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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 27 May 2024: Presidency's steering note

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

PRESIDENCY FLASH #5

Steering Note – OSOA / Essential uses

Monday 27 May 2024

AHWP – One Substance One Assessment Legislative Package and Essential Uses Communication.

(All day)

The first part of the ad hoc working party (10:00-13:00 / 14:30-16:00) will be devoted to the analysis of the presidency compromise texts for the three legislative proposals implementing the "One Substance, One Assessment" approach (COM(2023) 779 final, COM(2023) 783 final, COM(2023) 781 final).

The Presidency will invite delegations to indicate their support for the three compromise texts. In annex of this Flash, delegations will find a steering note related to the legislative proposal on the common data platform on chemicals.

T**he second part** will be devoted to a presentation and discussion of the recent Communication on Essential Uses (C(2024) 1995 final) (indicatively: after 16:00).

The Commission announced in the Chemicals Strategy for Sustainability that the most harmful substances should be phased-out in non-essential uses, in particular in consumer products, and minimised and substituted as far as possible in all uses. The Chemicals Strategy specifically committed to: '[…] define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments'.

The discussion at the WP will be organized as follows:

- A presentation by the COM, followed by a first tour de table for clarification questions.

- Delegations will be invited in a second tour de table to express their first impressions on the communication, including on the opportunities and challenges for the practical implementation of the essential use communication into EU regulations.

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

PRES submitted its latest version of the compromise text to the delegations and kindly invited them to indicate whether they could support the text.

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

PRES submitted its latest version of the compromise text to the delegations and kindly invited them to indicate whether they could support the text.

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

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

1) Confidentiality and data access/use: art 17(3) line 239.

The Presidency understands that it is necessary to provide for the originator principle to be explicitly included as an obligation when dealing with the confidentiality of information.

However, the Presidency is of the opinion that access to information (and more specifically, environmental information) is already governed by horizontal EU legislations. Among others, the Presidency refers to Article 4(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information; Article 4(2) and (4) of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

The Presidency notes that the initial proposal provided for 'consent' from the originator in order to disclose information, whereas there is no such condition for this in the aforementioned provisions. The Presidency recalls that "*the right to information means that the disclosure of information should be the general rule and that public authorities should be permitted to refuse a request for environmental information in specific and clearly defined cases. Grounds for refusal should be interpreted in a restrictive way, whereby the public interest served by disclosure should be weighed against the interest served by the refusal.*" (recital 16, dir. 2003/4/EC)

In order not to restrict unintentionally the right to information beyond what is already provided for in horizontal legislations, the Presidency proposes to keep the reference to the originator principle and not to frame further the access to information in that provision.

2) Involvement of the MS, delegated and implementing acts

At the request of the PRES during WP4, Delegations have indicated whether they support either the inclusion of implementing power without comitology (option 1) or implementing power with comitology (option 2) for the establishment of the implementation plan and the governance scheme (article 4(1) and article 4(4) or line 116 and 119 respectively). Based on the opinions received PRES proposes to include option 1 and thus to not have comitology for the implementing powers under Article 4(1) and 4(4).

Several delegations remain uncertain as to how the Member States would be involved in the framework of indicators and the commissioning of studies by ECHA. As mentioned in the previous WP, it is not possible to define this point further in the legal text. However, the ESRP wishes to point out that the Member States and the Commission can decide for themselves how participation is to be organised. For the sake of clarity, the Commission and the Member States may decide to use the existing OSOA expert group as a central contact point for consultation. PRES would also like to point out that this flexibility allows Member States to decide for themselves the level of involvement they wish to have on these aspects of the data platform, which also allows greater flexibility with regard to the workload of Member States.

3) Scope: definition, COM empowerment and review clause.

PRES understands that the scope initially proposed by the COM for medicinal products is a middle ground between the various views expressed. PRES proposal intends to clarify the scope (while remained unchanged) and the legal processes to amend this Annex.

PRES compromise text is as following regarding the scope:

- Annex I lists the regulations that are referred to from 3 (with now a division into part 1 and 2, the latter for medicinal products).

- The main provisions on the scope of the Common data platform are in art.3.

