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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° Cion doc.:	ST 16972/23, 16973/23, 16961/23 + ADD 1
Subject:	OSOA Package: Ad Hoc Working Party on One Substance One Assessment on 12 April 2024: Presidency's steering notes

With a view to the above AHWP, delegations will find attached the steering notes of the Presidency.

PRESIDENCY FLASH #3

Steering Note – OSOA

Friday 12 April 2024

AHWP – One Substance One Assessment Legislative Package

(All day)

The ad hoc working group will begin at 10a.m. and will be devoted to the analysis of the proposals for amendments made by the Presidency on the three legislative proposals implementing the "One Substance, One Assessment" approach.

The working group will proceed as follows:

- the morning session will be allotted to the proposals regarding the re-attribution of scientific and technical tasks and improving the cooperation among Union agencies in the area of chemicals (ST 16972/23 & ST 16973/23).
- the afternoon session will be devoted to the proposal establishing a common data platform on chemicals (ST 16961/23).

In annex of this Flash, delegations will find steering notes related to the three legislative proposals.

ANNEX I - OSOA – RoHS Directive (ST 16972/23)

The Presidency will go through their proposal, explaining the changes made to address Member States' comments and invite delegations to provide input.

The proposed changes are :

- Referring to the Regulation (EC) No 1907/2006 regarding public access to documents (recital 5a)
- Reflecting the need for guidelines on the involvement of the Committee for Risk Assessment in the exemption procedure (recital 5b and Art. 1(1)(d))
- Referring to the future REACH revision and its possible impact on the RoHS Directive (recital 8)
- Providing deadlines for the application process in the exemption procedure (Article 1(a), paragraph 4c)
- Providing a timeframe for a review of the list of restricted substances (Art. 1(3) point (a)
- Including possibility for an assessment of groups of substances as it is in the current RoHS (Art. 1(3) point (c))
- Re-shifting focus of assessment to the criteria set out in Article 6(1), for the restriction and exemption procedure (Art. 1(3) point (c) and Art. 1(4))
- Specifying where the intention to review and amend the list of restricted substances is going to be published (Art. 1 (4), point 3)
- Adding a consultation of an Expert Group by the Commission, before adopting a delegated act (Art. 1 (3a)).

To address the concerns of some Member States to not align the RoHS restriction procedure, which is hazard based, with the REACH restriction procedure, which could also be risk-based, the Presidency has drafted options A and B, for both Art. 1(3) point (c) and Art. 1(4). The Presidency invites the delegation to indicate which option they prefer.

The Presidency also invites the delegation to provide feedback on the Presidency's proposals regarding the timeframe for a review of the list of restricted substances.

Finally, the Presidency kindly invites the delegation to indicate whether they support the proposed amendments and to inform whether they could support the text as it stands.

ANNEX II - OSOA – Re-attribution of Tasks (ST 16973/23)

The Presidency will go through their proposal, explaining the changes made to address Member States' comments and invite delegations to provide input.

The proposed changes are:

- Article 8(1)(i) of Regulation (EU) 2019/1021 change the word provide to submit (Article 4 (1)(a)).
- Article 8(1a) of Regulation (EU) 2019/1021 delete 'as appropriate' in point (a) and point (d) (Article 4(2))
- Article 8(1a) of Regulation (EU) 2019/1021 change the reference from in 'the first subparagraph' to 'article 8(1)' (Article 4(2)).
- Article 8(1a) of Regulation (EU) 2019/1021 change the reference from in 'the report' to 'that report referred to in Article (8(1), point (i) (Article 4(2)).
- Article 15, paragraph 2 of Regulation (EU) 2019/1021 was amended to clarify the delegated acts' (Article 4(4)).
- Article 15, paragraph 2a was added to the Regulation (EU) 2019/1021 regarding an impact assessment to be carried out by the COM before adopting the delegated act (Article 4(4)).
- Article 18 (paragraph 2) of Regulation (EU) 2019/1021 change 'a period of five years' to 'a period of seven years' and a change of the data to the date of entry into force. Some additions were made to this paragraph (Article 4(5)).
- Article 6 numbering was changed to Article 5.

