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**CONTRIBUTION**

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| From: | General Secretariat of the Council |
| To: | Ad hoc Working Party on One Substance One Assessment |
| N° prev. doc.: | WK 6848/2024 |
| N° Cion doc.: | ST 16973/23, 16972/23, 16961/23 + ADD 1 |
| Subject: | OSOA Package: comments from delegations |

Following the call for comments on the above set out with WK 6848/2024, delegations will find attached comments from ES and PT.

# SPAIN

## Comments to the OSOA legislative package



### Directive amending Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency - Presidency compromise text

Article 24:

We support the Presidency text and particularly the new para 3 in Article 24.

### Regulation on Union agencies in the area of chemicals - Presidency compromise text

Article 3. (3) Section 10.4.3 Guidelines on phthalates

ECHA's evaluation should consider during its assessment not only the chemical perspective but also the benefit-risk balance of medical devices taking into account the opinion of experts in the field of medical devices. The benefit-risk assessment has to take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), which is now doing these assessments, does consider this. We understand the concept of one substance one assessment but it has to be adapted to each situation taking into account the risk-benefit ratio as mentioned above.
We also consider it important that ECHA has medical device experts to carry out this work and we therefore propose to insert the following sentence at the end of the paragraph:

*The assessment shall take into account the opinion of experts in the field of medical devices.*

Article 3 (4) Section 10.4.4 Guidelines on other CMR and endocrine-disrupting substances

As already explained above, here again we consider it important that ECHA has medical device experts to carry out this work and we therefore propose to insert the following sentence at the end of the paragraph:

*The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. The assessment shall take into account the opinion of experts in the field of medical devices.*

*When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.*

Article 4 Amendments to Regulation (EU) 2019/1021, paragraph (4):

We agree with the delegated act as the best instrument for this type of technical amendment. However, we cannot support the proposed wording and would prefer to revert to the original text. We understand that the delegated act will entail consensus building with the committee of competent authorities on the POPs Regulation.

Article 4 Amendments to Regulation (EU) 2019/1021, paragraph (6):

We support the new Article 21 b introduced in the Presidency text.

## Regulation establishing a common data platform on chemicals - Presidency compromise text

We broadly agree with the changes made by the PRES. However, we would like to point out some issues on which we do not agree:

**Personal data protection**

Line 146.b.new.

It is not clear to us what is involved in the processing of personal biomonitoring data in the development of binding legal rules as proposed in the new wording of point (g). We have no objection to the use of data in strategy development, but binding legal acts based on biomonitoring data deserve special treatment depending on other factors. We believe that it should not be an objective of this common data platform to prejudge binding legislation with uses of biomonitoring data.

We therefore propose to return to the original wording, referring exclusively to policy making:

*(g) supporting policy making ~~and the adoption by the European Parliament, the Council of the European Union and the European Commission of a legally binding act.~~*

Line 239.

Although the Presidency has modified the text with respect to the previous proposal, there is one issue that has not been modified and which ES had previously requested. Our proposal, for reasons of legal certainty, is to change the concept of 'consultation' to 'consent'.

Therefore, we propone this new wording:

***Where an Authority receives a request for data or information marked as confidential under Article 5(2) that the Authority is using, unless it is clear that the data or information shall not be disclosed, the Authority shall ~~consult with~~ not disclose the information or data without the consent of the originator ~~in order to take a decision that does not jeopardise the confidentiality of the data or information.~~***

**Confidentiality and data access/use**

Line 237.

We do not see a direct link between scientific studies and enforcement. Furthermore, we perceive a danger of complex data that need prior scientific interpretation being used for sanctioning procedures. Therefore, we cannot support the current proposal and suggest the following wording:

*The Authorities may use the chemicals data contained in the common data platform in the performance of any of their activities, where those activities support the development, or implementation* ~~*or enforcement*~~ *of chemicals legislation and policy.*

**Involvement of the MS, delegated and implementing acts**

- On the powers granted to the COM: we support option A (OSOA expert group).
- On the Implementation Plan and the governance scheme (lines 116 and 119): we support option A.