  In Art.3(2a), a reference to Part 2 of Annex I is introduced to alleviate the text.

  In Art 3(2a), point b, a reference is made to Part I of Annex I, since the scope proposed by the COM explicitly mentions "*substances that [...] have a relevance for other chemicals legislation, or environmental or health policies*" (see memorandum and recitals of the COM's proposal). Substances that do not meet that condition are thus not under the scope.

  Please note that a clean version of article 3(2a) is provided here below at the end of this note.

- Annex II (Part 1 deleted; Part 2 unmodified) lists reference values referred to in Article 8.

PRES compromise text is as following regarding the future potential modifications of the scope:

- Delegated acts are foreseen in Art 23, to amend Annex I, II and III, with a more precisely framed empowerment. A wording is also provided to allow for the amendment of annexes I and III referring to adoption and revision of any Union acts generating chemicals data.

- A delegated act procedure is provided for in Art 3a (line 99.a.new) allowing to amend Art(3)(2a)(c) only. It is important to note that para (c) contains only sub-sets of data types of regulations already listed in Annex I: this means that the empowerment is limited and bounded by Annex I part 2 as well as by the rest of article 3 and in particular art 3(2a), a and b.

- A review clause in Art 26a (line 298.b.new) allowing for a review of the scope in general and mentioning explicitly the medicinal products scope.

PRES indicates that **two editorials** are needed (PRES apologizes for this):

- in line 298.b.new : " [...] *referred to in Article 3(2a),* ~~***point c***~~*, as well as* [...]", because the provision on "point c" already exists in line 99.a.new.

- in line 159, since annex II part 2 is deleted: "[...] *Annex II,* ~~***Part 2***~~ [...]".

PRES kindly invites delegations to indicate whether they could support this approach.

4) Entry into force in relation to data inclusion

PRES highlights that there are two different timings for the inclusion of data: with or without as a pivotal date linked to the entry into force of this Regulation.

On the one hand, we are referring to "*all chemicals data*" in art.3 (except for medicinal products), PRES considerers that it includes data from before the entry into force. We refer also to recital 7 line 15.

On the other hand, delegations will also see that a "*unless specified otherwise*" wording is included in article 3(11) line 114: this wording has been included to cover the different timing aspects of medicinal data for which data held or generated before EIF are not to be included. Article 3a is therefore deleted: this means that data before the EIF will be included only through the review clause.

Regarding the inclusion of environmental sustainability data PRES proposes alternative wording to further streamline this provision and bring it in line with the "*all chemicals data*" approach. PRES would like to clarify that this specific provision under Article 13(4) has been retained in order to ensure that the Commission will actively follow-up on the ongoing developments regarding environmental sustainability data on chemicals.

PRES kindly invites delegations to indicate whether they could support this approach.

5) Studies notifications and enforcement

PRES noted overall support from the Delegations on the proposal to remove the definition on "studies to be notified" and the amendments made in Article 22(1). However, several Delegations requested explicit mention in the recitals that ECHA should develop guidance to further clarify the scope of this provision. PRES therefore proposes to add wording based on input from a Delegation in recital 28 (line 36).

On request by several Delegations PRES also included a proposal for a deadline of 1 month for business operators to notify that a study has been commissioned.

PRES kindly invites delegations to indicate whether they could support this approach.

Annex IV - Data platform proposal / Art 3(2a) / Clean version

PRES provides here below a clean version of Art 3(2a):

2a. By way of derogation from paragraph 2, the common data platform shall only provide access to the chemicals data related to human and veterinary medicinal products as part of the implementation of the Union acts listed in Annex I, part 2 , **as far as**:

(a) they are held by EMA and submitted to EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation, **and**

(b) they either relate to active substances subject to regulatory procedures under other Union acts listed in Annex I part 1 to this Regulation, or relate to active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment, **and**

(c) they fall into at least one of the following categories:

- Non-clinical safety data, including data related to environmental risk assessments, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the CouncilXXX1 and Regulation (EC) No 726/2004 of the European Parliament and of the CouncilXXX2; **or**

- Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3; **or**

- Data used to derive Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX3