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WK 7689/2024 INIT

LIMITE

ENV

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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 7124/2024
N° Cion doc.:	ST 16973/23
Subject:	OSOA Package: Follow-up to the Ad Hoc Working Party on One Substance One Assessment on 27 May 2024: Regulation regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals - comments from delegations

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Following the above Ad Hoc Working Party meeting, delegations will find attached comments on the proposal on the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals, from IE, ES, FR, IT and PT.

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WK 7689/2024 INIT

**LIMITE**

**EN**

## IRELAND

### **Regulation as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals**

Proposal for new recital 12a in the Regulation of Union agencies in the area of chemicals.

*(12) The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio- economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.*

*12.a.new: For the elaboration of the guidelines referred to in recitals 10 and 11, the European Chemicals Agency shall ensure **access to** the necessary expertise in medical devices.*

**IE comments:** IE support although we consider it is inefficient for ECHA to build expertise in medical devices but rather that they should collaborate with expertise in medical devices e.g. maybe through the expert panels (no specific mechanism currently available for this). So while no changes may be possible, adding in 'collaborate with expertise' or 'access to' may help.

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## SPAIN

### REGULATION ON UNION AGENCIES IN THE AREA OF CHEMICALS

#### **Introduction of a new recital 12a:**

We appreciate the discussion held during the last meeting and the support obtained from many Member States for the inclusion of a new recital 12.a, which reinforces the idea that the necessary expertise on medical products should be available in the process of drafting the new guides or guidelines that recitals 11 and 12 entrust to ECHA.

**12.a.new: For the elaboration of the guidelines referred to in recitals 10 and 11, the European Chemicals Agency shall ensure the necessary expertise in medical devices.**

#### **Article 4 (Amendments to Regulation (EU) 2019/1021 POPs)**

We believe it is necessary to maintain the broad approach to the delegation of acts for Annexes IV and V, **unambiguously covering the thresholds set out in the 4th column of Annex IV** (i.e. implying that the delegated act can modify the concentration limits, Article 7 paragraph 4.a). It is important to have an agile and professional mechanism to ensure that the maximum permissible limits for POPs in waste are updated, in order to ensure that these substances are not reintroduced into the value chain due to a slow procedure for updating the annexes. **Therefore, we prefer the original wording (without the added sentence at the end of the paragraph).**

*'2. The Commission is empowered to adopt delegated acts in accordance with Article 18, in order to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes I, II or III to this Regulation to the Convention or the Protocol or to modify existing entries in Annexes IV and V to this Regulation to adapt them to scientific and technical progress, ~~notably developments in waste treatment and decontamination technologies and new scientific information indicating that the hazards and risks associated to a substance in waste have been underestimated.~~'*

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## FRANCE

### **Règlement modifiant les règlements (CE) n°178/2002, (CE) n°401/2009, (UE) 2017/745 et (UE) 2019/1021 du Parlement européen et du Conseil en ce qui concerne la réattribution des tâches scientifiques et techniques et améliorant la coopération entre les agences de l'Union dans le domaine des produits chimiques**

Les autorités françaises sont favorables à la proposition de l'Italie de remplacer le terme « identifié » par le terme « classé » à l'article 3, paragraphe 1, pour ce qui concerne les perturbateurs endocriniens identifiés au titre du règlement CLP :

« (b) substances which are **classified** as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council [...] »

A l'article 4, paragraphe 4, les autorités françaises sont favorables au remplacement du terme « notably » par « including » tel que proposé par certaines délégations lors du dernier groupe.

Pour ce qui concerne les ajouts proposés par la Présidence à l'article 4, paragraphes 7 à 11, les autorités françaises partagent la nécessité d'adapter certaines entrées de l'annexe IV pour tenir compte du changement de procédure d'amendement de l'annexe IV. Néanmoins les autorités françaises considèrent que la nouvelle formulation des entrées doit reprendre l'intégralité des dispositions actuelles notamment lorsqu'il est question d'abaisser les valeurs limites de concentration. Elles proposent de modifier les paragraphes 7 à 11 de l'article 4 comme suit :

« (7) In Annex IV, for entry “Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value no later than 30 December 2027” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value**”;

(8) In Annex IV, for entry “Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and dioxin-like polychlorinated biphenyls (dl-PCBs)”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value, where such lowering is feasible in accordance with scientific and technical progress.**”

(9) In Annex IV, for entry “Hexabromocyclododecane”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value to not higher than 200 mg/kg no later than 30 December 2027.” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value to not higher than 200 mg/kg.**”;

(10) In Annex IV, for entry “Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, as set out in Annex I”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027.” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value, where such lowering is feasible in accordance with scientific and technical progress.**”;

(11) In Annex IV, for entry “Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value, where such lowering is feasible in accordance with scientific and technical progress.**” »

Les autorités françaises soutiennent les autres propositions de compromis de la Présidence.

