Council of the European Union

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ENV 410
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CHIMIE 40
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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 - Preparation for the trilogue

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 Directive concerning the re-attribution of scientific and technical tasks ('RoHS Directive') [1]

   - Proposal for a Regulation aimed at enhancing cooperation among Union agencies in the area of chemicals ('Reattribution Regulation')[2].

   - Proposal for a Regulation establishing a common data platform on chemicals ('Common Data Platform 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 16972/23.
2 16973/23.
3 16961/23 + ADD1.

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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 seven interinstitutional technical meetings with the Parliament, starting on 10 April 2025.

7. A meeting of the AHWP was held on 26 May 2025 to report back from those interinstitutional technical meetings.

8. The Presidency is presenting the following compromise package, which contains the results of the technical discussions, in preparation for the political trilogue on 12 June 2025.

III. STATE OF PLAY OF NEGOTIATIONS

a) RoHS Directive (ST 9230/1/25 REV 1)

9. All articles and recitals have been provisionally agreed by the co-legislators.

10. Regarding the provisional outcomes and the state of play, the Presidency would like to draw the attention of the delegations to the following points:

- The Council mandate was maintained regarding the introduction of deadlines for completing applications (Article 1 point (1)(a)) and the Commission obligation to publish guidelines on the application (Article 1 point (1)(d)).

[4] 10812/24 + ADD1 + ADD2 + ADD3.

- Regarding Art. 1 point (1)(ba) the Presidency agreed to the Parliament's proposal to set a deadline for Commission decision for renewal of an exemption based on the moment of receipt of the opinions from the Agency. The period for adoption of such delegated act however, was extended from 6 to 9 months.

- 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 Presidency and the Parliament agreed on a periodical review every 4 years, taking into account market developments and technical progress.

- Regarding Article 1 point (3)(c) and (6) the Parliament accepted to agree to the Council proposal to introduce an Annex IX to the RoHS directive, specifying in a coherent way the criteria for a restriction dossier, instead of referring to Annex XV to the REACH Regulation.

- Regarding Article 1 point (5) the Parliament accepted the Council version of the review clause aiming to ensure appropriate expertise, support and sound scientific assessments coming from the Scientific Committees, as well as their adequate resources and stable governance. The Commission will need to take into account any future regulatory changes regarding the governance of the Scientific Committees of the European Chemicals Agency with a view to revising Directive 2011/65/EU on relevant issues, if necessary.

- Regarding Article 2, in order to reach a compromise, the Presidency and the Parliament agreed to set the deadline for application of the provisions of this Directive at 20 months.

11. After receiving overall support for those provisional outcomes at the meeting of the AHWP on 26 May 2025, the Presidency is presenting the compromise proposals in the draft agreement column of the 4-column table in document ST 9230/1/25 REV 1.

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b) Reattribution Regulation (ST 9221/1/25 REV 1)

12. All articles and recitals have been provisionally agreed by the co-legislators.

13. Regarding provisional outcomes and the state of play, the Presidency would like to draw the attention of the delegations to the following points:

- Regarding Article 1 of the Reattribution Regulation, the Parliament agreed to withdraw its proposal on Article 30 of the General Food Law on diverging scientific opinions. Additionally, a reference to Article 30(2) was added to Article 27.

- In Article 2 the Parliament accepted the Council proposal regarding the amendment of the existing text of Article 15 point (1) of Regulation No 401/2009 on the European Environment Agency, instead of adding a new point (5).

- Regarding Article 3, in the spirit of compromise, the Presidency accepted the Parliament amendment including the word “classified” in Section 10.4.1, point (b).

- In Article 4 all rows concerning Article 4 points (1) (2) (3) (5) (6) (7) (8) (9) (10) (11) with regard to the Regulation (EU) 2019/1021 on persistent organic pollutants were accepted in line with the Council mandate.

- For Article 4 point (4), the Presidency maintained the Council mandate with regard to the limitations to the delegated powers concerning modifications of Annexes IV and V but agreed to the Parliament position on a simplified text.

14. After receiving overall support for those provisional outcomes by the AHWP on 26 May 2025, the Presidency is presenting the compromise proposals in the draft agreement column of the 4-column table in document ST 9221/1/25 REV 1.

