



Council of the European Union  
General Secretariat

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**Interinstitutional files:**  
**2023/0454 (COD)**  
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## MEETING DOCUMENT

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From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16973/23, ST 16972/23
Subject:	OSOA Package: Ad Hoc Working Party on One Substance One Assessment on 26 May 2025 - Presidency steering note (Part 1)

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With a view to the above AHWP on OSOA on 26 May 2025, delegations will find attached the first part of the Presidency steering note concerning the RoHS Directive and the Re-attribution Regulation.

Delegations are invited to note that the second part of the Presidency steering note relating to the Data platform Regulation will follow.

## Steering Note – OSOA– Part 1

Monday 26 May 2025

### AHWP – One Substance One Assessment Legislative Package

(All day)

The ad hoc working party meeting will begin at 10 a.m. and will be devoted to the analysis of the draft proposals for amendments made by the European Parliament on the three legislative proposals implementing the "One Substance, One Assessment" approach. The Presidency aims to prepare for the upcoming political trilogue, scheduled currently for 12 June 2025. In view of this political trilogue, the "One Substance, One Assessment" package will be discussed in COREPER on 4 June 2025 to achieve a revised mandate.

Delegations are kindly invited to consult the four-column tables, published in ST 9230/25 [RoHS Directive] and ST 9221/25 [Re-attribution Regulation]. The documents reflect the current state of technical negotiations with the European Parliament (EP).

In addition to the four-column tables, this steering note contains the provisional outcomes of the technical negotiations with the EP and the state of play on the outstanding issues in two separate parts:

- Part 1 dedicated to RoHS Directive (ST 9230/25) and the re-attribution of scientific and technical tasks and improving the cooperation among Union agencies in the area of chemicals (ST 9221/25).
- Part 2, for which a steering note will follow, is dedicated to the proposal establishing a common data platform on chemicals.

During the meeting, delegations will have the opportunity to inform the Presidency about their flexibilities and sensitivities in view of reaching the agreement in the interinstitutional negotiations. Results of the AHWP discussion will guide the Presidency in preparing a revised mandate to be discussed in COREPER on 4 June 2025 with a view to conclude the negotiations with the EP.

## STRUCTURE OF THE DISCUSSION

Member States will be invited to share their views and to indicate whether they support the proposed amendments on each legislative proposal separately in the following order:

- RoHS Directive (ST 9230/25)
- the re-attribution of scientific and technical tasks and improving the cooperation among Union agencies in the area of chemicals (ST 9221/25)
- proposal establishing a common data platform on chemicals (see part 2 of the steering note)

The Presidency will also indicate how it intends to proceed with the negotiations on these three legislative proposals.

## OUTCOMES OF TECHNICAL NEGOTIATIONS

### PART 1

The Presidency has engaged with the EP in constructive negotiations on the two files below in one Interinstitutional Technical Meeting (ITM), which was held on 19 May 2025:

#### 1.1. RoHS Directive (ST 9230/25)

The discussion on this legislative proposal at the technical level resulted in a number of provisionally agreed provisions. Nearly all substantive issues were resolved during negotiations with just a few rows still awaiting confirmation on the final wording.

With regards to provisional outcomes and state of play, the Presidency would like to draw the delegations' attention to the following points:

##### 1. Article 1 point (1)(a) – Deadlines for completing applications

The Council mandate was maintained with regard to introducing the deadlines for completing applications.

##### 2. Article 1 point (1)(d) - Obligation for the EC to publish guidelines

The Council mandate was maintained with regard to the Commission obligation to publish guidelines on the application of the relevant Article.

### **3. Article 1 point (3)(a) - Period of review of the restricted substances list**

The co-legislators agreed to set a deadline for the Commission to review the list of restricted substances. In order to reach a compromise, the Presidency and the EP set the period of review at every 4 years, taking into account market developments and technical progress, as a middle ground between the respective positions.

*The Presidency would kindly ask Member States to show their flexibility on this issue.*

### **4. Article 1 point (3)(c) and (6) - Annex IX to the RoHS directive**

The Presidency persuaded the EP to agree to the Council proposal to introduce 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. All relevant rows were amended accordingly, in line with the Council mandate.

### **5. Article 1 point (5) - Review clause**

The EP 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.

### **6. Article 2 - Deadline for application of the directive provisions**

In order to reach a compromise, the Presidency and the EP agreed to set the deadline for application of the provisions of this Directive at 20 months.

*The Presidency would kindly ask Member States to show their flexibility on this issue.*

## **1.2. Re-attribution of scientific and technical tasks and improving the cooperation among Union agencies in the area of chemicals (ST 9221/25)**

The discussion at the technical level of this legislative proposal resulted in a number of provisionally agreed provisions. All substantive issues were resolved during negotiations. The wording of recitals 21 and 22 is still open for the discussion, while two other rows for recitals are also still awaiting confirmation on the final wording.

With regards to provisional outcomes and state of play, the Presidency would like to draw the delegations' attention to the following points:

### **1. Article 1 - Amendments to Regulation (EC) No 178/2002**

The EP agreed to withdraw its proposal on Article 30 of the General Food Law on diverging scientific opinions, which is consistent with the Council mandate. In addition, a reference to Article 30(2) was added to Article 27 (rows 36a and 36b). The original amendment of Article 30 requires an amendment to Article 27, paragraph 4(b) of that regulation to keep the cross referencing accurate, which was omitted in the original Commission proposal.

The EP showed flexibility on a proposed text amendment as presented in row 42. However, the EP insists on retaining the wording with regard to the protection of vulnerable groups in recitals 21 and 22. The Presidency will continue to work on resolving these issues.

### **2. Article 2 - Amendments to Regulation (EC) No 401/2009**

The EP accepted the Council proposal with regard to amending 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).

### **3. Article 3 - Amendments to Regulation (EU) 2017/745**

The Presidency showed flexibility regarding the EP amendment including the word „classified” in Section 10.4.1, point (b) (row 54).

### **4. Article 4 - Amendments to Regulation (EU) 2019/1021**

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 EP position on a simplified text in row 82.

*The Presidency would kindly ask Member States to show their flexibility on this issue.*

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