Further clarifications are indicated in the text on elements where Presidency didn't propose text changes to explain the reasoning. Delegations are especially invited to indicate whether any of those elements require further discussion or clarification.

Finally, the Presidency kindly invites the delegations to indicate whether they support the proposed amendments and to inform whether they could support the text as it stands.

ANNEX III - OSOA – Common Data Platform (ST 16961/23)

The Presidency will go through their proposal, explaining the changes made to address Member States' comments and invite delegations to provide input.

The discussion at the WP will be organized according to the following blocs.

1) Personal data protection

PRES integrated the recommendations made by the EDPS and various drafting proposals on this subject kindly provided by the COM. PRES invites the delegates to indicate whether they can support these drafting amendments, and if not, that they provide with concrete text proposals.

- PRES invites delegations to give their opinion on drafting proposals in lines 20, 23.a.new, 32, 32.a.new, 88.b.new, 132, 136.a.new, 137, 140, 141, 146.a.new, 146.b.new, 146.c.new, 146.d.new, 146.e.new, 146.f.new, 148.

2) Involvement of the MS, delegated and implementing acts

Following several indications from MS, PRES developed drafting suggestions to ensure more involvement of the Member States in the decision making process of this regulation. Proposals were made regarding:

- implementing acts (see line 116 for explanation and line 293.a.new for proposal);

- involvement of Member states in the establishment of the framework of indicators (line 242 to 242.b.new.);

- and the commissioning of studies by ECHA (line 270).

PRES asks the delegations to indicate whether they can support these proposals, and to otherwise provide specific drafting suggestions. Please note that several of our suggestions are still being analysed by the Council Legal Service and might thus be developed further.

The following lines in the table include drafting proposals on the MS involvement:

- PRES will present the approach adopted on lines: 116, 117, 119, 190, 230, 242, 242a., 242b., 258, 270, 293a.
- PRES invites delegations for support on lines 282, 284, 285, 286.

3) Approach to adopt for medicinal products data

Following several MS comments, questions and drafting suggestions, PRES developed drafting proposals aiming at clarifying both which regulations containing data related to medicinal products are in the scope and which chemicals data related to medicinal products are out of scope. This is mainly achieved by excluding the clinical data from the scope (via Art.3(3)), by adding medicinal regulations into Annex I, and by deleting part I of Annex II. Moreover, a new provision is introduced in order to review the scope of the data to be included in the common data platform (line 298.b.new).

- PRES will present the proposal and invites for indications of support on the approach in general, or otherwise provide concrete text proposals.

- PRES invites for guidance on lines 99.a.new, 298.a, 298.b.new 371.a.new, 371.b.new, 371.c.new, 371.d.new, 372 to 377

4) Definitions and scope

PRES invites delegations to consider our amendment proposals and questions regarding the scope and definitions of this Regulation under the following lines:

- For support: 114, 128, 131, 150, 246, 263;
- Invites Delegates to give guidance on the following proposals: 99, 202.

Delegates will see that PRES proposes some additional definitions, including a definition on "studies to be notified" (see line 89.b.new.), to accommodate questions and suggestions made by Delegations on several aspects of the text.

Regarding the request by Delegations to include a definition of "products", we would like to refer to our justification not to include this at line 150.

5) Confidentiality and data access/use

PRES invites Delegates to consider the amendment proposals and questions regarding the confidentiality and data use/access under the following lines:

- The approach will be presented (lines 109, 113, 129, 233, 234, 235, 237, 238).

- PRES invites Delegates to give guidance on the following proposals: 22,239.

Delegates will see that PRES proposed clarifications to accommodate questions and suggestions made by Delegations.

6) Data generation and Animal testing

Several Delegations have submitted comments on animal testing and data generation,

- PRES will present the approach, introduced in line 56 (a recital drafting proposal) and explanations (at lines 56 and 265).

7) Studies notifications and enforcement

PRES invites Delegates to consider the amendment proposals and questions regarding the studies notifications and enforcement under the following lines:

- The approach will be presented (lines 273, 274, 275, 276, 277, 278, 281).

- Invites Delegates to give guidance on the proposals made in line 165a.