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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals - Analysis of the final compromise texts with a view to agreement

I. INTRODUCTION

1. On 7 December 2023, the Commission transmitted to the European Parliament and the Council the proposals of the "One Substance One Assessment (OSOA)" package:

   - Proposal for a Regulation establishing a common data platform on chemicals ('Common Data Platform Regulation') [1]

   - Proposal for a Directive concerning the re-attribution of scientific and technical tasks ('RoHS Directive') [2]

   - Proposal for a Regulation aimed at enhancing cooperation among Union agencies in the area of chemicals ('Reattribution Regulation')[3].

   These three proposals aim to streamline assessments of chemicals across relevant EU legislation, strengthen the knowledge base on chemicals, and ensure early detection and action on emerging chemical risks.

2. The Council consulted the European Committee of the Regions and the European Economic and Social Committee. The European Economic and Social Committee delivered its opinion on the OSOA package on 20 March 2024, while the Committee of the Regions did not issue an opinion.

3. Under the Belgian Presidency, an Ad Hoc Working Party on the implementation of the "one substance, one assessment" approach to chemical safety assessments (AHWP) was established to effectively address the cross-sectoral matters covered by the OSOA package and to carry out the preparatory work linked to their examination within the Council.

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1 16961/23 + ADD1.
2 16972/23.
3 16973/23.

II. WORK IN THE COUNCIL AND WITH THE EUROPEAN PARLIAMENT

4. Following the work of the AHWP, on 14 June 2024 the Committee of Permanent Representatives agreed on a Council position and gave a mandate to the Presidency to engage in negotiations with the European Parliament.[4]

5. The European Parliament adopted its report on the OSOA package in plenary on 1 April 2025.

6. On the basis of the negotiation mandate from the Committee of Permanent Representatives, the Presidency engaged in eight interinstitutional technical meetings with the Parliament, starting on 10 April 2025.

7. On 4 June 2025, Coreper revised the mandate for negotiations in line with the results of the interinstitutional technical meetings with the Parliament.[5]

9. On 12 June 2025, a political trilogue took place, confirming the results of the compromise text agreed upon at the technical level. At this trilogue, the Polish Presidency reached a provisional political agreement with the European Parliament on the entire OSOA package.

[4] 10812/24 + ADD1 + ADD2 + ADD3.
[5] 9439/25.

III. ANALYSIS OF THE FINAL COMPROMISE

10. The provisional agreement with the Parliament largely confirms the revised Coreper mandate of 4 June 2025. It includes the following key elements:

Common Data Platform Regulation (doc. 10413/25 ADD 1)

As regards the subject matter, scope and definitions the agreement follows largely the Commission proposals. New definitions proposed by the Parliament have been taken up ('peer-reviewed published research data', 'data processor'). A definition on 'third party' from the Council has been deleted and instead taken up in its relevant context regarding human biomonitoring data in Article 6(4f). The definition proposed by the Council on 'the public' has been agreed, and 'the public' replaces all references to 'the general public' throughout the legal text.

As regards the information systems and platforms the agreement expands the scope of information available on the platform to include voluntarily submitted scientific data (Article 3(2), point (ba)). However, to ensure feasibility and data quality this is limited only to data already held or accepted by the Commission and the Agencies.

The Council's mandate concerning data on medicinal products (Article 3(2a)) is upheld in the agreed text, including the text structure in enacting provisions and annexes. Legacy data will be gradually integrated into the platform as from six years after the regulation enters into force, however limited to the categories originally proposed in the Council's mandate for new medicinal data. The Commission will need to carry out an assessment and adopt a report within six years from the entry into force (Article 26a(1)) whether it is appropriate to include in the common data platform further chemicals data relating to medicinal products (substances other than active substances, substances that are now considered non-relevant, or held by national agencies).

Article 3(4a) clarifies that the European Chemicals Agency (ECHA) uses a unique technical identifier (and not a 'unique chemical identifier' as proposed by the Parliament) for each chemical to link various datasets on the same chemical.

The step-wise implementation of the database has been refined in the compromise text (Article 3(11)). Within three years of the entry into force of the regulation the database will need to contain at least the datasets set out in a newly created Annex IIIa.

Regarding data from research activities (Article 5(5) and (6)), as a compromise, human biomonitoring data will be included in the platform from national and Union framework programmes. For environmental sustainability related data the inclusion is limited to Union framework programmes.

The purposes, for which Commission and Agencies may process human biomonitoring data constituting personal data, have been streamlined in the text (Article 6).

Following to some extent the Parliament's proposals the compromise text expands the scope of the data platform to data on chemicals in articles or products (Article 10a) generated or submitted as part of the implementation of existing EU legislation listed in a new Annex IIIb. Regarding information on alternatives to substances of concern (Article 10b) the compromise reached requires the ECHA to create and manage a database on the common data platform for alternatives to substances of concern (as defined in Regulation (EU) 2024/1781), including alternative technologies and materials.

Following a Parliament's proposal, it has been agreed that the Commission and the Agencies should promote the development and use of tools and practices facilitating the uptake of peer-reviewed published research data in regulatory chemicals assessments (Article 15a).