Line 263, Article 20(4), point (c)

We are in favour of the publication of these data, but as they may create unnecessary alarm and confusion, there should be consultation with the competent Agencies prior to publication. Furthermore, we consider that data that have not been properly assessed by the Authorities or the Agencies should not be published. In this sense, there may be situations where, for example, after 20 years of evaluation of a substance, new data may emerge and be made directly available to the public without having gone through the competent evaluation authorities, thus generating alarmism. If the evaluating authorities are consulted beforehand and can establish the necessary measures before making them available to the public, we would gain time in improving the use of substances. And we should not wait for public alarm to be generated before making the necessary changes.

We propose the following wording:

*(c) make compiled data publicly available through the common data platform or other communication and outreach tools as appropriate, to facilitate,* ***in collaboration with the competent Agencies,*** *the identification of potential further research needs or risk management measures, to facilitate informed societal discussion and* ~~*increase*~~ *public awareness on the properties, use and safety aspects of specific chemicals, and regularly update that information.*

***This paragraph will not apply to data that have not been adequately evaluated by Competent Authorities and/or by the Agencies involved in the assessment.***

**PORTUGAL**

**Written comments on the One Substance, One Assessment Legislative Package follow-up of the AHWP-OSOA meeting on 13 May 2024**

**Reference documents**

- doc. ST 16972/23, 19.12.2023; WK 6525/2024 ADD 1, 06.05.2024 – RoHS compromise proposal;
- doc. ST 16973/23, 19.12.2023; WK 6525/2024 ADD 2, 06.05.2024 – Omnibus compromise proposal);
- doc. 16961/23 and ST 16961/23 add1, 18.12.2023; WK 5769/2024, 23.04.2024; WK 6525/2024 ADD 3, 08.05.2024 – Revised Presidency text on the common data platform;
- doc. WK 6525/2024, 06.05.2024; WK 6525/2024 ADD 4, 08.05.2024 - Presidency´s steering notes;
- doc. WK 5769/2024, 23.04.2024 and WK 5769/2024 ADD 1, 23.04.2024- Comments from delegations - follow-up to the AHWP OSOA on 12 April 2024.

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Please find bellow the Portuguese comments relating to the OSOA legislative package, following the 13th May meeting and taking into consideration the reference documents made available in this context.

**I. Amending Proposal to RoHS Directive**

- ***Comments on the Presidency´s compromise proposal***

PT believes that the PRES compromise proposal is going in the right direction. However, even though we share the ambition to conclude negotiations swiftly, we still would like to put forward some concerns/comments to be taken into consideration.

- **Implementing option B for both Art. 1(3) point (c) and Art. 1(4), to keep the restriction process separate from REACH. This was done based on comments received in writing and views expressed during the third Ad Hoc OSOA Working Party.**

PT agrees with the COM on the preference to refer to Annex XV to REACH Regulation (which could be restricted to the relevant requirements), rather than including an annex to this Directive. We also consider that the mention to 'risk assessment' is consistent with the scope of the RoHS Directive.

- **Inserting a review clause regarding the Agency's funding and expanded workload (recital 2A and Art 1(5))**

PT has been sharing concerns regarding the need to make sure that ECHA committees have the adequate and stable resources and governance to perform any additional tasks.

In fact, these committees have already a very significant and increasing workload: to address risk assessment and risk management under REACH and CLP Regulations; to provide OEL scientific opinions for occupational health and safety legislation; to provide scientific support to improve the co-operation between the Community, its Member States, international organisations and third countries relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on the sound management of chemicals in developing countries; to evaluate the safety of substances used in materials coming in contact with drinking water.

Besides the RoHS Directive, more tasks for ECHA scientific committees are expected as those introduced under the new Batteries Regulation.

In this sense, we agree with the first and second sentences of recital (2a). However, regarding the last sentence of this recital and article 1(5), we understand this is a horizontal issue that is not supposed to be addressed just at the level of this directive.

It seems to us that there is no need of a review clause to anticipate problems with ”future regulatory developments” relating to the Agency's governance. However, if this provision remains, we suggest the wording to be amended to better reflect the purpose, i.e., according to the COM clarification in the meeting.

