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LIMITE

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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 7123/2024, WK 7566/2024
N° Cion doc.:	ST 16961/23 + ADD 1
Subject:	OSOA Package: Regulation on data platform - comments from delegations

Following the call for comments on the above set out with WK 7566/2024, delegations will find attached comments from BG, DK, DE, IE, ES, FR, IT, PT, SI, SE and the Commission.

BULGARIA

Comments on the proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Bulgaria would like to thank the Presidency for the possibility to submit written comments on the OSOA legislative package.

We have comments on the Common Data Platform Regulation as follows:

Regarding the scope

We believe that Annexes I and III are essential elements of the act and therefore, we prefer their amendment to follow the ordinary legislative procedure.

Regarding the implementing acts in Art 4(1) and (4), Art. 14(8) and Art. 15(8):

In our view the legal procedure for adoption of the implementing acts in Art 4(1) and (4), Art. 14(8) and Art. 15(8) has to be clarified in the act. As already stated during the meeting of the AHWP on 13 May 2024, we would prefer implementing act with comitology for Art 4(1) and (4), in accordance with paragraph 3 of Article 24a, and implementing act with comitology for Art. 14(8) and Art. 15(8) in accordance with paragraph 2 of Article 24a. Therefore, for the sake of clarity we propose to return in the text the reference to the applicable procedure in Art. 24a (our proposals are below, marked in blue):

115	Article 4 Implementation plan and governance of the common data platform
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall ***by means of an implementing*** ~~decision~~ ***act, in consultation with Member States,*** adopt ~~and publish~~ an implementation plan identifying ~~datasets~~ ***chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion ~~by means of an implementing decision~~. ***[That implementing act shall be adopted in accordance with the procedure referred to in paragraph 3 of Article 24a.]*** ~~-~~Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.
192	Article 14 Standard formats
214	8. The Commission shall adopt an implementing ~~decision~~ ***act, in accordance with the procedure referred to in paragraph 2 of Article 24a,*** to remedy the divergence.
215	Article 15 Controlled vocabularies

230	8. The Commission shall adopt an implementing ~~decision~~ ***act, in accordance with the procedure referred to in paragraph 2 of Article 24a,*** to remedy the divergence. ~~Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.~~

Regarding the early warning and action system for emerging chemical risks:

We do not support the proposed wording of Art. 19(4) (line 254) and would prefer the original Commission's text:

244	Article 19 Early warning and action system for emerging chemical risks
254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. ~~[~~The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities ***for consideration of the need for regulatory or policy*** ~~***who shall undertake regulatory or policy actions accordingly or justify if they decide not to proceed with any***~~ action related to the early warning signals.

DENMARK

Ad hoc Working Party on One Substance One Assessment

Dear Presidency,
As this most likely will be our last opportunity to submit comments on the proposal for a **regulation establishing a common data platform on chemicals** we would like to congratulate you and once again thank you for carefully presenting our comments at all meetings in the Ad hoc Working Party.

Article 19 - Early warning and action system for emerging chemical risks

With regard to Article 19 (4), we have a strong preference for the Commission's original proposal: "The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities for consideration of the need for regulatory or policy action related to the early warning signals."

The amendment proposed by the Presidency presents a new obligation for Member States that is more extensive than what Denmark understands as in the purpose of establishing an early warning system. The annual reports to be provided by EEA will provide trends for occurrence of chemicals in the environment and thereby a valuable tool in the overall assessment of when regulatory or policy action is needed in order to maintain a high level of protection for human health and the environment from exposure to chemicals. These assessments often require several lines of evidence collected over time and therefore the original wording as referenced above suits the purpose more efficiently than the proposal to perform mandatory annual assessments and justifications for action and non-action for all chemicals covered by the early warning system by Member States and the Commission.

We note that REACH Article 69 already contains an obligation for the Commission and Member States to initiate a dossier when the Commission or MS considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed.

We hope the Presidency will revert to the original text proposal.

Article 3 Common Data Platform on Chemicals – Medical Products

With regard to article 3(3), on delegation of powers to the commission to amend article 3(2a)(c), we would have preferred that this paragraph was not included, and all amendments to article 3(2a) were made according to the legislative procedure.

GERMANY

OSOA Package

Follow-up to ad-hoc Working Party on One Substance One Assessment on 27 May 2024

Common data platform Regulation (ST 16961/23)

DE thanks the presidency for the further opportunity to submit written comments. We have the following comments on the amendments of the Common Data Platform Regulation which were partly already addressed in the ad hoc Working Party "One Substance One Assessment" on 27 May 2024.

