European Parliament
2024-2029

Committee on the Environment, Public Health and Food Safety

2023/0453(COD)

5.12.2024

AMENDMENTS
315 - 546

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

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

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

Amendment 315
Martin Hojsík

Proposal for a regulation
Article 5 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Researchers or research consortia funded by Union framework programmes shall make available to the ECHA any environmental sustainability data on chemicals or materials they collect or generate from [OP please insert: date of the entry into force of this Regulation].	6. Researchers or research consortia funded by ***national and*** 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].

Or. en

Amendment 316
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 5 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. Member States shall require researchers or research consortia funded by national programmes, to make available to the ECHA any chemicals data relevant for regulatory purposes other than biomonitoring data, including environmental sustainability and health related data on chemicals or materials they collect or generate from [OP please insert: 6 months after the entry into force of this Regulation].

Or. en

Amendment 317
Jutta Paulus

Proposal for a regulation
Article 5 – paragraph 7

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

Or. en

Justification

As much as there is an obligation for the Commission and the agencies to provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data, there should be a reciprocal obligation on ECHA to support the Commission and the agencies to facilitate the integration of the chemicals data.

Amendment 318
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 5 – paragraph 7

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

Or. en

Amendment 319
Beatrice Timgren

Proposal for a regulation
Article 5 – paragraph 8

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

Or. en

Amendment 320
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 5 – paragraph 8

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

Or. en

Amendment 321
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 5 – paragraph 9

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 322
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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: ***2*** years after entry into force of this Regulation] the Commission shall transfer any human biomonitoring data it holds to the EEA.

Or. en

Amendment 323
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 – introductory part

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

Or. en

Amendment 324
Martin Hojsík

Proposal for a regulation
Article 6 – paragraph 4 – point e

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

Or. en

Amendment 325
Daniel Buda

Proposal for a regulation
Article 6 – paragraph 4 – point e a (new)

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

Or. ro

Amendment 326
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 – point e a (new)

Text proposed by the Commission	*Amendment*
	(e a) supporting regulatory risk management;

Or. en

Amendment 327
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 – point e b (new)

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

Or. en

Amendment 328
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 – point e c (new)

Text proposed by the Commission	*Amendment*
	(e c) 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.

Or. en

Amendment 329
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. The Commission may process human biomonitoring data constituting personal data for the following purposes only:
	(a) scientific research aimed at policy making;
	(b) assessing the impact of chemicals on human health and the environment;
	(c) monitoring time and spatial trends in exposure;

(d) developing health risk and impact indicators;

(e) monitoring the impact of regulatory intervention;

(f) assessing the need for further regulatory action and prioritising such actions;

(g) supporting regulatory risk assessment and risk management.

Or. en

Amendment 330
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4 b. The ECHA may process human biomonitoring data constituting personal data for the following purposes only:
	(a) evaluating and prioritising required regulatory actions;
	(b) performing assessments of chemicals;
	(c) supporting regulatory risk management;
	(d) as part of the commissioning of studies under the data generation mechanism referred to in Article 21.

Or. en

Amendment 331
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4 c. The EFSA may process human

biomonitoring data constituting personal data for the following purposes only:

(a) evaluating and prioritising required regulatory action;

(b) performing assessments of chemicals;

(c) supporting regulatory risk management.

Or. en

Amendment 332
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 d (new)

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

Or. en

Amendment 333
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 e (new)

Text proposed by the Commission	*Amendment*
	4 e. The EU-OSHA may process human biomonitoring data constituting personal data for the following purposes only:
	(a) scientific research aimed at policy making;

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

(c) monitoring time and spatial trends in exposure;

(d) monitoring the impact of regulatory intervention;

(e) assessing the need for further regulatory action and prioritising such actions;

(f) supporting regulatory risk management.

Or. en

Amendment 334
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 4 f (new)

Text proposed by the Commission	*Amendment*
	4 f. 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 paragraph 4, 4a, 4b, 4c, 4d, and 4e shall not entail the sharing of such data with third parties.

Or. en

Amendment 335
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The EEA shall act as data controller for the human biomonitoring personal data ***it holds or hosts and processes*** for the	6. The EEA***, the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission*** shall act as data controller for

purposes referred to in paragraph ***2***.	the human biomonitoring ***data constituting*** personal data ***they hold or host or process*** for the purposes referred to in paragraph ***4, 4a, 4b, 4c, 4d and 4e***.

Or. en

Amendment 336
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The EEA, the ECHA, the EFSA, the EMA, the EU-OSHA 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.

Or. en

Amendment 337
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 6 – paragraph 6 b (new)

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

Or. en

Amendment 338
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. At the latest by [OP please insert date: ***3*** years after the date of entry into force of this Regulation], the Commission shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring at that moment to the ECHA for integration in the common data platform.	2. At the latest by [OP please insert date: ***2*** 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.

Or. en

Amendment 339
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
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: ***2*** 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.

Or. en

Amendment 340
Daniel Buda

Proposal for a regulation
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. After the completion of the transfer	4. After the completion of the transfer

referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA ***without undue delay*** for integration in the Information Platform for Chemical Monitoring.	referred to in paragraph 3, where the Commission or the Agencies host or hold occurrence data on chemicals and related chemicals data, they shall make that data available to the ECHA ***within a period of 30 days*** for integration in the Information Platform for Chemical Monitoring.

Or. ro

Amendment 341
Daniel Buda

Proposal for a regulation
Article 7 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The ECHA shall take into consideration research projects such as HBM4EU when integrating the results of human biomonitoring into the Information Platform for Chemical Monitoring, and shall regularly update the statistics on exposure of the population to chemical substances of interest.

Or. ro

Amendment 342
Beatrice Timgren

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The ECHA shall establish and manage a repository of reference values as part of the common data platform.	1. ***Once notified by the Authority responsible,*** the ECHA shall establish and manage a repository of reference values as part of the common data platform.

Or. en

Amendment 343
Martin Hojsík

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
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. ***Upon notification by the responsible Authority,*** 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.

Or. en

Justification

Clarification of the process of inclusion of reference values.

Amendment 344
Beatrice Timgren

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
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, in the repository of reference values without undue delay.

Or. en

Amendment 345
Martin Hojsík

Proposal for a regulation
Article 8 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. Upon the submission of reference values by researchers or research

consortia funded by Union framework or national programmes to the ECHA in accordance with Article 14, the ECHA shall include those in the repository.

Or. en

Amendment 346
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. 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 it in the standard formats provided for in Article 14, where developed.

Or. en

Amendment 347
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
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: ***one year*** after the date of entry into force of this Regulation].

Or. en

Amendment 348

Beatrice Timgren

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The ECHA shall store in the Database of Study Notifications ***the data notified*** to it ***in accordance with Article 22***.	2. The ECHA shall store in the Database of Study Notifications ***only chemical data submitted*** to it ***under Annex I-listed Union acts where such data are part of registrations, applications, or notifications required under Union law***.

Or. en

Amendment 349
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA shall integrate the data contained in the Database of Study Notifications in the common data platform once a corresponding registration, application, notification or other relevant regulatory dossier was submitted to the relevant Union or national institution, agency, or body in accordance with corresponding Union law and after a decision was taken by that Union or national institution, agency, or body on the disclosure of the accompanying studies in accordance with the applicable rules on confidentiality.	3. 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 ***summary*** in accordance with the applicable rules on confidentiality.

Or. en

Amendment 350
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation

Article 9 – paragraph 3 a (new)

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

Or. en

Amendment 351
Martin Hojsík

Proposal for a regulation
Article 9 – paragraph 3 a (new)

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

Or. en

Justification

The amendment intends to make full use of the data on the platform by the authorities.

Amendment 352
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 9 – paragraph 3 a (new)

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

Or. en

Amendment 353
Beatrice Timgren

Proposal for a regulation
Article 9 – paragraph 5

Text proposed by the Commission	*Amendment*
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 ***submitted*** to them in accordance with ***their respective mandates under Annex I-listed Union acts*** and facilitate the traceability of the studies ***included in*** their respective databases.

Or. en

Amendment 354
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 1

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

Or. en

Justification

It should be made explicit that the data base should specify when regulatory processes involve animal tests.

Amendment 355
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 1

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

Or. en

Amendment 356
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2

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

Or. en

Justification

In analogy to what is proposed by the Commission for paragraph 3 of this article, it is important to set out what information needs to be provided as a minimum so as to ensure coherence of the date with regard to regulatory processes. This coherence should not apply for the information to be provided by the Agencies and the Commission as in paragraph 3, but also to Member States.

Amendment 357
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2

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

Or. en

Amendment 358
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2 – point a (new)

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

Or. en

Amendment 359
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2 – point a (new)

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

Or. en

Amendment 360
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2 – point b (new)

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

Or. en

Amendment 361
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2 – point b (new)

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

Or. en

Amendment 362
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2 – point c (new)

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

Or. en

Amendment 363
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2 – point c (new)

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

Or. en

Amendment 364
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2 – point d (new)

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

Or. en

Amendment 365
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2 – point d (new)

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

Or. en

Amendment 366
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2 – point e (new)

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

Or. en

Amendment 367
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2 – point e (new)

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

Or. en

Amendment 368
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 2 – point f (new)

Text proposed by the Commission	*Amendment*
	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.

Or. en

Amendment 369
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 2 – point f (new)

Text proposed by the Commission	*Amendment*
	(f) where applicable, date of intention to start the regulatory process or activity, completion and latest update.

Or. en

Amendment 370
Christophe Clergeau, Estelle Ceulemans, Chloé Ridel, Pierre Jouvet

Proposal for a regulation
Article 10 – paragraph 3 – point a

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

Or. en

Amendment 371
Jutta Paulus

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

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

Or. en

Justification

It should be made explicit that the data base should specify when regulatory processes involve animal tests.

Amendment 372
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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

Text proposed by the Commission	*Amendment*
	(f a) where applicable, whether animal testing is required and for which endpoint.

Or. en

Amendment 373
Jutta Paulus

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The information referred to in paragraph 3, points (a) to ***(f)***, on a specific regulatory process or activity shall be made available to the public ***once that process or activity has formally started***.	4. The information referred to in paragraph 3, points (a) to ***(fa)***, on a specific regulatory process or activity shall be made available to the public.

Or. en

Justification

Consequential amendment to the proposed change of the previous paragraph by the same author. Some regulatory processes will only occur in the future. An example of that would be the current registry of intentions held by the ECHA (https://echa.europa.eu/registry-of-restriction-intentions). If a Member intends to prepare a restriction dossier for a chemical substance, it has to notify this to the ECHA. This may well be before it has actually started to work on the restriction dossier. It would therefore not be appropriate to make such information available only when the process has actually started, and it would require a second notification, which however amounts to unnecessary administrative burden.

Amendment 374
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 10 – paragraph 4

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

Or. en

Amendment 375
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Any planned new test, in particular tests on animals, shall be notified in advance and the ECHA shall record the intention in the database. Furthermore, the ECHA shall record where new animal testing has been requested by an Agency for regulatory purposes. These records shall be made public without undue delay.

Or. en

Amendment 376
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	Information on chemicals in products and their alternatives

1. The ECHA shall establish and manage, as part of the common data platform, a new database containing information on chemicals in products and their alternatives generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I.

This database shall integrate the information subject to paragraph 2 of Article 3, point (ca).

2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex I without undue delay.

3. Where the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment. For each chemical in a product, where available, at least the following information shall be included:

(a) chemical identity;

(b) product uses identified;

(c) uses for which available alternatives have been identified;

(d) alternatives identified for each use;

(e) available information on the suitability of alternatives;

(f) available information on substitution plans and efforts for each use;

4. The ECHA shall encourage providers of alternatives referred to in paragraph 3 points (c) and (d) to identify themselves.

Or. en

Amendment 377
Martin Hojsík, Sigrid Friis

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article10a
	Information on substances in articles and their alternatives
	1. The ECHA shall establish and operate, as part of the common data platform, a new database containing information on substances in products and their alternatives generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I. This database shall also integrate the information subject to paragraph 2 of Article 3, point (ca).
	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex I without undue delay.
	3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment.
	4. The ECHA shall encourage providers of alternatives referred to in this Article to identify themselves.
	5. The database shall include, where available, following information and shall be user-friendly:

(a) substance identity;

(b) sector of use;

(c) alternatives identified for each use;

(d) technical function;

(e) material article category ;

Or. en

Justification

AM follows a proposal of the rapporteur to collect on the CDP information on available alternatives, that should be included in user-friendly form, in order to allow business operators to find suitable alternatives. The platform would also help EU´s SMEs to pass on the information about alternatives they make available.

Amendment 378
Jutta Paulus

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	Information on substances in articles and their alternatives
	1. The ECHA shall integrate, as part of the common data platform, a new database containing information on substances in articles and their alternatives generated or submitted as part of the implementation of Union chemicals legislation listed in Annex I.
	This database shall integrate at least the information subject to Article 9(1)(i) of Directive 2008/98/EC and of Article 14 of Regulation (EU) 2024/1781.
	2. Where Member State competent authorities as referred to in any of the Union acts listed in Annex I hold the information referred to in paragraph 1, they shall make that information available to the Union agency responsible under the respective Union act listed in Annex I

without undue delay.

3. Where the ECHA, EEA, EFSA, EU-OSHA or the Commission hold the information referred to in paragraph 1, they shall make that information available to the ECHA for integration in the common data platform in the standard formats provided for in Article 14 without undue delay and, where relevant, once the responsible agency or the Commission has performed the validity assessment.

4. The ECHA shall encourage providers of alternatives to identify them and to provide all relevant data.

(For SCIP data base, see herehttps://echa.europa.eu/scip)

Or. en

Justification

Amendment similar to amendment 58 by the rapporteur, but with the explicit addition of the SCIP database established pursuant to Article 9(1)(i) of the Waste Framework Directive. The SCIP database ensures that the information on articles containing substances of very high concern that are on the REACH candidate list is made available throughout the whole lifecycle of products and materials, including at the waste stage. Such information is crucial for moving to clean circular economy. It is crucial to integrate this existing database into the common data platform.

Amendment 379
Jutta Paulus

Proposal for a regulation
Article 11 – paragraph 2

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

Or. en

Justification

For the sake of clarity, it should be specified that ECHA shall update the information in the database at least annually.

Amendment 380
Beatrice Timgren

Proposal for a regulation
Article 12 – paragraph 2

Text proposed by the Commission	*Amendment*
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 ***Annex I***, the ECHA shall include them in the common data platform.

Or. en

Amendment 381
Ivan David

Proposal for a regulation
Article 13

Text proposed by the Commission	*Amendment*
Article 13	***deleted***
Database on 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.	
2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has	

completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.

3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.

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.

Or. en

Justification

The term "environmental sustainability" is not clearly defined in this proposal, nor in the two related proposals, nor in any existing legislation.Article 13(4) as proposed gives the Commission too broad a power, which could allow officials to set requirements that are impossible to meet in practice.

Amendment 382
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 13 – title

Text proposed by the Commission	*Amendment*
Database on environmental sustainability	Database on environmental sustainability

related data	***and health*** related data

Or. en

Amendment 383
Beatrice Timgren

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. At the latest within ***three*** years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.	1. At the latest within ***five*** 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.

Or. en

Amendment 384
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. At the latest within ***three*** years after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.	1. At the latest within ***two*** 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.

Or. en

Amendment 385
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***At the latest within three years*** after the publication of the decision referred to in paragraph 4, the ECHA shall establish and manage, as part of the common data platform, a database containing environmental sustainability related data.	1. ***One year*** 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 ***and health*** related data.

Or. en

Amendment 386
Jutta Paulus

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.	2. Where the Commission or the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data. ***The ECHA shall ensure the necessary support to the Commission and the agencies to facilitate the integration of these data.***

Or. en

Justification

As much as there is an obligation for the Commission and the agencies to provide the necessary technical cooperation to the ECHA to enable the integration of the chemicals data,

there should be a reciprocal obligation on ECHA to support the Commission and the agencies to facilitate the integration of the chemicals data.

Amendment 387
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the Commission ***or*** the Agencies host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without undue delay once the Commission or the Agency hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The Commission and the Agencies shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.	2. Where the Commission***,*** the Agencies ***or the Member States*** 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 ***and the Member States*** 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.

Or. en

Amendment 388
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the ***Commission or the Agencies*** host or hold environmental sustainability related data in addition to the chemicals data already available in the common data platform, they shall make that data available to the ECHA without	2. Where the ***Authorities*** host or hold environmental sustainability ***or health*** 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

undue delay once the ***Commission or the Agency*** hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The ***Commission and the Agencies*** shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related data in the database on environmental sustainability related data.	delay once the ***Authority*** hosting or holding that data has completed, where relevant, validity and confidentiality assessments. The ***Authorities*** shall provide the necessary technical cooperation to the ECHA to enable the integration of environmental sustainability related ***and health*** data in the database on environmental sustainability ***and health*** related data.

Or. en

Amendment 389
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.	3. Where researchers or research consortia***, especially those*** funded by Union ***and national*** framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data ***without undue delay***.

Or. en

Amendment 390
Martin Hojsík

Proposal for a regulation
Article 13 – paragraph 3

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

programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.

national programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals or materials they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.

Or. en

Amendment 391
Beatrice Timgren

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals ***or materials*** they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.	3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data.

Or. en

Amendment 392
Pietro Fiocchi

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals ***or materials*** they collect or generate, the ECHA shall integrate the relevant data in the database on environmental	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 they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related

sustainability related data.	data.

Or. en

Amendment 393
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 13 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. The ECHA shall integrate the environmental sustainability or health related data on chemicals or materials, made available in accordance with Article 5(6a), in the database on environmental sustainability and health related data.

Or. en

Amendment 394
Beatrice Timgren

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision***, in consultation with Member States,*** 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.

Or. en

Amendment 395

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

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By [OP please insert date: ***three*** years after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and ***shall design relevant related database functionalities***.	4. By [OP please insert date: ***two*** 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 ***and 3***, for inclusion in the common data platform and ***request the ECHA to host and maintain them in accordance with Article 5(1)***.

Or. en

Amendment 396
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By [OP please insert date: ***three years*** after the date of entry into force of this Regulation], the Commission shall adopt an implementing decision identifying existing datasets on environmental sustainability related data, other than those referred to in paragraph 2, for inclusion in the common data platform and shall design relevant related database functionalities.	4. By [OP please insert date: ***one year*** 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.

Or. en

Amendment 397
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation

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

Text proposed by the Commission	*Amendment*
	(e a) increase transparency

Or. en

Amendment 398
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 14 – paragraph 4

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

Or. en

Amendment 399
Beatrice Timgren

Proposal for a regulation
Article 14 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
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 ***listed in Annex I***:

Or. en

Amendment 400
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 14 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
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 ***Authorities*** 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:

Or. en

Amendment 401
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 14 – paragraph 5 – point i a (new)

Text proposed by the Commission	*Amendment*
	(i a) (j) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1a];
	[1a] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 24.11.2009, p. 1).

Or. en

Amendment 402
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 14 – paragraph 5 – point i a (new)

Text proposed by the Commission	*Amendment*
	(i a) Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1a].
	[1a] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Or. en

Amendment 403
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 14 – paragraph 5 – point i b (new)

Text proposed by the Commission	*Amendment*
	(i b) Regulation (EC) No 396/2005 of the European Parliament and of the Council[1b];
	[1b] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

Or. en

Amendment 404
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 14 – paragraph 5 – point i b (new)

Text proposed by the Commission *Amendment*

(i b) Regulation (EC) No 396/2005 of the European Parliament and of the Council[1a]

[1a] 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).

Or. en

Amendment 405
Dennis Radtke

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission	*Amendment*
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. ***When appropriate, they shall also consult stakeholders.***

Or. en

Amendment 406
Pietro Fiocchi

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the	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.	standard formats with the common data platform and with existing data submission approaches. ***They shall also consult stakeholders.***

Or. en

Amendment 407
Beatrice Timgren

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission	*Amendment*
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. ***They shall also consult stakeholders.***

Or. en

Justification

Standard data formats and controlled vocabularies must be developed in consultation with stakeholders and especially the industry, as the expectation is that in the longer term the formats and vocabularies set by the Agencies will be used also for the submission of data by the duty holders under the individual pieces of legislation.

Amendment 408
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the	6. The Commission and the Agencies shall cooperate when setting standard formats to ensure ***transparency and*** coherence with other formats and the

standard formats with the common data platform and with existing data submission approaches.	interoperability of the standard formats with the common data platform and with existing data submission approaches.

Or. en

Amendment 409
Martin Hojsík

Proposal for a regulation
Article 15 – paragraph 5 – point a

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

Or. en

Justification

Supporting the rapporteur´s clarification.

Amendment 410
Pietro Fiocchi

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
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. ***The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies and will consult stakeholders***

Or. en

Amendment 411
Dennis Radtke

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
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 ***and shall consult stakeholders***.

Or. en

Amendment 412
Beatrice Timgren

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
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 ***and will consult stakeholders***.

Or. en

Justification

Standard data formats and controlled vocabularies must be developed in consultation with stakeholders and especially the industry, as the expectation is that in the longer term the formats and vocabularies set by the Agencies will be used also for the submission of data by the duty holders under the individual pieces of legislation.

Amendment 413
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	Uptake of research data

1. Researchers shall be able to submit publicly available research data on chemicals related to an entry in the common data platform. Research data shall be submitted in a format prescribed by the ECHA.

2. By [OP: insert 18 months after the entry into force of this Regulation], the ECHA shall establish and maintain an online platform for the submission process referred to in paragraph 1.

3. The ECHA shall assess the compliance of research data submitted through the portal referred to in paragraph 2 with the requirements set in the guidance referred to in paragraph 4. Where research data submitted are deemed to fulfil these requirements, the data shall be hosted on the common data platform together with the corresponding entry.

4. By [OP: insert 12 months after the entry into force of this Regulation], the Commission shall publish a guidance setting minimum quality and reporting requirements to improve the uptake of research data.

5. In order to ensure a uniform format of the research data submitted, 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).

Or. en

Amendment 414
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 16 – paragraph -1 (new)

Text proposed by the Commission	*Amendment*
	-1. The public shall have access to all the chemicals data contained in the common data platform.

Or. en

Amendment 415
Radan Kanev

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.	1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence. ***Access to confidential data shall be limited to authorised entities performing regulatory tasks, with clear audit trails to monitor access and prevent misuse.***

Or. en

Justification

Limiting access to confidential data to only authorized entities ensures that sensitive information is handled strictly for regulatory purposes, minimizing the risk of misuse, unauthorized disclosure, or competitive harm. This approach aims to protect proprietary sensistive information, fostering trust among stakeholders while maintaining the integrity of the regulatory process.

Amendment 416
Jutta Paulus

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*

1. The Authorities shall have access to all the chemicals data contained in the common data platform, including data which is deemed to be confidential under Article 5(2), second sentence.	1. The Authorities***, scientific committees, and agencies which have rights and obligations in social security issues,*** 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.

Or. en

Amendment 417
Radan Kanev

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public.	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with Article 5(2) is not made public. ***In the event of a conflict between confidentiality protections under this Regulation and sector-specific legislation, the latter shall prevail.***

Or. en

Justification

By ensuring sector-specific legislation prevails and limiting access to authorized entities with clear oversight, the amendments prevent legal ambiguity, reduce misuse risks, and balance transparency with the protection of sensitive data.

Amendment 418
Pietro Fiocchi

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Authorities shall take the	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.	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 ***in accordance with the provisions on confidentiality under the originating Union act***.

Or. en

Amendment 419
Kristoffer Storm

Proposal for a regulation
Article 16 – paragraph 2

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

Or. en

Justification

Support for amendment 68 in the draft report

Amendment 420
Beatrice Timgren

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Authorities shall take the necessary measures to ensure that information contained in the common data	2. The Authorities shall take the necessary measures***, including security measures,*** to ensure that information

platform marked as confidential in accordance with Article 5(2) is not made public.	contained in the common data platform marked as confidential in accordance with Article 5(2)***, second sentence,*** is not made ***available to the*** public.

Or. en

Amendment 421
Radan Kanev

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.	3. The 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. ***The designation of data as public shall respect existing confidentiality safeguards under Union acts, including protections for trade secrets as defined in Directive (EU) 2016/943.***

Or. en

Justification

Explicitly stating that sector-specific confidentiality protections take precedence prevents ambiguity or unintended weakening of existing protections.

Amendment 422
Jutta Paulus

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***general*** public shall have access to all the chemicals data contained in the common data platform ***and considered as available to the public in***	3. The public shall have access to all the chemicals data contained in the common data platform***, except data which is marked to be confidential*** under ***Article***

accordance with the Union act under ***which the data was generated or submitted***.	***5(2), second sentence***.

Or. en

(Linked to the amendment by the same author on Article 5(2).)

Justification

Clarification of the approach: the default is that access, unless confidentiality applies.

Amendment 423
Beatrice Timgren

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act under which the data was generated or submitted.	3. The general public shall ***only*** 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.

