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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 13 May 2024: Presidency Flash

With a view to the above AHWP, delegations will find attached the Presidency Flash. In annex of this Flash, delegations will find a steering note related to the legislative proposal on the common data platform on chemicals.

PRESIDENCY FLASH #5

Steering Note – OSOA

Monday 13 May 2024

AHWP – One Substance One Assessment Legislative Package

(All day)

The ad hoc working party 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.

In annex of this Flash, delegations will find a steering note related to the legislative proposal on the common data platform on chemicals.

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 indicate their support and provide input.

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

1) Personal data protection

Comments and amendment proposals were received from delegations and COM. Some amendments made relate to editorials or minor issues. A revised wording is proposed for the processing of personal data by the Agencies and COM, including for allowing to process HBM data for which the consent was given before the EIF, to allow JRC to process data, to avoid joint responsibility between Agencies as data controllers.

The lines corresponding to this bloc are listed here below (***bold italics***: amended after WP3 specifically in relation to this block). PRES provided detailed written explanations in sidenotes to the revised text.

- lines 20, ***23.a.new***, 32, ***32.a.new***, ***32.b.new***, ***32.c.new***, ***32.d.new, 88.b.new***, ***132***, ***136.a.new***, 137 and following (140, 141, 146, 146.a.new, 146.b.new, ***146.c.new***, 146.d.new, 146.e.new, 146.f.new, ***148, 148.b).***

PRES invites delegations to indicate if their concerns are addressed, and if at this stage there is general support to consider this block as not needing major amendments anymore (otherwise, delegations are invited to provide specific drafting suggestions).

2) Confidentiality and data access/use

Comments and amendment proposals were received from delegations and COM, on the interaction of this regulation with existing EU and national regulations on access to data, and on the role of EU vs national Authorities in this respect.

PRES proposes amendments. No additional information was received on the need to mention IPR in recital 14, PRES proposes to delete that amendment, as IPR applies anyway, and similar provisions don't exist in other related regulations.

The lines corresponding to this block are listed here below (***bold italics***: amended after WP3 specifically in relation to this block). PRES provided detailed written explanations in sidenotes to the revised text.

- lines ***22***, 109, ***113***, ***129***, ***233, 234***, 235, 237, 238, ***239***.

PRES invites delegations to indicate if their concerns are addressed, and if at this stage there is general support to consider this block as not needing major amendments anymore (otherwise, delegations are invited to provide specific drafting suggestions).

3) Involvement of the MS, delegated and implementing acts

PRES noted from input of the delegations that uncertainty and unclarity remains on the different ways in which Member States (MS) will be involved in the different processes under the common data platform. In an attempt to clarify this, PRES has made several drafting proposals and included explanations with these proposals. In general, PRES identified the following ways in which MS can be involved within the current text:

a. OSOA expert group: this group has been formalised under the delegated procedure and will be consulted on decisions for the addition of categories of datasets in annex II (Article 24).
b. Implementing act **without** comitology: to try and clarify the involvement of MS in this procedure, PRES has included a new recital 18a - which attempts to explain that COM involves MS when preparing these implementing decisions. The ways in which MS can be involved are open to be decided by the COM and the Member States. It would be possible for example to involve the above-mentioned OSOA expert group using this approach. MS will be free to decide their level of involvement in this procedure. This procedure is proposed as an option for the implementation plan and the governance (Article 4); and proposed for the divergence of opinions for standard formats and controlled vocabularies (Articles 14 and 15).
c. Implementing act **with** comitology: within this procedure MS will be involved via a Member State committee, which will have a different mandate compared to the above mentioned OSOA expert group. However, MS are free to appoint the same members for both groups. This procedure is proposed as an option for the implementation plan and the governance (Article 4); and proposed for the addition of chemicals data regarding environmental sustainability data (Article 13) and the Observatory on emerging chemical risks (Article 20).
d. Reference to "Member States" in the legal text and recitals: in certain parts of the text PRES proposed to refer to Member States. In this case – like option b – COM, the Agencies and MS can choose themselves in what way the involvement should be facilitated, this again could be via the OSOA expert group. MS will be free to decide their level of involvement in this procedure. PRES would like to highlight that it was decided to not include "expert" wording when referring to MS, this was decided as legal advice indicated that it would not be advisable to refer to experts because this wording is not defined within the legal text. This approach is proposed for the adoption of standard formats and controlled vocabularies (Recital 38), the framework of indicators (Article 18) and the data generation mechanism (Article 21).

Regarding the implementation plan and the governance scheme under Article 4, PRES identified divergent views on the level of involvement that would be preferred. Therefore, PRES proposed 2 options:

- option a would be to go back to the original proposal by the Commission (i.e. implementing act without comitology as described above under point b.)
- option b would be to keep the comitology procedure (as described above under point c) and which would then be via the advisory procedure.

Delegations are invited to consult the proposals on line 116 and 119 of the revised text and to indicate which of the options they prefer, and otherwise to provide specific drafting proposals. Additionally, PRES will invite the Commission to further explain how they see the exact role and the impact of the governance scheme on the common data platform in order to ensure that MS have a clear view of what level of involvement would be most appropriate.

PRES would also like to highlight that legal analysis and advice showed that it is not possible to include delegated or implementing powers for the formalization and the development of the Framework of Indicators (Article 18), reason being that this is a report developed by EU Agencies and does not give any binding legal obligations for Member States.

The following lines include drafting proposals on the MS involvement:

- Lines 26, 26a. new, 46, 117, 190, 193, 214, 216, 230, 242, 243, 258, 270 and 293 a. new.
- PRES asks delegations to indicate their preference regarding the different options on lines 116 and 119.

