



Brussels, 15 January 2024
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5259/24

LIMITE

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'I' ITEM NOTE

From:	Presidency/General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
Subject:	Ad Hoc Working Party on One Substance One Assessment (creation and mandate)
	- Approval

1. On 7 December 2023, the Commission adopted three legislative proposals (“OSOA legislative proposals”):
 - 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 chemicals¹;
 - 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 Agency²;

¹ 16961/23 + ADD1 + ADD 2.

² 16972/23 + ADD1.

- 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 chemicals³.
2. These proposed legislative acts aim to apply the “one substance, one assessment” approach announced in the Chemicals Strategy for Sustainability⁴ and thus strengthen the efficiency, effectiveness, consistency and transparency of chemical safety assessments across EU legislation.
 3. In order 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, the Presidency proposes to establish, in accordance with Article 19(3) of the Council’s Rules of Procedure⁵, an Ad Hoc Working Party (AHWP) on the implementation of the “one substance, one assessment” approach in the context of chemical safety assessments (“AHWP OSOA”) in order to involve experts from the different sectors concerned (environment, agriculture, health, trade, etc.).
 4. Under the authority of the Permanent Representatives Committee, the AHWP OSOA will report to the “Environment” configuration of the Council as well as, where appropriate, to the “Agriculture and fishing” configuration of the Council, the “Employment, social policy, health and consumers” configuration of the Council, and the “Competitiveness” configuration of the Council.

³ 16973/23 + ADD 1 + ADD 1 COR 1.

⁴ 11976/20 + ADD 1 - COM(2020) 667 final + Annex.

⁵ Council Decision of 1 December 2009 adopting the Council's Rules of Procedure (2009/937/EU).

5. The AHWP OSOA will operate in accordance with the mandate set out in the Annex to this note and will draw on the expertise of delegates working in the relevant areas, where appropriate. It will cease to exist upon the adoption of final legislative acts based on the proposed OSOA legislative acts or upon decision of the Permanent Representatives Committee. The mandate of the AHWP OSOA may be updated or revised, including its possible extension, in order to carry out the necessary legislative or non-legislative preparatory work related to the proposed OSOA legislative acts.
 6. The AHWP OSOA will carry out its tasks in close coordination and avoiding duplication with other preparatory bodies of the Council.
 7. In this context, the Permanent Representatives Committee is invited to approve:
 - the establishment of an Ad Hoc Working Party (AHWP) on the implementation of the “one substance, one assessment” approach in the context of chemical safety assessments (“AHWP OSOA”);
 - the mandate, as set out in the Annex to this note.
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Draft Mandate

Ad Hoc Working Party on the implementation of the "one substance, one assessment" approach to chemical safety assessments ("AHWP OSOA").

Code	<i>J.3</i>
Council configuration	The <u>Ad Hoc Working Party on the implementation of the "one substance, one assessment" approach to chemical safety assessments ("AHWP OSOA")</u> operates under: ☐ General affairs ☐ Foreign affairs ☐ Economic and financial affairs⁶ ☐ Justice and home affairs⁷ ☐ Employment, social policy, health and consumer affairs ☐ Competitiveness (internal market, industry, research and space)⁸ ☐ Transport, telecommunications and energy ☐ Agriculture and fisheries ☒ Environment ☐ Education, youth, culture and sport⁹
Sub-areas or subgroups (if applicable)	n/a
Policy areas	On 19 December 2023, the European Commission submitted three legislative proposals: • 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 (2023/0455(COD)); • 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

⁶ Including budget

⁷ Including civil protection

⁸ Including tourism

⁹ Including Audio-visual affairs

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- European Chemicals Agency (2023/0454(COD));
 - 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 (2023/0453(COD))

Under the authority of the Permanent Representatives Committee¹⁰, the AHWP OSOA will report to the Environment configuration of the Council and, as appropriate, to the Agriculture and Fisheries configuration of the Council, to the Employment, Social Policy, Health and Consumer Affairs configuration of the Council and to the Competitiveness configuration of the Council.

The AHWP OSOA is responsible for the conduct of the work necessary to prepare the content of the position of the Council on the above-mentioned legislative proposals of the Commission.

Type of work

The Working Party is mainly in charge of the following:

☒ **Work on Union legal acts (i.e. legislative acts and other legal acts)**

☐ **Policy preparation**

In particular, the AHWP is in charge of

☒ **legislative act(s):**

- **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 (2023/0455(COD));**
 - **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 (2023/0454(COD));**
 - **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 (2023/0453(COD)).**
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¹⁰ In accordance with Article 240(1) TFEU and the Council's Rules of procedure

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- ☐ other Union legal acts:
 - ☐ external documents or instruments:
 - ☐ policy document(s):
 - ☐ other:
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**Chairing
arrangement**

The Working Party is chaired by:

- ☒ the six-monthly Presidency
 - ☐ a representative of the High Representative
 - ☐ other, namely:
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Observations

- Date of establishment:
 - Duration of the mandate:
The AHWP OSOA will cease to exist upon the adoption of the legislative proposals above, or upon decision by the Permanent Representatives Committee.
 - Main links with other working parties: Working Party on Environment (J.1), Working Party on Technical Harmonisation (G.7), Working Party on Food and Food Systems (F.27), Working Party on Pharmaceuticals and Medical Devices (I.4), Working Party on Social Questions (I.1)
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