As regards the confidentiality of data and the access to data which is not marked as confidential (Article 9(3)(4a)(4b)(4c), Articles 16 and 17) the Agencies will make available to the public only the data that is available to the public according to the originating acts, while ensuring that the horizontal legislation governing public access to information (Regulation (EC) no 1049/2001) applies to all data that is not confidential. The Authorities will have access to all the chemicals data contained in the common data platform, including commercially sensitive information and data not available to the public under the originating Union act. The Authorities will also be responsible for taking the necessary measures to ensure that data contained in the platform indicated as not available to the public under the originating Union act will not be available to the public.

As regards the data generation mechanism (Article 21) the ECHA will be able to request that a business operator provide a sample of a substance for studies conducted under the data generation mechanism when needed.

Under the data generation mechanism, the ECHA will commission a Union-wide human biomonitoring study four years after the regulation enters into force, covering all Member States (new Article 21a). The ECHA will cover the full cost of the study, and Member States will only provide the necessary technical assistance and administrative support. After the study is completed, the Commission will review the possibility of conducting regular, Union-wide human biomonitoring studies and may present a legislative proposal to that effect.

Regarding the notification of studies, the deadline for the application of the study notification obligation is set at 22 months (Article 22 (6)), and the possibility for Member States to allow for exemptions from the notification obligations in the interest of defence is upheld, while an exemption in the interest of national security will be possible in cases where this is foreseen in the originating act (Article 22(6a)).

Regarding the delegated powers to amend the Annexes (Article 23), the compromise text largely follows the Council mandate. A new paragraph (Article 23(3a)) to amend the newly created Annex IIIb is taken up in the text.

The provision for reports and reviews (Article 26a) is streamlined and most reviews are to be carried at about six years from the entry into force.

The final compromise text is set out in document 10413/25 ADD 1.

RoHS Directive (doc. 10413/25 ADD 2)

Regarding the directive amending Directive 2011/65/EU, the Council mandate regarding the introduction of deadlines for completing applications (Article 1 point (1)(a)) and the Commission's obligation to publish guidelines on the application (Article 1 point (1)(d)) has been maintained.

The compromise agreement sets the deadline for a Commission decision (i.e., a delegated act) for the renewal of an exemption based on the moment of receipt of the Agency's opinions at nine months (Article 1 point (1)(ba)).

Regarding Article 1, point (3)(a), the co-legislators agreed to set a deadline for the Commission to review the list of restricted substances. The agreement is to have periodic reviews every four years, taking into account market developments and technical progress.

Regarding Article 1, points (3)(c) and (6), the agreement adheres to the Council's mandate to introduce Annex IX to the RoHS Directive. This new annex coherently specifies the criteria for a restriction dossier instead of referring to Annex XV of the REACH Regulation.

The delegated powers in Article 1, point (4a), have been streamlined in line with the Council's mandate.

Regarding Article 1, point (5), the Council version of the review clause is upheld to ensure the Scientific Committees provide appropriate expertise, support, and sound scientific assessments, as well as adequate resources and stable governance. The Commission must consider any future regulatory changes to the governance of the European Chemicals Agency's Scientific Committees when revising Directive 2011/65/EU, if necessary.

Regarding Article 2, the deadline for the application of the provisions of this Directive is set at 20 months.

The final compromise text is set out in document 10413/25 ADD 2.

Reattribution Regulation (doc. 10413/25 ADD 3)

Regarding Article 1 of the Reattribution Regulation, the amendments to Regulation (EC) No 178/2002 (also known as the General Food Law), a reference to Article 30(2) has been added to Article 27 of that legal act. The rest largely follows the Commission proposal.

Regarding Article 2, the Council proposal to amend the text of Article 15(1) of Regulation No. 401/2009 on the European Environment Agency is upheld.

Regarding Article 3 and the amendments to Regulation (EU) 2017/745 on medical devices, the compromise text includes the word "classified" in Section 10.4.1, point (b).

Regarding Article 4 and the amendments to Regulation (EU) 2019/1021 on persistent organic pollutants, the text in Article 4, points (1), (2), (3), (5), (5a), (5b), (5c), (5d), (5e), and (5f), has been accepted in line with the Council mandate. Regarding Article 4, point (4), limitations to the delegated powers concerning modifications to Annexes IV and V have been agreed upon.

The final compromise text is set out in document 10413/25 ADD 3.

IV. CONCLUSION

11. Against this background, the Permanent Representatives Committee is invited to:

(a) approve the final compromise text as set out in documents 10413/25 ADD 1, 10413/25 ADD 2 and 10413/25 ADD 3 with a view to reaching an agreement at first reading with the European Parliament;

(b) authorise the Chair of the Permanent Representatives Committee to send a letter to the Chair of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) confirming that, should the European Parliament adopt its position at first reading in the exact form as set out in documents 10413/25 ADD 1, 10413/25 ADD 2 and 10413/25 ADD 3, subject to revision by the lawyer-linguists of both institutions, the Council will approve the European Parliament's position and the act will be adopted in the wording which corresponds to the European Parliament's position at first reading.