PRES invites the delegations to indicate whether they can support the proposals, and to otherwise provide specific drafting suggestions.

4) Medicinal products data: scope and structure of the text.

At WP3, PRES proposed to clarify the structure of the text, by treating the medicinal product as the other products already encompassed within the scope of this Regulation, i.e. by mentioning them in annex I.

About the scope, PRES proposed to delete annex II, make the scope explicit and clear in art.3, and to have a clarification of the scope that delegations consider appropriate.

For remaining issues, PRES proposed to add a review clause.

Several comments from delegations were received, regarding the appropriate scope and in particular about: data held at national level, confidential quality data, clinical trials data, data for procedures before the EIF, environmental relevant data, timing of inclusion of the data, inclusion of products vs active substances, pre-clinical studies, non-clinical safety data, confidential data in the Active Substance Master Files (ASMF), structured data vs unstructured data (pdfs). Some delegations don't support an extension of the original scope.

PRES is of the opinion that some clarifications are necessary regarding the original proposal, as shown through three WP commenting rounds:

- recital 8 does not reflect the scope as in the text proposed by the COM (products are in fact not covered - as specified in annex II, and only active substances are in the scope)
- in recital 8, the considerations regarding relevant substances are not reflected in the text (on uses, PBT, and residues)
- the first implementation plan is not meant to cover medicinal data (annex II, part1 refers to art.4(5).b)
- the justification for treating differently medicinal products is limited
- there is no justification for having all regulations in annex I and medicinal products in annex II, and this is not helping in understanding the scope, all the more that reference in annex II is made back to art.2, 3, 4, 8, 12, 17, 23
- national authorisations of products are not covered in the original proposal (per art.3(2).c))
- environmental risk assessments are only mentioned for reg.2019/6 (veterinary) and not for human medicinal products
- reference values are only PNEC in 2001/83 & 726/2004.

PRES proposes thus the following way forward: to retain the proposed approach (i.e., to delete annex II part 1; to include "medicinal"-related regulations in Annex I as the other products; to have a clear and agreed scope in art.3).

It is proposed to maintain the original scope proposed by the COM as diverging opinion exists on the extension/reduction of that scope and keep the review clause, but making it more general so the above-mentioned subjects of discussion can be covered.

The lines corresponding to this bloc are listed here below (***bold italics***: amended after WP3 specifically in relation to this block). PRES provided detailed written explanations in sidenotes to the revised text.

- lines ***16, 16.a.new, 16.b.new, 17, 17.a, 99.a.new***, 298.a, ***298.b.new***, 371.a.new, 371.b.new, 371.c.new, 371.d.new, 372 to 377.

Delegations are invited to indicate whether they could support:

- **the Presidency's approach and the specific amendments on the structure of the text (having medicinal products in annex I, and the scope in art.3);**

- **for limiting the scope to the original COM proposal, with a review clause.**

5) Definitions and scope

PRES would like to highlight that the wording of "datasets" has been changed to "chemicals data" or modified to "datasets of chemicals data" through the text, which is in line with a previous change proposed under line 114.

PRES invites delegations to consider our amendment proposals and questions regarding definitions in this Regulation under the following lines: 26, 27, 50, 88b. new, 89.a, 99, 114, 116, 164, 190, 249, 260.

Moreover, a proposal to add a new annex IV listing environmental sustainability related regulations from which data could be integrated in the common data platform is envisaged since WP3 (with updates by delegated acts). PRES understands that there is a possibility that juridically adding those new data to the database, even with the original proposal wording, might even require a co-decision. At the same time, there is a need for flexibility. PRES is seeking legal advice on this.

6) Data generation and Animal testing

Several delegations had submitted comments before the previous WP on animal testing and data generation. During the previous WP, PRES presented a drafting proposal based on similar wording used in the REACH text. Taking due account of the delegations and COM's inputs, PRES proposes a new wording as a compromise proposal.

PRES invites the delegations to indicate their support for the drafting proposal made in Line 56.

7) Studies notifications and enforcement

Several delegations showed support for PRES proposals. Comments were received from delegations and COM, on: the purpose of the notification and how it is reflected in the text, on the need (or not) and the content of a definition of studies to be notified, on which authorities should have access to the database of study notifications, on the access to notifications before their publication to the data platform, on the cases when a business operator should inform a laboratory, on the identification of the enforcement authorities.

PRES introduced amendments to take those concerns into account (see below). PRES also introduced a change to the title of art.25 to "Cooperation on compliance" as PRES understands that this corresponds better to the scope of art.25.

PRES would also like to point the attention of the delegations to the definition of "studies to be notified". Based on comments received from the delegations, PRES proposes to not have a specific definition for studies to be notified under Article 2. One of the main reasons being that the definition is only used once in the legal text and thus could be explained in the Article 22 in which it is used. PRES proposes to remove the definition of studies to be notified from Article 2 and revert to the original text in Article 22. However, to clarify the scope of the studies to be notified, PRES proposes to link the term study with the generation of "chemicals data", which is defined under Article 2(10).

Delegations are invited to consult the proposal on line 275 of the revised text and to indicate their support, or otherwise provide specific drafting proposals.

The lines corresponding to this block are listed here below (***bold italics***: amended after WP3 specifically in relation to this block). PRES provided detailed written explanations in sidenotes to the revised text.

- lines 36 to 43, ***89.b.new***, 162 to 167 (***164, 165a***), 273 to 281 (***275,277***), and 294 to 298 (***295,297***).

PRES invites delegations to indicate if their concerns are addressed, and if at this stage there is general support to consider this block as not needing major amendments anymore (otherwise, delegations are invited to provide specific drafting suggestions).