Or. en

Amendment 424
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The general public shall have access to all the chemicals data contained in the common data platform ***and considered as available to the public in accordance with the Union act*** under ***which the data was generated or submitted***.	3. The general 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***.

Or. en

Amendment 425
Martin Hojsík

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The general public shall have access to all the chemicals data contained in the common data platform and considered as available to the public in accordance with the Union act ***under which the data was generated or submitted***.	3. The 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 ***originating*** Union act.

Or. en

Justification

Clarification of the wording.

Amendment 426
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 17 – paragraph 1

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

Or. en

Amendment 427
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation

Article 17 – paragraph 1

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

Or. en

Amendment 428
Martin Hojsík

Proposal for a regulation
Article 17 – paragraph 1

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

Or. en

Justification

The Authorities shall make full use of the information in the common data platform to simplify regulatory processes, including for the enforcement of legislation that is important to ensure fair and well-functioning internal market.

Amendment 429
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 17 – paragraph 2

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

Or. en

Amendment 430
Martin Hojsík

Proposal for a regulation
Article 17 – paragraph 2

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

Or. en

Justification

The amendment clarifies that the purpose of the common data platform is to improve re-use of data by the Authorities and to simplify regulatory processes.

Amendment 431
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
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 ***as provided for in paragraph 1***, the Authorities shall respect the confidentiality of ***that*** data as marked by the originator and shall not disclose that data to the public without the consent of the originator.

Or. en

Amendment 432
Jutta Paulus

Proposal for a regulation
Article 17 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. It shall be clearly mentioned on the common data platform, for the attention of the general public and business operators, where relevant, that the data is owned by a third party and that any commercial use of the data without prior approval from the data owner might infringe their rights. The common data platform shall also include terms and conditions, particularly regarding intellectual property rights and other related rights.

Or. en

Justification

Amendment similar to AM 72 by the rapporteur with three main modifications: a) specify that mention of data ownership should only be made where relevant, b) respect for data ownership does not only apply to the general public but also to other business operators, and c) that potential infringement of rights only occur in case of commercial use of the data.

Amendment 433
Jutta Paulus

Proposal for a regulation
Article 18 – paragraph 1

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

Or. en

Justification

More specific wording identical to what is in the Council general mandate.

Amendment 434
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 18 – paragraph 1

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

Or. en

Amendment 435
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall 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, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.

Or. en

Amendment 436
Beatrice Timgren

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall ***establish***, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall***, in consultation with Member States***, 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.

Or. en

Amendment 437
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 18 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The EEA, on the basis of the framework of indicators referred to in paragraph 1, as well as data from the database on environmental sustainability and health related data referred to in Article 13, the Union early warning system for emerging chemical risks referred to in Article 19, and human biomonitoring data shall establish, operate, maintain, and update as appropriate an aggregated territory-based risk indicator at different administrative levels (Country, NUTS2 and NUTS3) based on the Nomenclature of territorial units for statistics (NUTS) as defined in Regulation (EC) No 1059/200, to monitor time and spatial trends in exposure of populations to individual and multiple chemicals and health risks associated to such exposure and co-exposure.
	Where possible, the EEA shall cross-reference the results of the aggregated risk indicator with other health and environment datasets, including epidemiological data, to identify potential emerging risks for the purpose of Article 19.

Or. en

Amendment 438
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The framework of indicators referred to in paragraph 1 shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.	2. The framework of indicators referred to in paragraph 1***, and the aggregated indicator referred to in paragraph 1a,*** shall be accessible in the form of an indicator dashboard, which the EEA shall establish and which the ECHA shall make available through the common data platform.

Or. en

Amendment 439
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 18 a (new)

Text proposed by the Commission	*Amendment*
	Article18a
	Substantiated concerns
	1. Any natural or legal person, individually or in association, shall be entitled to submit to an Agency a substantiated concern regarding impacts of chemicals on humans and the environment, relating in particular to the properties, use, exposure, risk, occurrence and emissions of substances or groups of substances, and which is based on objective and verifiable information such as peer-reviewed studies, human biomonitoring data, or environmental monitoring data.
	2. Where the concern does not correspond to the mandate of the Agency to which it is submitted, this Agency shall make it available to the authority or authorities with a corresponding mandate.
	3. The authority or authorities with a mandate corresponding to the submitted concern shall diligently and impartially assess it and, where appropriate, take one

or more of the following actions:

(a) regulatory measures under Union legislation, including by imposing obligations on duty holders, such as to corroborate the evidence or mitigate any detrimental effects; (b) initiate or develop new policies addressing the concern submitted;

(c) transfer the concern indicating a non-compliance to enforcement agencies.

4. The authority or authorities shall, within 6 months, inform the natural or legal persons referred to in paragraph 1 of any decision taken under paragraph 3, providing the reasons for such decision.

5. Any substantiated concern submitted under paragraph 1 and the information subject to paragraph 3 shall be made available to ECHA and compiled for publication in an annual report. The report shall be integrated in the common data platform without undue delay.

Or. en

Amendment 440
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 18 a (new)

Text proposed by the Commission	*Amendment*
	Article 18a
	Substantiated concerns
	1. Any natural or legal person, individually or in association, shall be entitled to submit to an Agency a substantiated concern regarding impacts of chemicals on humans and the environment, relating in particular to the properties, use, exposure, risk, occurrence and emissions of chemicals or groups of chemicals, and which is based on objective and verifiable information such

as peer-reviewed studies, human biomonitoring data, or environmental monitoring data.

2. Where the concern does not correspond to the mandate of the Agency to which it is submitted, this Agency shall make it available to the authority or authorities with a corresponding mandate.

3. The authority or authorities with a mandate corresponding to the submitted concern shall diligently and impartially assess it and, where appropriate, take one or more of the following actions:

(a) regulatory measures under Union legislation, including by imposing obligations on duty holders, such as to corroborate the evidence or mitigate any detrimental effects;

(b) initiate or develop new policies addressing the concern submitted;

(c) transfer the concern indicating a non-compliance to enforcement agencies.

4. The authority or authorities shall, within 6 months, inform the natural or legal persons referred to in paragraph 1 of any decision taken under paragraph 3, providing the reasons for such decision.

5. The ECHA shall publish an annual report compiling all substantiated concerns submitted under paragraph 1 and the information subject to paragraph 3. The report shall be integrated in the common data platform without undue delay.

Or. en

Amendment 441
Jutta Paulus

Proposal for a regulation
Article 19 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*

(b) ***existing*** national early warning systems;	(b) national early warning systems;

Or. en

Justification

The reference to "existing" national early warning systems should be deleted to make the legislation future-proof.

Amendment 442
Jutta Paulus

Proposal for a regulation
Article 19 – paragraph 2 – subparagraph 1 – point c

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

Or. en

Justification

As both human biomonitoring data as well as data from the framework of indicators are of particular relevance for an early warning and action system, explicit reference should be made to them here.

Amendment 443
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 19 – paragraph 2 – subparagraph 1 – point c

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

Or. en

Amendment 444
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 19 – paragraph 2 – subparagraph 1 – point c

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

Or. en

Amendment 445
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

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

Text proposed by the Commission	*Amendment*
	(e a) substantiated concerns submitted in accordance with Article 18a and made available by an Agency.

Or. en

Amendment 446
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

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

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

Or. en

Amendment 447
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 19 – paragraph 2 – subparagraph 1 – point e b (new)

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

Or. en

Amendment 448
Pietro Fiocchi

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA.	3. The ECHA, the EFSA, the EU-OSHA and the EMA shall identify and gather relevant available data on early warning signals from the field falling within their mandate and provide this data to the EEA. ***The EEA shall develop guidance for identification of emerging chemicals risks in cooperation with ECHA, the EFSA, the EU-OSHA and the EMA and other relevant parties.***

Or. en

Amendment 449
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 19 – paragraph 3

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

Or. en

Amendment 450
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals.	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals. ***Within six months of the presentation of the report, the Authorities shall consider undertaking regulatory, policy or enforcement actions accordingly or and justify if they decide not to proceed with any action related to any of the early warning signals identified by the report.***

Or. en

Amendment 451
Jutta Paulus

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*

4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the ***Commission, relevant Union agencies and Member State competent*** authorities ***for consideration of the need for*** regulatory or policy action related to the early warning signals.	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. [The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the ***Authorities. The*** Authorities ***shall undertake enforcement,*** regulatory or policy ***action necessary to address the emerging risks in a timely manner. They shall justify if they decide not to proceed with any*** action related to the early warning signals***, including an assessment of the costs of non-action***.