- **Specifying the need for consultation of an expert group before the publishing of guidelines by the Commission regarding the involvement of the Committee for Risk Assessment in the exemption procedure (recital 5b)**

PT does not agree with the amendment made in this recital and respective article 1(d), as in our opinion a reference to RAC in the text is not sufficient. **RAC's tasks/intervention** shall be clearly identified and included in the text of the directive. In our view, this is not a subject to be established in guidelines, and in this respect, we consider it to be more adequate to achieve an agreement at the Council level.

This would create legal certainty regarding the involvement of RAC which will also be helpful as a legal basis in relation to predict the financial and human resource needs to be reflected in the ECHA funding Regulation. We believe that the involvement of the RAC should be defined regarding what is necessary within the framework of the established competences, particularly with regards to the Risk Assessment to Human Health and the Environment, bearing in mind the Waste Management particular issues.

In our view, the work of RAC could be limited to the assessment of applications for renewal of exemptions that have not been previously assessed by this committee (as the previous assessment was probably based on different criteria and expertise) or where there are changes to the exemption that are considered "significant changes" (quantitative; technology, etc.). We consider that slight changes to the exemption do not warrant a review of the RAC and the tenderer must clearly state in the application what changes the renewal will have in relation to the exemption previously granted.

These procedures should be clearly laid down in the operative part of the proposal.

Considering this background, we do not agree with the definition of the main competences/tasks of the RAC's intervention by means of publishing COM's guidelines.

- **Specifying the need for taking into account assessments on any part of the lifecycle of the substance used in EEE for the restriction procedure (Art. 1(3) point (c))**

No objections.

- **Re-shifting focus of assessment to all of the criteria set out in Article 6(1), for the restriction and exemption procedure, including the assessment of alternatives (Art. 1(4))**

No objections.

- **Changing of the entry into force of this Directive to 24 months after publication (Art. 2)**

We believe the PRES means the "application" of the Directive instead of the "entry into force".

We do not oppose to establish the application of the directive starting 24 months after the publication of the directive instead of 12 months, as previously proposed.

- ***Other Comments on the Presidency´s compromise proposal***

- **Opinion of the Agencies' committees (article 6.b.2)**

We can be flexible and accept the Presidency proposal.

- **Providing deadlines for the application process in the exemption procedure (Article 1(a), paragraph 4c)**

We support clear definition of the deadlines in order to improve legal certainty for the actors concerned.

Regarding the proposed amendment, we agree with the deadlines alignment with those given in REACH Article 69 (4) for restrictions proposals, as there are no similar deadlines under the authorisation scheme in REACH.

Still on this amendment, we would like to state that we understand the COM's concerns about the difficulty to define a general maximum period for completing the application as, in certain cases, some flexibility would be welcomed, and in this sense, it makes sense to foresee these situations in the text. However, and considering the actual text of this article, it should be noted that by giving the possibility to ECHA to extend the established deadlines when there's a reason for not complying with them, these deadlines might become merely indicative. Therefore, we would prefer to stay with the established deadlines without any possibility of an extension.

- **Referring to the future REACH revision and its possible impact on the RoHS Directive (recital 8)**

We support the first part of the recital, since the procedures established in this proposal are based on the REACH Regulation, which is expected to be amended in the medium term, and as this directive might also be affected by future legislation on these matters.

However, we still have some doubts about the second part of the recital in legal terms and therefore we would like to have clarification on the reasons behind this option instead of a RoHS Directive amendment being carried out, taking into consideration the specificities of this Directive and also its connection with pieces of legislation other than REACH Regulation.

**- Adding a consultation of an Expert Group by the Commission, before adopting a delegated act (Art. 1 (3a)).**

As already mentioned in our previous written comments, we would prefer to have the following wording: "shall consult an expert group with representation of Member States" (in line with the Danish proposal and as referred in the REACH Regulation), instead of "shall consult experts designated by each Member State".

In our opinion, consultation of Member States should not be addressed by "the designation of experts" on a case-by-case basis, as it should be carried out within the frame of a specific "Expert Group" in the context of the exercise of the powers of delegated acts.



## II. Omnibus Proposal (amending POP Regulation)

- ***Comments on the Presidency´s compromise proposal***

PT has no objections to the proposal amendments as referenced in the Presidency´s steering note. Overall, we can support the proposed compromise text regarding the POP Regulation amendment, without prejudice of the following comment:

- **Inserting a review clause regarding the Agency's governance and expanded workload to the Committees (recital 14A and Art. 21b)**

PT has been sharing concerns regarding the need to make sure that ECHA committees have the adequate and stable resources and governance in order to perform any additional tasks.