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c) Common Data Platform Regulation (ST 9331/25)

15. All articles and most of the of the recitals have been provisionally agreed by the co-legislators. The remaining recitals have not yet been aligned with the agreed-upon enabling provisions. All substantive issues were resolved during negotiations.

16. A compromise was reached in response to the Parliament's proposals to expand the scope of the data platform to include all information on substances in articles and safer alternatives to substances of concern (Articles 10a and 10b). It was agreed that information on substances in articles and products, which is already available under existing legislation, would be listed in a new Annex IIIb. Regarding the information on safer alternatives, the Parliament accepted that the database cannot determine whether an alternative is "safer". The compromise reached requires the European Chemicals Agency (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. Furthermore, a provision was added stating that Member States holding information on substances in articles and products may voluntarily make it available to responsible Agencies, including ECHA.

17. The agreement reached expands the scope of information available on the platform to include voluntarily submitted scientific data (Article 3(2), point (ba), (bb)). However, to ensure feasibility and data quality this data was limited only to data already held or accepted by the Commission and the Agencies. Furthermore, it was agreed that the Commission and the Agencies should promote the development and use of tools and practices to facilitate the uptake of data from peer-reviewed scientific publications in regulatory chemicals assessments.

18. The Parliament's proposal to introduce a mandatory unique chemical identifier (Article 3(4a)) was considered unfeasible to implement. Instead, it was clarified that ECHA uses a unique technical identifier for each chemical to link various datasets on the same chemical.

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19. The Council's mandate concerning data on medicinal products (Article 3(2a), Article 26a) was upheld in the agreed text, including the text structure and a review clause that requires the Commission to carry out an assessment and adopt a report within six years from the entry into force 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). Regarding legacy data, a compromise was reached: 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.

20. Regarding the Parliament's proposal to add research data (Art. 5(5) and (6), Art. 13(13)), as a compromise, the Presidency agreed to include that data from Union framework programmes and from national programmes concerning only human biomonitoring data, but not from national programmes concerning environmental sustainability related data.

21. Both Parliament and Council proposed in their negotiation mandates (Article 1(2), point (ba), Article 9(1a) (2), Article 22(-1), second and third subparagraph) that the public should have access to all data which is not marked as confidential. However, during negotiations it was concluded that this solution would not be practical, since all the data which is currently non-public at Agencies would need to be made public unless assessed and marked as confidential, creating excessive workload for the Agencies. A compromise was found that allows the Agencies to 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.

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22. The Parliament's proposal requiring ECHA to establish a mechanism for the exchange of information and studies with third countries (Article 9(1a)), and to store the data on studies obtained through this exchange mechanism in the database of study notifications (Article 9(2)), was not maintained in the final text. The Council's proposal concerning the possibility for Member States to allow for exemptions from the notification obligations in the interest of defence was upheld, while an exemption in the interest of national security will be possible in cases where this is foreseen in the originating act. To reach a compromise, the Presidency and the Parliament agreed to set the deadline for the application of the study notification obligation at 22 months.

23. As regards the data generation mechanism (Article 21) the Parliament's proposal concerning sampling was agreed with clarifications. As a result, 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.

24. Recognizing the clear benefits of regular human biomonitoring studies in understanding the EU population's exposure to chemicals, it was agreed, based on the Parliament's proposal, that under the data generation mechanism ECHA would commission a Union-wide human biomonitoring study four years after the regulation enters into force, covering all Member States (new Article 21a). 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.

25. All of the timelines in the Common Data Platform proposal were agreed upon in accordance with the Council mandate, except for the deadline for study notifications (see above). Additionally, the Presidency and the Parliament agreed to synchronize all elements of the review clause (Article 26a) at six years from the entry into force.

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26. After receiving overall support for the provisional outcomes at the AHWP meeting on 26 May 2025, the Presidency is presenting the compromise proposals in the draft agreement column of the four-column table in document ST 9331/25.

IV. CONCLUSION

27. With a view to the political trilogue scheduled for 12 June 2025, the Committee of Permanent Representatives is invited to examine the compromise proposals outlined above, as well as the four-column documents referred to, and to give a mandate to the Presidency to conclude the negotiations with the European Parliament, with a view to reaching a first-reading agreement.

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