Or. en

Justification

It is important that the new Regulation lives up to its intention to establish an early warning and ACTION system for emerging chemical risks. It is not enough that authorities only "consider" the need for regulatory or policy action based on an annual report by the EEA. They should be obliged to take follow-up action. Such action should also include enforcement action. If no action is taken, this needs to be justified, including an assessment of the costs of non-action.

Amendment 452
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 19 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Within two months after receipt of this report, the Commission, relevant Union agencies and Member State competent authorities shall publicly respond to the received early warning signals with the details and timeline of the undertaken or planned regulatory or policy action related to the early warning signals, or a justification of the lack of action.

Or. en

Amendment 453
Pietro Fiocchi

Proposal for a regulation
Article 19 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The EEA shall make all ***relevant*** data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform.	5. The EEA shall make all ***confirmed*** 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. ***To avoid confusion, data that is not a positive identification of an emerging risk as described in article 19(3) will not be included in the common data platform.***

Or. en

Amendment 454
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 19 – paragraph 5

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

Or. en

Amendment 455
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 19 – paragraph 5

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

Or. en

Amendment 456
Jutta Paulus

Proposal for a regulation
Article 19 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. If the data analysis indicates that there is a risk that has to be tackled urgently, the EEA shall inform the authorities without undue delay.

Or. en

Justification

There needs to be a provision to allow the EEA to inform the authorities without undue delay in case of an emergency.

Amendment 457
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 19 – paragraph 5 a (new)

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

Or. en

Amendment 458
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 19 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5 b. The Commission shall take into account the emerging chemicals risks identified in accordance with this Article in the strategic planning of R&I activities of Regulation (EU) 2021/695[1a], where relevant.
	[1a] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013

Or. en

Amendment 459
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 20 – paragraph 1

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

Or. en

Amendment 460
Jutta Paulus

Proposal for a regulation
Article 20 – paragraph 1

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

Or. en

Justification

The observatory should be a scientific process and therefore be led by the ECHA and not by the Commission.

Amendment 461
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of ***an*** implementing ***decision***. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means.	2. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall adopt and publish a list of the selected chemicals by means of implementing ***acts***. The Commission shall review the list of selected chemicals regularly adopt any revision thereof by the same means. ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24a(2).***

Or. en

Amendment 462

Jutta Paulus

Proposal for a regulation
Article 20 – paragraph 2

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

Or. en

Justification

The observatory should be a scientific process and therefore be led by the ECHA and not by the Commission.

Amendment 463
Jutta Paulus

Proposal for a regulation
Article 20 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***Commission*** shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.	3. The ***ECHA*** shall select the chemicals referred to in paragraph 1 based on the scientific and technical progress and using the signals of the early warning system referred to in Article 19. The selection shall include potential contributors to new and emerging chemical risks among innovative rationally designed materials with new or enhanced properties or targeted or enhanced structural features at nanoscale.

Or. en

Justification

The observatory should be a scientific process and therefore be led by the ECHA and not by

the Commission.

Amendment 464
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 20 – paragraph 4 – point c

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

Or. en

Amendment 465
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 20 – paragraph 4 – point c

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

Or. en

Amendment 466
Martin Hojsík

Proposal for a regulation
Article 20 – paragraph 4 – point c

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

Or. en

Amendment 467
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 – paragraph 1

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

Or. en

Amendment 468
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 – paragraph 1 – point a (new)

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

Or. en

Amendment 469
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 – paragraph 1 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) investigate further emerging chemical risks identified in the report referred to in Article 19(4) of this Regulation;

Or. en

Amendment 470
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 – paragraph 1 – point c (new)

Text proposed by the Commission	*Amendment*
	(c) conduct Union-wide data sampling survey of human biomonitoring in collaboration with Member states.

Or. en

Amendment 471
Martin Hojsík

Proposal for a regulation
Article 21 – paragraph 2

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

Or. en

Justification

Addition of a missing cross-reference.

Amendment 472
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall ***prioritise the use of non-animal methods, with animal tests only proposed as a last resort. Full justification for the need to perform any new test on animals shall be provided. It shall*** not commission studies with a predominant research objective.

Or. en

Amendment 473
Jutta Paulus

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall ***give priority to the use of non-animal methods, with animal testing on vertebrate animals only as a last resort. It shall*** not commission studies with a predominant research objective.

Or. en

Justification

Addition in line with Article 25 of REACH.

Amendment 474
Jutta Paulus

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. It shall not commission studies with a predominant research objective.	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I ***or if data is incomplete or restricted to certain sectors***. It shall not commission studies with a predominant research objective.

Or. en

Justification

The early warning system can only be viable if the data included are complete. ECHA should therefore also be able to commission scientific studies to complement the data

Amendment 475
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I. ***It shall not commission studies with a predominant research objective.***	3. The ECHA shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I.

Or. en

Amendment 476
Jutta Paulus

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. The ECHA may request business operators to provide samples of substances necessary for performing the scientific studies referred to in paragraph 1. Business operators shall, upon request by the ECHA, provide the requested sample free of charge to the ECHA or to any body commissioned by the ECHA to perform the scientific study.

Or. en

Justification

In order to be able to conduct monitoring studies, a proper sample is needed. ECHA should therefore have the authority to request such a sample from a business operator, who in turn should be obliged to provide such a sample free of charge.

Amendment 477
Pietro Fiocchi

Proposal for a regulation
Article 21 – paragraph 5

Text proposed by the Commission	*Amendment*

5. The ECHA shall commission these scientific studies in an open and transparent manner.	5. The ECHA shall commission these scientific studies in an open and transparent manner. ***ECHA are to request industry to provide comments on the studies commissioned by ECHA, including comments on testing protocol and methodology.***

Or. en

Amendment 478
Laurent Castillo

Proposal for a regulation
Article 21 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The ECHA shall commission these scientific studies in an open and transparent manner.	5. The ECHA shall commission these scientific studies in an open and transparent manner ***and shall open a public consultation to stakeholders affected by them***.

Or. fr

Amendment 479
Beatrice Timgren

Proposal for a regulation
Article 21 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The ECHA shall commission these scientific studies in an open and transparent manner.	5. The ECHA shall commission these scientific studies in an open and transparent manner ***and after a consultation of stakeholders and the public on the intended studies***.

Or. en

Justification

Before undertaking new scientific studies, it is important that all relevant information is taken into consideration, including on the methodologies of the study and to avoid potential

duplication of work (incl. at global level). The industry has vast experience in designing scientific studies and with other stakeholders could share specific expertise on studies to be commissioned under the data generation mechanism.

Amendment 480
Pietro Fiocchi

Proposal for a regulation
Article 21 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. ECHA shall publish, on its website, the study identified to commission along with the relevant justification, the study protocol, and the financing mechanism. A public consultation shall run for 60 days for interested stakeholders to comment.

Or. en

Amendment 481
Laurent Castillo

Proposal for a regulation
Article 21 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. When a study is commissioned, the ECHA shall publish electronically the subject of the study, the reasons for it, details of the funding arrangements and the protocol to follow for its implementation.

Or. fr

Amendment 482
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation

Article 21 – paragraph 6

Text proposed by the Commission	*Amendment*
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***, the EMA*** 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 ***and studies undertaken by EMA***. ***The agencies shall aim to avoid duplication and to ensure animal testing takes place only as a last resort and is fully justified.***

Or. en

Amendment 483
Pietro Fiocchi

Proposal for a regulation
Article 21 – paragraph 6

Text proposed by the Commission	*Amendment*
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***, EMA*** 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.

Or. en

Amendment 484
Martin Hojsík

Proposal for a regulation
Article 21 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*

6 a. The ECHA may request from a business operator a sample of substance that 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 sample of substance to perform the scientific study. The obligation shall not result in costs for the business operator.

Or. en

Amendment 485
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 – paragraph 6 a (new)

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

Or. en

Amendment 486
Jutta Paulus

Proposal for a regulation
Article 21 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. Every three years, the ECHA, in cooperation with the EFSA, shall commission an EU-wide human biomonitoring study to assess the exposure of humans to relevant chemicals. Member States shall cooperate with the ECHA and the EFSA in the planning and organization of the study. Member States shall collect the samples in their territories and ensure that the data is representative and of good quality and submit the data to the ECHA.