### Courtesy translation

#### **Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals**

The French authorities support Italy's proposal to replace the term "identified" by "classified" in Article 3(1) for endocrine disruptors identified under the CLP Regulation:

« (b) substances which are **classified** as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council [...] »

In Article 4(4), the French authorities are in favour of replacing the term "notably" by "including", as proposed by some delegations during the last working party.

With regard to the additions proposed by the Presidency to Article 4(7) to (11), the French authorities share the need to adapt certain entries in Annex IV to take account of the change in the procedure for amending Annex IV. Nevertheless, the French authorities consider that the new wording of the entries should include all the current provisions, particularly when it comes to lowering concentration limit values. They propose amending paragraphs 7 to 11 of Article 4 as follows:

« (7) In Annex IV, for entry “Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value no later than 30 December 2027” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value**”;

(8) In Annex IV, for entry “Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) and dioxin-like polychlorinated biphenyls (dl-PCBs)”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value, where such lowering is feasible in accordance with scientific and technical progress.**”

(9) In Annex IV, for entry “Hexabromocyclododecane”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value to not higher than 200 mg/kg no later than 30 December 2027.” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value to not higher than 200 mg/kg.**”;

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(11) In Annex IV, for entry “Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds”, in Column 4, the sentence “The Commission shall review that concentration limit and shall, where appropriate, adopt a legislative proposal to lower that value, where such lowering is feasible in accordance with scientific and technical progress, no later than 30 December 2027” is replaced by “The Commission shall review that concentration limit by 30 December 2027 **to lower that value, where such lowering is feasible in accordance with scientific and technical progress.**” . »

The French authorities support the Presidency's other compromise proposals.

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## ITALY

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

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

We thank the Presidency of the editorial changes

We agree with the:

- ✓ new recital 14a and the new ‘Article 21b’ in the Regulation (EU) 2019/1021 concerning the review clause for the new task of Scientific Committees of ECHA under POPs.
- ✓ modification of annex IV of POPs concerning the deadline to review the limit by the EU Commission by 30 December 2027.
- ✓ Rephrase of art 2.2 that modifies the art 15 paragraphs 1 and 4 of Regulation (EC) No 401/2009

Anyway, **we reiterate** that concerning the Article 3 on Annex I to Regulation (EU) 2017/745 section 10.4.1, point (b) we would prefer that the word “**identified**” was substituted by the word “**classified**” in coherence with the CLP or in alternative it would be better to delete the word “identified” in coherence with the previous point (a) on CMR. For us it is a significant editorial change. We deem inappropriate use of the word “identified” because it is more consistent with the “old” REACH rules.

Concerning art.4.4 (on the replacement of Article 15, paragraph 2) of the reg.POPs, we would still prefer to have more flexibility by not specifying the scientific and technical progress. Consequently, we propose the following modification: “2. The Commission is empowered to adopt delegated acts in accordance with Article 18, in order to amend Annexes IV and V to this Regulation to adapt them to the changes to the list of substances set out in the Annexes I, II or III to this Regulation to the Convention or the Protocol or to modify existing entries in Annexes IV and V to this Regulation to adapt them to scientific and technical progress, ~~notably~~ **including** developments in waste treatment and decontamination technologies and new scientific information indicating that the hazards and risks associated to a substance in waste have been underestimated.”

Concerning the clause on the reducing of the limit (article 4 and article 21b) raised by DK during the 5<sup>th</sup> meeting it does not appear necessary.

Concerning the ES proposal on new recital on medical device we support it.

We agree with the text.

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## PORTUGAL

### II. OSOA – Re-attribution of tasks Omnibus (ST 16973/23) (amending POP Regulation)

PT can globally support the PRES proposal. However, we still have the concern regarding the review clause (Recital 14a and Article 21(b)) referred in our previous comments.

#### **Recital 14A and Article 21b**

- We keep our comments submitted as a follow-up to the 27<sup>th</sup> May meeting: *“PT have 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: (...).*

*Besides 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 sense, we agree with the first and second sentences of recital (2a). However, regarding last sentence of this recital and article 21(b), 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.”.*

- We also agree with DE that the relevant aspects concerning workload, capacities and structures of committees should be discussed more widely in the context of the ECHA basic Regulation.

In this respect, we consider that the COM's wording proposal would be more appropriate:

*“For that purpose, Regulation (EU) 2019/1021 should remain coherent with any future revision of provisions governing the functioning of the committees of the European Chemicals Agency. In accordance with any such revision, the Commission should assess whether an amendment of Article 8 of Regulation (EU) 2019/1021 is required”.*

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