In fact, these committees have already a very significant and increasing workload: to address risk assessment and risk management under REACH and CLP Regulations; to provide OEL scientific opinions for occupational health and safety legislation; to provide scientific support to improve the co-operation between the Community, its Member States, international organisations and third countries relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on the sound management of chemicals in developing countries; to evaluate the safety of substances used in materials coming in contact with drinking water.

Besides the POP Regulation, more tasks for ECHA scientific committees are expected as those introduced under the new Batteries Regulation and the future RoHS Directive.

In this regard, we agree with the first and second sentences of recital (14a). However, regarding last sentence of this recital and article 21b, we understand this is a horizontal issue that is not supposed to be addressed just at the level of this regulation.

It seems to us that there is no need of a review clause to anticipate problems with "future regulatory developments" relating to the Agency's governance. However, if this provision remains, we suggest the wording to be amended to better reflect the purpose, i.e., according to the COM clarification in the meeting.

**III. Common Data Platform**

- ***Comments on the revised Presidency´s compromise proposal to thematic blocs in the steering note***

In our view, the PRES compromise proposal is going in the right direction. In this regard, we present the following comments:

**1) Personal data protection**

**Line 23.a.new - Recital (15a)** – we can accept the PRES revised text, which is aligned with the COM proposal to delete 'any other user'.

**Lines 32 - Recital 24, *32.a.new*** *(delete),* **32.b.new - Recital (24a), 32.c.new - Recital (24b) and 32.d.new - Recital (24c) –** we have a scrutiny reservation on this point.

**Line 132 – Article 5(5) –**PT supports the previous wording of the PRES, without the inclusion of "after consultation of the Agencies", as we do not see the added value of this proposal**.**

**Line 136.a.new - Article 5(10) –** we agree with the PRES amendment.

**Line 146 – Article 6(3), point (e) –** we do not support the PRES proposal. We agree with the COM amendment proposal to delete point (e) considering that EEA is not performing risk assessment.

**Line 146.a.new - Article 6(3), point (f)** – we do not support the PRES proposal. We agree with the COM amendment proposal to delete point (f) considering that EEA is not performing risk management.

**Line 146.b.new - Article 6(3), point (g**) – we agree with the first part regarding policy making. Regarding the second part "the adoption by the European Parliament, the Council of the European Union and the European Commission of a legally binding act", we still have some doubts on the purpose and the wording. Also, the link with the first part of the sentence raises some doubts as "policy making" is a broader concept not always linked to "legal acts".

**Line 146.c.new - Article 6(4) –** we do not oppose to the wording of the PRES compromise proposal which is aligned with the COM´s suggestion to accommodate activities already in place that use existing data.

**Concerning Article 6(4), point (h),** we have the same doubts as in the previous point.

**Line 146.d.new - Article 6(5)** – we support the PRES proposal.

**Line 146.e.new - Article 6(6)** – we support the PRES proposal.

**Line 146.f.new - Article 6(7) –** we support the PRES proposal.

**Line 148 – Article 6(9) –** we agree with PRES proposal, which is aligned with COM´s purpose of avoiding joint liability.

**Line 148.b** - **Article 6(10)** – we agree with PRES proposal, which is aligned with COM´s purpose of avoiding joint liability.

**2) Confidentiality and data access/use**

**Line 129 – Article 5(2)** – we support this amendment.

**3) <u>Involvement of the MS, delegated and implementing acts</u>**

PT has a scrutiny reservation on this point.

**4) <u>Medicinal products data: scope and structure of the text</u>**

**Line 16.a.new – Recital 8a –** we do not support the inclusion of this amendment, considering the COM´s comments on medicinal data. In our opinion, the inclusion of additional medicinal data can be reassessed at a later stage. Additionally, PT would like to present scrutiny reservation concerning Recital 8a and Annex II as we need a more in-depth assessment on the inclusion of the medicinal products in this proposal.

**5) <u>Definitions and scope</u>**

**Line 114 – Article 3(11) -** we support the PRES amendments substituting the term "datasets" by "chemicals data" throughout the text.