1 C) Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

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

DE supports the reference to the originator principle. However, we are still in favour of including a reference to Article 5 (2) which could further clarify that data are only confidential if marked in accordance with the originating Union act.

A Possible Text could be:
Art. 17(3)
When using chemicals data as provided for in paragraph 1 that is deemed confidential under Article 5(2), second sentence, the Authorities shall respect the confidentiality of information data as marked by the originator.

We could nonetheless support the current proposal.

2) Involvement of the MS, delegated and implementing acts

We do not oppose the approach taken by the current proposal.

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

DE welcomes the further restriction of the empowerment in Article 23 para 1 and 2 to amend the annexes. This seems to be a viable compromise.

As a general comment in relation to Article 26a and the review with regard to the medicinal products it is from our point of view important, that the established reporting channels via the national authorities to the EMA should be maintained.

4) Entry into force in relation to data inclusion

We would like to further understand why Art. 3 para 3a was deleted. For us, it is not clear whether data other than medicinal data originating from before the entry into force of the regulation will only be included through the review clause. We would like to ask the PRES for clarification. In general, we would like to provide for the possibility of data from before the entry into force to be included in the data base.

5) Studies notifications and enforcement

DE supports the inclusion of the reference to ECHA guidance in the recital. We are also in favour of the 1 month notification deadline for business operators.

IRELAND

Comments on the One Substance, One Assessment Legislative Package

Follow-up to the Ad Hoc Working Party on One Substance One Assessment on 27 May 2024

Thank you for the opportunity to provide comments.

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

IE comments: IE notes the text as proposed and is grateful that previous comments have been substantively addressed. Following our review, we would submit one further observation for consideration:

The final paragraph of recital 9 (paragraph 17b) now reads as follows:

> *Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data, and other data related to other substances contained in medicinal products besides active substances. Moreover, a relevant part of the medicinal data is held by the National Competent Authorities. The Commission should thus assess in close cooperation with Member States and the Agencies whether such additional data should be included in the common data platform.*

There could be an argument for seeking to add the following or similar to the end of this recital:
"This assessment should take into account the relevancy, the anticipated added value as well as the cost-benefit balance of incorporating the additional data".

SPAIN

Comments

REGULATION ESTABLISHING A COMMON DATA PLATFORM ON CHEMICALS

Recital 9 (line 17.b.new)

In this recital we propose, for consistency with the wording of Article 26 on Review, (specifically for consistency with Line 298.b.new), to **eliminate the reference to *clinical data***.

Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, ~~clinical data~~, and other data related to other substances contained in medicinal products besides active substances. Moreover, a relevant part of the medicinal data is held by the National Competent Authorities. The Commission should thus assess in close cooperation with Member States and the Agencies whether such additional data should be included in the common data platform.

Article 17, use of chemical data contained in the common data platform, line 237:

It seems very appropriate to us that national competent authorities and enforcement officers have free access to the data on the Common Platform, and this is stated in Article 9.3.a (line 165a). However, it does not seem appropriate to use data from scientific studies published on the Portal in enforcement activity. Enforcement authorities, when monitoring compliance with a sectoral regulation, must monitor compliance with the regulated values, thresholds and conditions set out in that particular sectoral regulation. And in this context, it seems to us that **we run the risk of using complex data, which require prior scientific interpretation, in sanctioning procedures**. Therefore, we would like to suggest a modification in the wording, simply **deleting the word enforcement**.

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.*

FRANCE

Objet : Commentaires des autorités françaises à la suite de la réunion du groupe de travail du 27 mai 2024 sur le paquet législatif « Une substance, une évaluation »

Règlement établissant une plateforme de données commune sur les produits chimiques fixant des règles visant à garantir que les données qu'elle contient sont faciles à trouver, accessibles, interopérables et réutilisables et définissant un cadre de surveillance et de prospective pour les produits chimiques

Bloc 2 : Participation des États membres aux actes délégués et actes d'exécution

Les autorités françaises considèrent que le paragraphe 2 de l'article 24a doit être supprimé puisqu'il n'y a pas de référence à ce paragraphe dans le reste du texte.

Bloc 3 : Champ d'application : définitions, habilitation de la Commission et clause de revoyure

Les autorités françaises soutiennent le commentaire porté par la Commission lors du dernier groupe pour ce qui concerne la référence aux substances pertinentes. Elles considèrent que le cadrage des substances pertinentes dans les considérants plutôt que dans le corps du texte, à l'article 3, paragraphe 2a, point b, est préférable afin de maintenir de l'agilité dans la mise en oeuvre tel qu'indiqué par la Commission.