Or. en

Justification

Human biomonitoring studies are of crucial relevance to assess risks and to the effectiveness of Union legislation with regard to chemicals. EFSA has an annual budget of 15 mio € for verification studies pursuant to the General Food Law. ECHA will be given an annual budget of 5 mio € for data generation. A clear mandate should be given to ECHA and EFSA to conduct EU-wide human biomonitoring studies. For real added value, such studies should be conducted every three years.

Amendment 487
Pietro Fiocchi

Proposal for a regulation
Article 21 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. Interested stakeholders can appeal the decision to commission the study before the Board of Appeal.

Or. en

Amendment 488
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 21 – paragraph 7

Text proposed by the Commission	*Amendment*
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 ***and shall, in advance, record the intention to perform new studies in accordance with Articles 9 and 10 of this Regulation***.

Or. en

Amendment 489
Martin Hojsík

Proposal for a regulation
Article 21 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. If a scientific study commissioned according to paragraph 1 or 2 is a human biomonitoring study, Member States shall coordinate with and support the ECHA and EFSA, as mandated under the Regulation (EC) No 178/2002, in organisation of the human biomonitoring activities within their territories, to ensure sampling and collection of the data, adequate representativeness and quality of the data. The EU-wide human biomonitoring shall cover all Member States and adhere to ethical and confidentiality standards.

Or. en

Amendment 490
Kristoffer Storm

Proposal for a regulation
Article 21 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*

7 a. In alignment with the REACH regulation and the CLP regulation, the obligations put forward in article 22 shall not apply to substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD).

Or. en

Justification

This regulation should be aligned with the REACH and CLP regulations. There is a need to exempt substances used in scientific research and development(SR&D). An exemption for SR&D is crucial for business operators competing on a global stage, particularly for innovators, including SMEs. Without such an exemption, EU facilities would become less favorable locations for process development and commercialization.

Amendment 491
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 a (new)

Text proposed by the Commission	*Amendment*
	Article 21a
	Centralised data generation mechanism
	1. The Commission, the Agencies, and Member states competent authorities may submit request for studies to the Commission in accordance with the governance scheme referred to in Article 21b(4).
	A request for studies shall include, at the minimum, the following:
	(a) a rational for the request, summarizing the current knowledge and latest relevant findings;
	(b) a proposal for testing, including technical feasibility, the involvement of national or EU reference laboratories where necessary, and possibilities for appropriate sample acquisition;

(c) a preliminary cost estimate;

(d) an estimated timeline.

2. Using the best independent resources available, the Commission may commission scientific studies on the basis of request submitted in accordance with paragraph 1 to:

(a) 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;

(b) investigate further emerging chemical risks identified in the report referred to in Article 19(4) of this Regulation;

(c) conduct Union-wide data sampling survey of human biomonitoring in collaboration with Member states.

2. The Commission may mandate the Agencies to commission the scientific studies referred to in paragraph 1, in accordance with the governance scheme referred to in Article 21b(4).

3. The Commission shall only commission scientific studies when results cannot be obtained through existing legal provisions or processes under Union legislation listed in Annex I.

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

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

6. The Agencies shall closely cooperate with each other on the submission of requests for and planning of scientific studies undertaken in accordance with paragraph 1.

7. 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 Agencies to commission scientific studies with the objective of verifying evidence used in its hazard and risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.

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

Or. en

Amendment 492
Ivan David

Proposal for a regulation
Article 21 a (new)

Text proposed by the Commission	*Amendment*
	Article21a
	Consultation of stakeholders
	When carrying out activities under Articles 14, 15, 18 and 21, the Commission and the Agencies shall consult organisations representing, at Union level, economic operators who manufacture or otherwise handle the chemicals concerned in the course of their business.

Or. en

Justification

In order to avoid confusion in the drafting of documents resulting from cooperation between the agencies and the Commission, it is necessary to oblige them to consult representatives of the industry and business sectors concerned when exercising their powers.

Amendment 493
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 21 b (new)

Text proposed by the Commission	*Amendment*
	Article21b
	Governance of the centralised data generation mechanism
	1. The Commission shall establish and manage a centralised data generation mechanism.
	2. The Commission shall prepare and adopt a governance scheme for the data generation mechanism, in collaboration with the Agencies.
	3. The Commission shall publish the governance scheme referred to in paragraph 2 and any revision thereof by means of implementing acts.
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24a(2).
	4. That governance scheme shall describe:
	(a) the organisation of the main work structures supporting the development and implementation of the data generation mechanism;
	(b) the centralised system for the submission of testing proposals, the eligibility check, and the assessment and submissions;
	(c) the decision-making process for approval and prioritisation of the requests;
	(d) the procedural steps and assignment of responsibilities at the execution stage of data generation.
	5. The Commission may establish an expert working group for the purpose of point (c) of paragraph 4. The expert working group shall be composed of representatives from the Commission, Union agencies, and Member States.
	Or. en

Amendment 494
Beatrice Timgren

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
Article 22	***deleted***
Notification of studies	
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	
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.	
3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and	

testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.

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

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

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

Or. en

Justification

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

Amendment 495
Dennis Radtke

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
Article 22	***deleted***
Notification of studies	
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	
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.	
3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	

4. For the purposes of paragraph 3, laboratories and testing facilities shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, intended starting and planned completion dates of any test they carry out, as well as the name of the business operator who commissioned the test.

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

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

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

Or. en

Justification

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

Amendment 496
Radan Kanev

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to	1. Business operators shall notify to

the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. ***Studies conducted as part of Scientific Research and Development (SR&D) or Product and Process-Oriented Research and Development (PPORD), as defined under REACH (Article 9) and CLP, are exempt from this notification requirement unless explicitly mandated by the corresponding regulatory act. Notifications for SR&D and PPORD activities shall be limited to high-level summaries ensuring no disclosure of proprietary data, including detailed chemical identification or testing plans, which could compromise competitive interests or future intellectual property rights.***

Or. en

Justification

SR&D and PPORD activities are exploratory and pre-commercial, involving proprietary testing plans and sensitive data. Requiring full notifications risks exposing confidential research, undermining intellectual property protections. REACH (Article 9) and CLP exempt these activities to foster innovation while ensuring safety. Extending this exemption ensures regulatory consistency, protects trade secrets, and avoids duplicative compliance burdens, supporting scientific progress without compromising safety or environmental standards.

Amendment 497
Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***without undue delay***, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***within three months of the date of the commissioning***, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. ***The confidentiality of information on business operators will be respected.***

Or. en

Amendment 498
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***without undue delay***, any studies ***on*** chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior ***to*** placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***within one month from the date of the commissionning***, any studies ***that generate data*** 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 ***hazard,*** risk or safety assessment, prior ***or after the*** placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the

studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

Or. en

Amendment 499
Jutta Paulus

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***without undue delay***, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***within one month from the date of commissioning***, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

Or. en

Justification

There should be a clear deadline for business operators for the notification to the Database of Study Notifications to ensure a level playing field for all.

Amendment 500
Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, ***any*** studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority***, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market***, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, ***information referred to in article 22(2) related to*** studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. ***Business operators shall provide a valid justification for the non-notification of studies in accordance with this paragraph.***

Or. en

Amendment 501
Laurent Castillo

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***without undue delay, any*** studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ***within three months, any*** studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

Or. fr

Amendment 502
Martin Hojsík

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. ***However,*** business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without 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. Business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

Or. en

Justification

Operators should notify the studies without delay, as is the case of Notification according to Article 32b of Regulation (EC) No 178/2002. Therefore we suggest to keep those provisions aligned with EFSA´s practical arrangements to have common approach.

Amendment 503
Billy Kelleher

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any studies on chemicals they commission to support an application, notification or regulatory dossier notified

or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment , prior to placing on the market, under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 ***studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.***	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**,** ***laboratories and testing facilities*** shall not notify to the Database of Study Notifications referred to in Article 9**,**

Or. en

Amendment 504
Billy Kelleher

Proposal for a regulation
Article 22 – paragraph 1 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) in case of studies that are to be notified under Article 32b of Regulation (EC) No 178/2002;

Or. en

Amendment 505
Billy Kelleher

Proposal for a regulation
Article 22 – paragraph 1 – point b (new)

Text proposed by the Commission	*Amendment*
	(b) when a valid justification for late or non-notification is provided by business operators. The assessment of the validity of justifications for non-notifications shall be done by ECHA. [For research in and development of medicinal products,] studies conducted in the context of Scientific Research and Development (SR&D) or Product and Process Orientated Research and

Development (PPORD), each as defined in Regulation (EC) No 1907/2006 (REACH), are sensitive data and commercially confidential by nature and shall be considered a valid justification for non-notification; or,

Or. en

Amendment 506
Billy Kelleher

Proposal for a regulation
Article 22 – paragraph 1 – point c (new)

Text proposed by the Commission	*Amendment*
	(c) in case of studies under Articles 40, 41 and 46 of Regulation (EC) No 1907/2006 (REACH). They shall be excluded from the notification requirement, given that such studies are carried out in response to a request from the authority.

Or. en

Amendment 507
Billy Kelleher

Proposal for a regulation
Article 22 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. For the purpose of paragraphs 1 and 2, business operators, laboratories and testing facilities may claim all or part of the information in paragraph 2 is confidential in accordance with the provisions on confidentiality under the originating Union act.

Or. en

Amendment 508
Kristoffer Storm

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, business operators ***shall notify*** to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.	2. For the purposes of paragraph 1, ***information to be notified by*** business operators to the Database of Study Notifications referred to in Article 9 ***shall be limited to*** 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. ***For medicinal products, notification is only required after the market authorisation application has been submitted.***

Or. en

Justification

Support for amendment 80 in the draft report.

Amendment 509
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles	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***, relevant GLP or equivalent compliance monitoring authority***

40, 41 or 46 of Regulation (EC) No 1907/2006.	***responsible for ensuring test facility compliance*** 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.

Or. en

Amendment 510
Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or testing facility carrying out the study, the intended starting and planned completion dates and, where relevant, whether the study is commissioned to comply with a decision of the ECHA pursuant to Articles 40, 41 or 46 of Regulation (EC) No 1907/2006.	2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the 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. ***For medicinal products, notification is only required after the market authorisation application has been submitted.***

Or. en

Amendment 511
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, business operators shall notify to the Database of Study Notifications referred to in Article 9 the title, scope, laboratory, or	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)***

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.

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.

Or. en

Amendment 512
Kristoffer Storm

Proposal for a regulation
Article 22 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. For the purpose of paragraphs 1 and 2, business operators may claim part of the information in paragraph 2 is confidential in accordance with the provisions on confidentiality under the originating Union act.

Or. en

Justification

Support for amendment 81 in the draft report.

Amendment 513
Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Laboratories and testing facilities shall also, ***without undue delay***, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion,	3. Laboratories and testing facilities shall also, ***within three months of the date of the commissioning***, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific

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.	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. ***The confidentiality of information on laboratories and testing facilities will be respected.***

Or. en

Amendment 514
Kristoffer Storm

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. ***The confidentiality of information on laboratories and testing facilities shall be respected.***

Or. en

Justification

Support for parts of amendment 82 in the draft report.

Amendment 515
Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Laboratories and testing facilities shall also, without undue delay, notify ***any study*** commissioned by business operators to support a regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	3. Laboratories and testing facilities shall also, without undue delay, notify ***information referred to in article 22(2) related to studies*** 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.

Or. en

Amendment 516
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support ***a*** regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.	3. Laboratories and testing facilities shall also, without undue delay, notify any study commissioned by business operators to support ***an application, notification, or*** regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002.

Or. en

Amendment 517
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 22 – paragraph 4

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

Or. en

Amendment 518
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 22 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. By ... [OP please insert date: 5 years after the date of entry into force of this Regulation], business operators shall notify to the Database of Study Notifications referred to in Article 9 any studies commissioned to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment, for chemicals placed on the market before the entry into force of this Regulation, under the Union acts listed in Annex I.
	Subparagraph 1 shall only apply to chemicals placed on the market before the entry into force of this Regulation, under the Union acts listed in Annex I, and which are still authorised on the Union

market by ... [OP please insert date: 5 years after the date of entry into force of this Regulation].

Studies notified in accordance with this paragraph shall only be included in the database for information and scientific purposes, and shall not, under any circumstances, have retroactive legal application.

Or. en

Amendment 519
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 22 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The obligations set under this article shall apply from [OP please insert date: ***24*** months after the date of entry into force of this Regulation].	6. The obligations set under this article shall apply from [OP please insert date: ***12*** months after the date of entry into force of this Regulation].

Or. en

Amendment 520
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 22 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The obligations set under this article shall apply from [OP please insert date: ***24*** months after the date of entry into force of this Regulation].	6. The obligations set under this article shall apply from [OP please insert date: ***12*** months after the date of entry into force of this Regulation].

Or. en

Amendment 521

Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article.	7. The ECHA shall lay down the practical arrangements for implementing the provisions of this Article***, and engage business operators where relevant***.

Or. en

Amendment 522
Jutta Paulus

Proposal for a regulation
Article 22 – paragraph 7

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

Or. en

Justification

The EFSA is already running a Database of Study Notification pursuant to the Regulation on General Food Law. It is therefore appropriate for the ECHA to closely cooperate with EFSA in that context. There is no need to consult stakeholders on the practical implementation of this Article. Not such consultation is foreseen in the Regulation on General Food Law.

Amendment 523
Martin Hojsík

Proposal for a regulation
Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The ECHA shall lay down the practical arrangements for implementing	7. The ECHA shall***, in consultation with EFSA,*** lay down the practical arrangements for implementing the

the provisions of this Article.	provisions of this Article.

Or. en

Justification

ECHA shall consult EFSA to align approach under the CDP with existing notification obligation under Article 32b of Regulation No 178/2002.

Amendment 524
Stine Bosse

Proposal for a regulation
Article 22 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. The requirements outlined in this article do not apply to substances that are manufactured, imported, or used for Scientific Research and Development (SR&D) or Product and Process-Oriented Research and Development (PPORD), each as defined in Regulation (EC) No 1907/2006 (REACH), when used in, or for, research in, and development of, medicinal products.

Or. en

Justification

This amendment is necessary to completely safeguard against the disclosure of commercially sensitive data and prevent a competitive disadvantage compared to industrial climates in competing nations, which would occur if business operators have to notify studies during R&D activities. Furthermore, it brings the legislation into alignment with the already existing legislative framework by highlighting that the scope of studies to be notified should not go beyond the obligations set out in the REACH regulation.

Amendment 525
Billy Kelleher

Proposal for a regulation
Article 22 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*

7 a. This article shall not apply to substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD), each as defined in Regulation (EC) No 1907/2006 (REACH), when used in or for research in and development of medicinal products.

Or. en

Amendment 526
Niels Flemming Hansen, Jessica Polfjärd

Proposal for a regulation
Article 22 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. The obligations set under this article shall not apply to substances manufactured, imported, or used in Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD).

Or. en

Justification

This Regulation should not contradict the provisions in the REACH regulation (Regulation (EC) No 1907/2006) on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD). Article 9 of REACH outlines an exemption, recognizing the importance of SR&D activities in advancing scientific knowledge and technological innovation. Similarly, the CLP regulation (Regulation (EC) No 1272/2008) acknowledges the need for exemptions for substances used in SR&D, provided that such use does not compromise human health or the environment. Exemptions for SR&D under REACH and CLP have demonstrated that such activities can be conducted safely with appropriate risk management measures. It would be therefore more efficient and to extend similar exemptions to this Regulation and thus that SR&D activities continue without compromising safety standards. Failing to do so would create a direct contradiction between this Regulation and the REACH and CLP regulations. An exemption for SR&D is essential for business operators competing on a global stage, particularly for innovators who can be SMEs. Exclusion of an exemption for SR&D will make EU facilities less favourable locations to conduct process development and commercialisation. Fulfilment of the study notification

obligation will result in the disclosure of sensitive chemical identification information and testing plans on proprietary materials. An exemption for SR&D is a necessary measure to protect intellectual property, supporting innovation in the development of new and safer chemical substances. Exemptions for SR&D will facilitate the exploration of innovative solutions that can lead to significant advancements in various industries, including pharmaceuticals, agriculture, and materials science.

Amendment 527
Pietro Fiocchi

Proposal for a regulation
Article 22 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. The obligations set under this article shall not apply to substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD).

Or. en

Amendment 528
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Chapter VII a (new)

Text proposed by the Commission	*Amendment*
	VII a Chapter VIIa
	ACCESS TO JUSTICE
	Article 22a
	Access to Justice
	1. Any natural or legal person which has submitted substantiated concerns in accordance with Article 18a shall have access to an administrative or judicial procedure to review the procedural and substantive legality of the decisions, acts or omissions of the relevant authority

under paragraph 3 of Article 18a.

2. Member States shall ensure access to administrative or judicial procedures to review their decisions, acts and omissions, in accordance with national law or practice. Decisions and omissions by the Commission shall be subject to review in accordance with Regulation EU (No) 1367/2006.

3. The procedures referred to in paragraph 2 shall be fair, equitable, timely and not prohibitively expensive while providing adequate and effective remedies, including injunctive relief where necessary. Member States shall ensure that practical information is made available to the public on access to administrative and judicial review procedures.

Or. en

Amendment 529
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Chapter VIII – title

Text proposed by the Commission	*Amendment*
VIII DELEGATED POWERS	VIII DELEGATED ***AND IMPLEMENTING*** POWERS

Or. en

Amendment 530
Pietro Fiocchi

Proposal for a regulation
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission is empowered to adopt delegated acts in accordance with	2. The Commission is empowered to adopt delegated acts in accordance with

Article 24 to amend Annex II by adding, ***where relevant***, new categories of data types.	Article 24 to amend Annex II by adding, ***respecting the confidentiality of certain data***, new categories of data types.

Or. en

Amendment 531
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 24 a (new)

Text proposed by the Commission	*Amendment*
	Article24a
	Committee procedure
	1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011[1a].
	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
	[1a] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

Amendment 532
Beatrice Timgren

Proposal for a regulation
Article 25 – title

Text proposed by the Commission	*Amendment*
Enforcement	***Cooperation on compliance***

Or. en

Amendment 533
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article26a
	Reports
	1. By [OP: please insert date: 2 years after the end of the first calendar year after entry into force of this Regulation], the Commission shall draw up a report, analysing the adequacy between the resources of the agencies and their current tasks, their new tasks under this Regulation, and a prospective view of the resources needed to address key areas of regulatory challenge. 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 date: 2 years after the end of the first calendar year after entry into force of this Regulation], the Commission shall draw up a report, compiling and analysing data on the impacts of cumulative exposure to chemicals on health and the environment, and analysing the efficacy of the current risk assessment of chemicals to adequately address the combination effect of chemical mixtures to ensure a high level of protection of health and the environment. The Commission shall present this report to the European Parliament, the Council, the European Economic and Social Committee, and the

Committee of the Regions.

Or. en

Amendment 534
Anja Hazekamp, Jonas Sjöstedt, Emma Fourreau, Lynn Boylan, Sebastian Everding, Catarina Martins

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article26a
	Access to justice
	1. Any natural or legal person which has submitted substantiated concerns in accordance with Article 18a shall have access to an administrative or judicial procedure to review the procedural and substantive legality of the decisions, acts or omissions of the relevant authority under paragraph 3 of Article 18a.
	2. Member States shall ensure access to administrative or judicial procedures to review their decisions and omissions, in accordance with national law or practice. Decisions and omissions by the Commission shall be subject to review in accordance with Title IV of Regulation EU (No) 1367/2006.
	3. The procedures referred to in paragraph 2 shall be fair, equitable, timely and not prohibitively expensive while providing adequate and effective remedies, including injunctive relief where necessary. Member States shall ensure that practical information is made available to the public on access to administrative and judicial review procedures.

Or. en

Amendment 535
Christophe Clergeau, Chloé Ridel, Estelle Ceulemans, Pierre Jouvet

Proposal for a regulation
Article 26 b (new)

Text proposed by the Commission	*Amendment*
	Article 26b
	Review
	1. No later than ... [OP: please insert the date = 5 years after the date of application of this Regulation], the Commission shall carry out a review of this Regulation. This review shall assess in particular
	(a) the efficacy of the early warning and action mechanism
	(b) whether it is appropriate to include additional data into the common data platform.
	2. No later than ... [OP: please insert the date = 2 years after the date of application 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.
	3. The Commission shall present a report on the main findings of the evaluation under paragraph 1, to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions. 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. Based on the findings of the assessment referred to in paragraph 2 and the report referred to in paragraph 3, the Commission may, as appropriate, submit

legislative proposals to the European Parliament and to the Council in this regard.

Or. en

Amendment 536
Martin Hojsík, Sigrid Friis

Proposal for a regulation
Article 27 a (new)

Text proposed by the Commission	*Amendment*
	Article27a
	Review
	No later than … [OP: please insert 1 year after the entry into force of this Regulation], the Commission shall assess workload and further needs of the European Chemicals Agency, stemming among others from the additional tasks related to the establishment of database of information on substances in products and their available alternatives, and where appropriate, provide it with adequate further resources.

Or. en

Amendment 537
Beatrice Timgren

Proposal for a regulation
Annex I – point 9

Text proposed by the Commission	*Amendment*
9. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)	***deleted***

Or. en

Amendment 538
Beatrice Timgren

Proposal for a regulation
Annex I – point 29

Text proposed by the Commission	*Amendment*
29. Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)	***deleted***

Or. en

Amendment 539
Beatrice Timgren

Proposal for a regulation
Annex I – point 65

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

Or. en

Amendment 540
Jutta Paulus

Proposal for a regulation

Annex I – point 70 a (new)

Text proposed by the Commission	*Amendment*
	70 a. 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)

Or. en

Justification

In the course of 2024, the new Regulation on ecodesign was adopted. It includes a web portal with information on chemicals in products. Such data should also be included in the common data platform. Therefore, this Regulation needs to be included in Annex I.

Amendment 541
Jutta Paulus

Proposal for a regulation
Annex II – Part 1 – paragraph 1

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

Or. en

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

Justification

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

Amendment 542
Jutta Paulus

Proposal for a regulation
Annex II – Part 2 – paragraph 1

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

Or. en

Justification

According to information from EMA, there are currently 1,110 medicinal products containing chemically active substances authorised under the centralised procedure. On average, every year, the Agency assesses 61 such medicinal products. That amounts to just over 5% of the total. Limiting the inclusion to procedures finalised or submitted after the entry would mean that the very large majority of data held by EMA would not be included in the common data platform for many years to come (if at all). That is not appropriate. The fact that many data

that EMA holds are not yet available in machine-readable format must not be used against inclusion of such data into the common data platform, as it would perpetuate outdated circumstances. The common data platform should be filled over a period of eight years after entry into force. This is more than enough time for EMA to digitalize the data it holds. There should be certainty as to when this data will be included. It is therefore appropriate to specify that existing data has to be included no later than eight years after entry into force.

Amendment 543
Beatrice Timgren

Proposal for a regulation
Annex III – point 21

Text proposed by the Commission	*Amendment*
21. Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)	***deleted***

Or. en

Amendment 544
Beatrice Timgren

Proposal for a regulation
Annex III – point 31

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

Or. en

Amendment 545
Jutta Paulus

Proposal for a regulation
Annex III – point 34 a (new)

Text proposed by the Commission	*Amendment*
	34 a. 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)

Or. en

Justification

In the course of 2024, the new Regulation on ecodesign was adopted. It includes a web portal with information on chemicals in products. Information about regulatory processes in the context of that Regulation should also be included in the common data platform. Therefore, this Regulation needs to be included in Annex III.

Amendment 546
Jutta Paulus

Proposal for a regulation
Annex III b (new)

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

o ECHA Prior Informed Consent (PIC): Data on substances subject to PIC the Regulation.

o 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.

o EFSA OpenFoodTox: Summary of all EFSA chemical risk assessments including chemical identifiers, critical endpoints, toxicological reference values and metadata from EFSA outputs.

o 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 call for data.

o EFSA OpenEFSA: All information related to EFSA's scientific work. Tracking of the risk assessment process from receipt of dossier to adoption of the opinion. Information available includes status of assessments, dossiers and studies, meeting agendas and minutes, information on experts (DOIs), public consultations).

o 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.

o EEA Air Quality: Air quality data from a wide range of sources including 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'.

o 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.

o 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.

o EEA Industrial emissions: Data reported by Member States in the scope of the E-PRTR Regulation and Industrial Emissions Directive.

o EEA National Emission reductions Commitments (NEC) Directive emission inventory data: Data on emissions of air pollutants.

o EMA human medicinal products data (environmental risk assessment and non-clinical safety data)

o EMA veterinary medicinal products (environmental risk assessment and maximum residue limit (MRL) values and MRL assessment data)

Or. en

Justification

There needs to be clarity from the outset of what should be integrated into the common data platform at the moment of establishment. The datasets to be included for the "Minimum Viable Product", as set out in the Staff Working Document SWD(2023) 850, p. 141 - 143), should be specified in the Annex.