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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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Subject:	One Substance One Assessment (OSOA) Package: 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 establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals Proposal for a Regulation of the European Parliament and of the Council 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 - Mandate for negotiations with the European Parliament

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" package:

   - Proposal for a Directive concerning the re-attribution of scientific and technical tasks[1]

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

   - Proposal for a Regulation establishing a common data platform on chemicals[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 European Parliament is expected to start examination of the OSOA package after the European elections.

3. The Council consulted the European Committee of the Regions on and the European Economic and Social Committee respectively on 16 and 22 February 2024. The European Economic and Social Committee voted its opinion on the package on the plenary session of 20 March 2024. The Committee of the Regions renounced to issue an opinion on the OSOA package.

4. Under Belgium Presidency, an Ad Hoc Working Party on OSOA (AHWP) has been established to effectively address the cross-sectoral matters covered by the OSOA legislative proposals 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.

II. STATE OF PLAY

5. Delegations have welcomed the three proposals. Moreover, during the examination at working party level, solutions were found on many issues. As a result, the Ad Hoc Working Party succeeded in converging views on many aspects of the Re-attribution of scientific and technical tasks Directive (RoHS) and on the Regulation on the European Chemicals Agency (ECHA).

6. Regarding the Regulation on the platform for chemical data, several issues were discussed and the Presidency prepared a compromise with a view to address the remaining issues raised by delegations.

7. The Presidency compromise texts are set out in Addendum 1 to 3 to this Note[4].

III. MAIN ELEMENTS OF THE PRESIDENCY COMPROMISE TEXTS

Re-attribution of scientific and technical tasks Directive (RoHS)

8. With regard to the RoHS Directive, a number of amendments were made, which met with broad support. In order to ensure legal certainty, predictability and transparency of administrative procedures , some **deadlines have been further specified**: to provide a framework for handling applications to the agencies for exemption (Art. 1(1), point a) and to set a mandatory deadline for the Commission to review the list of restructured substances (Art. 1(3), point a).

9. Noting that ECHA's scientific committees have been given a new task of assessing requests for exemption in certain cases, the compromise text introduces an obligation for the Commission to publish, after consultation with representatives of the Member States, **guidelines for the harmonised implementation** of the new related procedure (Art. 1(1), point d).

[4] Changes compared to the Commission proposal are marked in ***bold italic*** for the additions, in ~~strikethrough~~ for the deletions.

10. Based on the outcome of the discussions on the specific features of the to restrict substances procedure in the RoHS Directive compared to the REACH restriction procedure, the Presidency has proposed **a new Annex IX** to address specifically the particularities of the RoHS Directive (Art. 1(3), point c), and Art. 1(6)). In this respect, it was also specified that ECHA could develop guidance on the application of Annex IX (recital 6b).

Regulation on the European Chemicals Agency (ECHA)

11. Several delegations raised concerns about the **governance and capacity of ECHA's scientific committees,** highlighting the increasing number of additional tasks allocated to them since the establishment of the Agency. A consensus has emerged, that these issues should be discussed as part of the wider discussions relating to the governance of the European Chemicals Agency's scientific committees. It has been therefore suggested to include a review clause to ensure that the relevant provisions are reviewed when the Commission will adopt any future basic act funding ECHA (SEAC and RAC), (ROHS Directive recital 2a and Art. 1(5)), (ECHA Regulation recital 14a and Art. 4(6)).

12. More substantial discussions were held **on delegating powers to the Commission** to adopt delegated acts to review Annexes IV and V of the Persistent Organic Pollutants Regulation (EU) 2019/1021. The empowerment has been reworked to circumscribe its coverage (Art. 4(4)).

13. Noting the political support for revising Annexes IV and V by a delegated act, the Presidency suggests **aligning the revision clauses laid down for 5 (groups of) substances in Annex IV** in order to provide for revision by delegated act and no longer by ordinary legislative procedure (Art. 4(7 to 11)).