**Line 26 – Recital 18 –** we agree with the COM´s text proposal, leaving to Article 4 the details on the implementation plan.

**Line 89.a.new - Article 2(16) –** we agree with the revised PRES compromise proposal which is aligned with COM´s proposal to include 'the public' instead of 'public'.

**Line 9.a.new - Article 3(3), point (c) –** PT has a scrutiny reservation on this point.

**Line 116 - Article 4(1) –** PT has a scrutiny reservation on this point.

**Line 190 – Article 13(4) –** PT has scrutiny reservation on this point.

**Line 249 - Article 19(2), point c) –** PT prefers the previous wording of the PRES proposal**.**

**6) <u>Data generation and Animal testing</u>**

**Line 56 - Recital 48 –** we support the wording suggested by PRES in the revised compromise proposal.

**7) <u>Studies notifications and enforcement</u>**

**Line 89.b.new- Article 2(17)** – we understand COM's concerns and thus we can accept the PRES's amendment (deletion of the definition).

**Line 164 – Article 9(2) -** PT has scrutiny reservation.

**Line 165a – Article 9(3a)** – We agree with the PRES revised wording.

**Line 275 – Article 22(1)** – PT has scrutiny reservation on this point.

- ***Other comments on Presidency´s compromise proposal revision (WK6525/2024 ADD3)***

**Line 22 – Recital 14 –** we agree with the COM´s arguments for not changing the recital, and therefore we would prefer to keep the previous wording.

**Line 28 – Recital 20 -** we agree with the PRES´s rewording

**Line 63 – Article 1(1) –** bearing in mind the objectives and scope of this regulation, we support the revised PRES compromise proposal which is in line with COM´s explanation based on standing with a broader term.

**Line 82 – Article 2(11) –** PT has scrutiny reservation on this point.

**Line 117 - Article 4(2) and Line 119 - Article 4(4) –** we have a positive opinion on this amendment.

**Line 128 - Article 5(1) and Line 29 - Recital 21 –** We agree with the amendments, we see merit in not multiplying the number of different actors, which are already covered by the reference to "Member State". However, we would like to propose the following amendment in order to assure the alignment of recital 21 with the wording in article 5(1).

> " recital (21) Other parties, such as Member States, ~~**scientific bodies of Member States or national authorities**~~, should be able to offer chemicals data to the Agencies for hosting and maintenance..."

**Line 131 – Article 5(4) –** we support the PRES amendment

**Line 157 – Article (8) –** we agree with the PRES proposal.

**Line 165a – Article 9 (3a) –** we propose the following amendment:

> "**National Competent** ~~A~~authorities**, including** ~~and~~ national enforcement authorities**,** shall have a permanent access to the data contained in the Database of Study Notifications before that data is integrated in the common data platform" .

**Line 170 – Article 10(2) –** PT has scrutiny reservation on this point.

**Line 232.a.new – Article 16 -** we have a positive opinion on this point.

**Line 239 ~~–~~ Article 17(3)** - PT has scrutiny reservation on this point.

**Lines 242 to 243 - Article 18** – we support the proposal.

**Line 254 – Article 19(4)** – we share the concerns/position of the COM regarding the additional administrative impacts resulting from this amendment. In this regard, we propose the following text amendment:

> "The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities ~~who~~ **which can be used to support any** ~~shall undertake~~ regulatory or policy actions accordingly or justify if they decide not to proceed with any action related to the early warning signals."

**Line 270 – Article 21(5)** – we do not support this proposal amendment, as we do not see the need of the intervention of the MS in this process, also considering the COM's arguments.

**Line 275 – Article 22(1):** we agree with the PRES proposed wording.

**Line 276 – Article 22(2):** we agree with the PRES proposed wording.

**Line 277 – Article 22(3):** we agree with the PRES proposed wording.

**Lines 284, 285 and 286 – Article 23** – PT has scrutiny reservation on this point.

**Line 294 - Chapter IX** – we suggest that the chapter title should also be revised from "ENFORCEMENT AND PENALTIES" to "**COMPLIANCE AND PENALTIES**".

**Line 298.b.new- Article 26a** - we have a positive reservation.