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CONTRIBUTION

From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
N° prev. doc.:	WK 5468/2024
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Subject:	OSOA Package: Follow-up to the Ad Hoc Working Party on One Substance One Assessment on 12 April 2024 - comments from a delegation

Following the call for comments on the above set out with WK 5468/2024, delegations will find attached additional comments from DK.

DENMARK

Remarks from Denmark
Ad hoc Working Party on One Substance One Assessment

April 23, 2024
J.nr. 2023-12466
Ref. piago

Thank you for giving us the possibility to submit comments on the proposal for a regulation establishing a common data platform on chemicals. We appreciate the careful presentation of our comments at the three first meetings.

Article 10 - Information on regulatory processes on chemicals
Denmark would like to ask the Commission for a list of which Union acts in Annex III MS have a right of initiative and therefore would be covered by the proposal. Denmark would also like to ask if the Member State obligations in the expanded notification system proposed in Article 10 will be broader than where Member States has a right of initiative today?

Article 19(2), point c - Monitoring and outlook framework for chemicals
Denmark prefers a clear reference to Framework of indicators in Article 19. Denmark suggests the following amendment in Article 19(2), point c (line 249):

> (c) data that the EEA holds**, including data from the Framework of indicators mentioned in Article 18;**

Personal data protection
Denmark welcomes amendments reflecting recommendations of the EDPS. Denmark can support the Presidency's amendments in line 141-146.b. + 146.d-14b.f.

At the last meeting on the 12th of April 2024, the Presidency presented a compromise text reflecting the recommendations of the EDPS on the clarification on the roles of the Commission and agencies (line 32.a.). In line with the EDPA, Denmark understands that the purposes in article 6(4) are meant to achieve the objective of providing support to the Commission and the agencies, as provided for in the original article 6(3) in line 140 of the proposal.

The proposal (line 141-146.b. + 146.d-14b.f.) focuses mainly on the processing of human biomonitoring data constituting personal data by the EEA, the Commission, the EFSA and the ECHA. Denmark questions whether the EMA and the EU-OSHA would benefit from processing human biomonitoring data constituting personal data as well? Denmark prefers to keep the original article 6(3), line 140, but with the following amendment:

> Article 6(3):
> The ~~EEA~~ **Commission and Agencies** may process human biomonitoring data constituting person data to support the Commission in its policy making or to support Agencies in fulfilling their missions.

Regarding line 136.a.new and 148, Denmark prefers to not have a joint controllership between the Commission and the Agencies. Denmark can support line 136.a. with the following amendments:

> The Commission and the Agencies shall act as ~~joint~~ data controllers for any personal data stored in the platform.

Involvement of the MS, delegated and implementing acts

In general Denmark welcomes an enhancement of Member State involvement with reference to Regulation (EU) No 182/2011.

Article 4 – implementation plan and governance and Article 13 - environmental sustainability

Denmark questions the added value of an implementing act in line 116, line 119 and line 190. These decisions are rather technical and does not benefit from an implementing act adopted in accordance with the procedure referred to in article 24a(3). Denmark prefers the original wording.

If Member States are to be involved in these decisions, Denmark proposes to amendment the procedure in line 116, line 119 and line 190 to "consulting the experts designated by each Member States referred to in article 24(4)".

Article 18 - Framework on indicators

On the 17th of April 2024, the European Environment Agency published the "EU indicator framework for chemicals: an indicator dashboard developed" with the European Chemicals Agency (ECHA), the European Commission, and a series of other European agencies, accompanied by a synthesis report written jointly with ECHA (link: https://www.eea.europa.eu/en/european-zero-pollution-dashboards/chemicals-strategy-for-sustainability).

How does this publication affect the proposal specifically the wording of article 18 and 19 of the original proposal, and is the original proposal by the Commission a codification of the publication? Furthermore, does the publication affect the Presidency's amendments in line 242-242.b.?

We believe that the framework of indicators will benefit from involvement from the Member States, but we question if delegated acts is the most appropriate way to make this kind of decision. We therefore prefer to amend the new article 18(1a) in line 242.a.new to:

> 1a. Based on that report, the Commission shall adopt ~~a delegated act~~ **an implementing act** by... [OP: please insert one year after the entry into force of this regulation] in order to establish the framework of indicators referred to in paragraph 1. **This implementing act shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.**

Article 20 - observatory list
In line 258, Denmark can support the Presidency's amendments, but prefer to adopt an implementing decision in according to paragraph 2 of Article 24a, the advisory procedure, instead of paragraph 3, the examination procedure and suggest this change.

Medicinal products data
Denmark has understood the original proposal for the common data platform in a way that meant that data related to medicinal products was excluded, with some specific exceptions introduced in Annex II of the original Commission's proposal.

The Danish Medicines Agency assumes that the considerations made by the Commission to exempt medicinal products from the regulation include aspects on confidentiality as well as the fact that data related to medicines are highly granulated and relate to multifaceted aspects of the products that go beyond the scope of the regulation. Data related to medicinal products are highly confidential data and essential to protect. As the proposal stands, all agencies across the EU and all authorities across the EU will have access to the database. The Danish Medicines Agency understands that access could be differentiated and that there should be the same confidentiality around data as there is today. However, The Danish Medicines Agency would like to draw attention to concerns about how confidentiality is established and ensured. For example, different authorities within the same Member State should not have the same access due to company-confidential data. The same probably applies to agencies and authorities across the EU to an even greater extent. It is therefore The Danish Medicines Agency's assessment that by allowing data related to medicinal products to be included in the database, there might be a risk that data access will not be established in a way where the pharmaceutical companies and authorities can be absolutely sure that deeply confidential data is not passed on to unauthorized parties. If this happens, this could mean that the companies will suffer significant financial damage, as the information can be used by a potential competitor for competitive purposes. It will potentially harm the development of medicines, the supply of medicines and can thus ultimately also be a risk to patient safety. Therefore, The Danish Medicines Agency tends to agree with the Commission that data related to medicinal products should not be covered by the proposal.

Definitions and scope
Denmark can in general support the amendments regarding definition and scope. However, Denmark seeks justification for adding "model" in line 89.b.new.

Confidentiality and data access/use
Denmark can support the Presidency's amendment.

Data generation mechanism
Denmark can in general support the amendments regarding Member State involvement in line 270 with the following amendment to streamline with the procedure proposed in line 216:

> Article 21(5). The ECHA shall commission these scientific studies in an open and transparent manner. The ECHA shall consult **the experts designated by each Member States referred to in article 24(4)** ~~Member Stat~~ prior to commissioning those scientific studies.

Studies notifications and enforcement
Denmark can support the amendments regarding studies notifications and enforcement