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Regulation on a common data platform on chemicals

14. **The scope** of chemicals data to be included in the common data platform has been thoroughly restructured and clarified to meet delegations' requests. It's proposed that **all data relating to chemical products** should appear on this platform (Art. 3(2)). Based on this principle, there is no possibility of making a distinction between data generated or submitted before and after the regulation came into force. This is further clarified in recitals 7 and 24c as well as in Articles 3(11) and 6(11).

15. By way of derogation and on the basis of objective criteria, **not all data relating to medicinal products** will have to be included in the common data platform at this stage. In order to ensure greater legal certainty and readability of the text, the Presidency has decided to include the arrangements relating to these data in **Article 3** and not in Annex II as initially proposed by the Commission. The Presidency stresses that the scope has not been modified. A number of amendments have been made however to ensure maximum clarity as regards the scope of application (recitals 8, 9, and Art. 1(2), *in fine* and Art. 3(2a)).

16. Based on the overall consensus among delegations, the Presidency proposes to introduce a **clause to review the scope of medicinal products** (recital 9a, and first paragraph of Article 26a). With regard to this revision, the Presidency proposes not to depart from the procedural route initially proposed by the Commission, notably an empowerment to adopt delegated acts. At the same time, a number of amendments have been made to frame this delegation of power (recital 9b, and Art. 3(3)).

17. The Presidency took note of the **EPDS opinion** and aligned the proposal with the recommendations made (recitals 12, 15a, 23, 24a, 24b, 24c, and Artt. 5(5), 5(10), 6(3) to (7), 6(9) to (10)). With the support of the delegations, the Presidency has also made a number of proposals to facilitate the informed use of the data on chemicals accessible on the common data platform (Art. 3(5), *in fine* and 3(6)).

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18. With regard to the **obligation to notify certain studies**, the Presidency has chosen to specify the concept in Article 22(1) rather than providing a specific definition of such notification. It should be noted that ECHA is now required to develop guidance for duty holders to facilitate the implementation of this notification obligation, specifying in particular the types of study to be notified (recital 28). In order to take account of the specific interests of national security and defence, the Presidency suggests incorporating the language usually used in this context (as in Article 2(3) of the REACH Regulation) into this Regulation to allow Member States to adopt exemptions (Article 22(6a)).

19. In terms of the involvement of the Member States in **comitology procedure** in view of the implementation of this Regulation, the Presidency has heard the call for pragmatism and to avoid unnecessarily burdening the consultation processes of the Member States. In that sense in addition to empowering the Commission to adopt delegated acts in two specific cases (Art. 3(3) and Art. 23), only one provision now envisages the adoption of implementing acts ; for the adoption and publication of the list of selected chemicals requiring in-depth examination (Article 20(2)). The standard clause for this type of secondary legislation is set out in Article 24a.

20. As regards other provisions envisaging the adoption of an implementing act, but without comitology (Articles 4(1), 4(4), 14(8) and 15(8)), recital 18a specifies how the Member States will be involved in the decision-making process. Finally, the Regulation explicitly states in Articles 13(4) and 18(1) that the Commission must consult the Member States in the decision-making process that does not result in the adoption of a secondary legislative act.

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21. In order to ensure this legislation is future-proof and agile, the Presidency proposes that the Commission preserves the power to adopt delegated acts to revise Annexes I, II and III. However, the delegation of power has been redrafted to ensure that it is legally sound and circumscribed (recitals 49, 49a, 49b and Article 23). As provided for in Art. 24(4), the Commission will have to consult a group of experts appointed by each Member State before adopting a delegated act; this will most likely be the OSOA expert group already set up by the Commission.

IV. CONCLUSION

22. In view of the above, the Permanent Representatives Committee is invited to examine the Presidency compromise text set out in Addendum 1 to 3 to this note with a view to reach an agreement on a mandate for negotiations with the European Parliament.

23. In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 20203[5], and in full consistency with Regulation (EC) 1049/2001 and the Council's Rules of Procedure, the text of the mandate once agreed will be made public unless the Permanent Representatives Committee objects.

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5 9493/20.

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