	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45)	32. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45) Text Origin: Commission Proposal
Annex III, point 33.				
430	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)	33. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1)

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Annex III, point 34.				
431	34. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].	34. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].	34. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference].	34. Regulation (EU) …/… of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 (OJ …/ELI: … [OP: please add number and publication reference]. Text Origin: Commission Proposal
Annex III, point 34a.				
431a		***34a. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)***		***34a. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024)*** Text Origin: EP Mandate
Annex IIIa				
431b		***Annex IIIa Datasets to be included at the date of***		***Annex IIIa Datasets to be included at the date of***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		establishment of the common data platform referred to in Article 3		***establishment of the common data platform referred to in Article 3*** See separate word document
Annex IIIa, paragraph 1				
G	431c	***ECHA REACH: REACH registrations including Chemical Safety Reports (CSR).*** ***ECHA Classification, Labelling and Packaging (CLP): classification and labelling (C&L) inventory.*** ***ECHA Biocidal Products Regulation (BPR): biocidal active substance approval process data.*** ***ECHA Prior Informed Consent (PIC): data on substances subject to PIC the Regulation.*** ***ECHA Persistent Organic Pollutants (POP): (1) List of POPs; (2) List of substances proposed to be included in the POP list of the Stockholm Convention.*** ***ECHA SCIP database: information on Substances of very high concern in articles as such or in complex objects (products) established under the Waste Framework Directive (WFD).***		***All chemicals data of the datasets specified in the table below shall be included in the common data platform, within three years after the date of entry into force of this Regulation. This includes data generated or submitted before the entry into force of this Regulation, unless specified otherwise, as well as data indicated in accordance with Article 5(2) as not being made available to the public under the originating Union act.*** The list of datasets is included in the table in row 431d	G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Commission data from the Digital Product Passport Webportal: information on substances of concern present in products · ***EFSA OpenFoodTox: summary of all EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs.*** ***EFSA Chemical Monitoring Data: chemical monitoring data for pesticides and veterinary medicinal product residues and contaminants data. The individual measurements of chemicals in food/feed and other materials sampled as part of official controls and enforcement activities. Measurements of chemicals in food and feed received from industry or other sources in response to a call for data.*** ***EFSA OpenEFSA: all information related to EFSA's scientific work. Tracking of the risk assessment process from receipt of the dossier to adoption of the opinion. Information available includes the status of***		

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		assessments, dossiers and studies, meeting agendas and minutes, information on experts (DOIs), public consultations). · ***EFSA EU PPP Agency IUCLID: IUCLID dossiers submitted by applicants (industry) under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.*** ***EEA Air Quality: air quality data from a wide range of sources including the current status of Europe's air quality through five different air pollutants (European Air Quality Index), latest measurements from Europe's air quality monitoring network and statistics for air pollutants calculated from officially-verified country data for years until 'X-2'.*** ***EEA Waterbase Water Quality: time series of concentrations of nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters. Records reported under the Water Framework Directive Watch List for chemicals in surface waters.***		

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		EEA Waterbase emissions: time series of emissions of nutrients and hazardous substances to water, reported by EEA member countries and cooperating countries. Data on yearly riverine input loads to transitional, coastal and marine waters. ***EEA Industrial emissions: data reported by Member States in the scope of the E-PRTR Regulation and Industrial Emissions Directive.*** ***EEA National Emission reductions Commitments (NEC) Directive emission inventory data: data on emissions of air pollutants.*** ***EMA human medicinal products data (environmental risk assessment and non-clinical safety data)*** ***EMA veterinary medicinal products (environmental risk assessment and maximum residue limit (MRL) values and MRL assessment data)***		
Annex -1, second paragraph, Table 1				
431d				Table 1
Annex IIIb				
431e				***ANNEX IIIb***

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex IIIb, first paragraph				
G	431f			***UNION ACTS REFERRED TO IN ARTICLE 10A*** G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex IIIb, second paragraph				
G 431g				***Reference to each Union act listed herein shall be understood as a reference to the data on chemicals in articles or products generated or submitted as part of the implementation of the respective Union act.*** G
Annex IIIb, point 1.				
G 431h				***1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC*** G
Annex IIIb, point 2.				
G 431i				***2. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives*** G

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	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex IIIb, point 3.				
G 431j				***3. Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for setting ecodesign requirements for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC*** G

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Draft Agreement Table 1

Dataset	Description	Data provider
Datasets behind dedicated services	Chemicals data covered by:	
	Information Platform for Chemical Monitoring (Article 7) This includes all chemicals data contained in the Information Platform for Chemical Monitoring operated by the Commission before transfer of the operation to ECHA.	Commission
	Repository of reference values (Article 8) This includes the following data: a. regulatory reference values formally adopted under Union acts listed in Annex I, Part 1; b. scientific reference values available in formal opinions delivered under Union acts listed in Annex I; and c. scientific reference values specified in Annex II, Part 2 resulting from relevant procedures that are concluded after the entry into force of this Regulation.	Agencies
	Information on regulatory processes on chemicals (Article 10): This includes the following information: a. information contained in the existing Activities Coordination Tool of the ECHA; b. information on regulatory processes on chemicals available via the existing Open EFSA of the EFSA; and c. other information as provided to the ECHA in accordance with Article 10.	Authorities
	Information on the obligations under Union acts on chemicals (Article 11) This includes information on the obligations under Union acts listed in Annex I, including information available through the existing European Union Legislation Finder of the ECHA.	ECHA
	Repository of standard formats and controlled vocabularies (Article 12) This includes standard formats and controlled vocabularies available in accordance with Article 12.	Agencies, Commission
REACH registrations	Registration dossiers submitted under Title II of the Regulation (EC) 1907/2006	ECHA
CLP Classification and labelling inventory	- Classification and labelling information submitted in registration dossiers under Title II of the Regulation (EC) No 1907/2006 and notified under Title V of the Regulation (EC) No 1272/2008; and - Harmonised classification and labelling entries from Annex VI of Regulation (EC) No 1272/2008.	ECHA
BPR applications for approval and renewal of active substances and	- Applications for approval or renewal of approval of biocidal active substances under Chapter II and III of Regulation (EU) No 528/2012 and available in IUCLID; and -	ECHA

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summaries of biocidal product characteristics	*Summaries of biocidal product characteristics submitted by applicants for Union authorisation under Chapter VIII of Regulation (EU) No 528/2012 and by applicants under Regulation (EU) No 414/2013 and available in IUCLID.*	
DWD applications for inclusion of substances in the European positive lists	*Applications to add new entries, and to amend or remove existing entries from the European positive lists of substances in contact with drinking water, submitted by economic operators or relevant authorities under Article 11 of the Directive (EU) 2020/2184*	*ECHA*
Study notifications	*Study notification information once a corresponding registration, application or other relevant regulatory dossier has been submitted and any confidentiality claims assessed: - from the ECHA database of study notifications under Article 9 of this Regulation; and - the EFSA database referred to in Article 32b of Regulation (EC) No 178/2002 as made available to the ECHA in accordance with Article 9(4) of this Regulation*	*ECHA, EFSA*
OpenFoodTox	*EFSA's chemicals hazard database that compiles, in a structured format, EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs*	*EFSA*
Chemical Monitoring Data	*EFSA chemical monitoring data1 covering multiple regulations under EFSA's remit and including - chemical monitoring data for pesticides and veterinary medicinal product residues and contaminants data; - the individual measurements of chemicals in food/feed and other materials sampled as part of official controls and enforcement activities; - measurements of chemicals in food and feed received from industry; and - other sources in response to a call for data.*	*EFSA*
Food chain	*Food chain application dossiers containing chemicals data submitted through the E-submission Food Chain Platform by applicants under different regulated product areas under Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004, Regulation (EC) No 1924/2006 and Regulation (EU) 2015/2283 and available in structured formats.*	*EFSA*
Applications under PPPR	*Dossiers submitted by applicants under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, including the active substance, maximum residue levels and basic substance submission types and available in IUCLID.*	*EFSA*
AirQuality	*Air quality data from a range of sources including - time series of measurements from Europe's air quality monitoring network; and - statistics for air pollutants calculated from*	*EEA*

	officially verified country data as compiled under Directive (EU) 2024/2881 but not including EEA-held near-real time information on air quality and associated data products e.g. Air Quality Index.	
Waterbase WaterQuality	*Time series of concentrations of nutrients, organic matter, hazardous substances and other chemicals in rivers, lakes, groundwater, transitional, coastal and marine waters as reported in accordance with Watch List for chemicals in surface waters under Directive 2000/60/EC (also identified as WISE-6).*	*EEA*
Waterbase Emissions	*Time series of emissions of nutrients and hazardous substances to water, reported on yearly riverine input loads to transitional, coastal and marine waters under Directive 2000/60/EC (also identified as WISE-1).*	*EEA*
Industrial Emissions	*Chemicals data on releases, transfers and emissions of regulated pollutants as reported by Member States into the European Pollutant Release and Transfer Register under the Regulation (EU) 166/2006 and the Directive 2010/75/EU.*	*EEA*
NEC emissions inventory	*Data on emissions of air pollutants as reported by Member states under the Directive (EU) 2016/2284 and contained in the emission inventory.*	*EEA*
Human medicinal products data on environmental risk assessment and non-clinical safety data	*Environmental risk assessment and non-clinical safety data from marketing authorisation applications for medicinal products for human use under Directive 2001/83/EC and Regulation (EC) No 726/2004. This includes only data on relevant active substances submitted to the EMA in the context of the relevant procedures that are concluded after the entry into force of this Regulation.*	*EMA*
Veterinary medicinal products data on environmental risk assessment and on maximum residue limits	*Environmental risk assessment data, maximum residue limits (MRLs) values and MRL assessment data from marketing authorisation applications for medicinal products for veterinary use under Regulation (EU) 2019/6 and Regulation (EC) No 470/2009. This includes only data on relevant active substances submitted to the EMA in the context of the relevant procedures that are concluded after the entry into force of this Regulation.*	*EMA*

1. data collection: chemical monitoring | EFSA