Les autorités françaises partagent également le commentaire de la Commission qui vise à déplacer les dispositions de la ligne 99 b nouvelle vers l'article 23 afin de concentrer l'ensemble des délégations de pouvoir dans le même article.

Pour ce qui concerne la clause de revoyure prévue à l'article 26a, les autorités françaises souhaitent que les dispositions précisent l'ensemble des éléments à évaluer dans le rapport de la Commission, ces éléments étant spécifiés aux considérants (8) et (9). Il s'agira notamment d'évaluer l'opportunité d'intégrer les données générées avant l'entrée en vigueur du texte, les données sur d'autres substances actives que les susbtances actives pertinentes, mais aussi les données sur d'autres substances contenues dans les médicaments qui ne sont pas des substances actives.

Bloc 4 : Entrée en vigueur pour ce qui concerne l'inclusion des données

Les autorités françaises souhaitent souligner une incohérence entre le paragraphe 1 et le paragraphe 4 de l'article 13. En effet, le paragraphe 1 mentionne une décision prévue au paragraphe 4 alors que la procédure de décision du paragraphe 4 a été supprimée.

Bloc 5 : Notifications des études et contrôle

Les autorités françaises comprennent que le délai proposé par la Présidence au dernier alinéa du paragraphe 1 de l'article 22 ne concerne que l'échange d'informations entre les opérateurs économiques et les laboratoires. Elles considèrent davantage utile de fixer un délai pour les notifications des études prévues au premier alinéa du paragraphe 1 (par les opérateurs économiques) et au paragraphe 3 (apr les laboratoires) de l'article 22. Un délai d'un mois pourrait être proposé, cela permettrait notamment de faciliter les contrôles et d'avoir des pratiques harmonisées dans l'Union. Pour l'échange d'informations entre les opérateurs économiques et les laboratoires, les autorités françaises soutiennent la proposition de la Commission d'indiquer que cet échange doit se faire au moment de la commande des études. A la dernière phrase du paragraphe 1, les autorités françaises proposent également de supprimer la première partie de phrase qui constitue une redondance avec le reste de la phrase. Elles proposent donc les modifications suivantes des paragraphes 1 et 3 de l'article 22 :

« 1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ~~**without undue delay**~~, any studies that generate chemicals data which they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment under the Union acts listed in Annex I **within one month from the date of the commissionning of studies**. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. ~~**When a study falls under the notification obligation of paragraph 3**~~ **At the time of the commissioning of studies**, business operators shall inform ~~**in this respect**~~ the laboratory or testing facility in which the study to be notified is carried out about the fact that the study falls under the notification obligation of paragraph 3. »

« 3. Laboratories and testing facilities shall also~~, **without undue delay,**~~ notify any study commissioned by business operators to support an application, notification or regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I **within one month from the date of the commissionning of the study**. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. »

Par ailleurs, les autorités françaises souhaitent introduire une exemption défense à l'article 22 dans la mesure où le règlement retient une acception large des « *business operators* » susceptibles d'englober des entités publiques et pourrait porter atteinte à la confidentialité des études réalisées par les Armées. A cet égard, elles proposent l'ajout d'un paragraphe 8 à l'article 22 formulé de la façon suivante :
« **8. The obligations set under this article shall not apply insofar as such requirements imply a risk to national security and defence** ».

Autres commentaires

Contrairement à la position exprimée par la Commission lors du dernier groupe, les autorités françaises réitèrent leur soutien aux modifications du paragraphe 4 de l'article 19 imposant notamment aux autorités de justifier si aucune action n'est mise en place à la suite des alertes précoces remontées par l'Agence européenne pour l'environnement.

Les autorités françaises peuvent soutenir le reste du compromis de la Présidence.

COURTESY TRANSLATION

This is a courtesy translation and in the event there are any differences between the French and English texts, the French text governs.

Subject: Comments following the working group meeting of 27 May 2024 on the "One substance, one assessment" legislative package

Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Cluster 2: Involvement of the MS, delegated and implementing acts

The French authorities consider that paragraph 2 of Article 24a should be deleted as there is no reference to this paragraph in the rest of the text.

Cluster 3: Scope: definition, COM empowerment and review clause

The French authorities support the comment made by the Commission in the last working group regarding the reference to relevant substances. They consider that framing the relevant substances in the recitals rather than in the body of the text in Article 3(2a)(b), is preferable in order to maintain flexibility in implementation as indicated by the Commission.

The French authorities also agree with the Commission's comment that the provisions of the line 99bnew should be moved to Article 23 in order to concentrate all the delegations of power in the same article.

With regard to the review clause provided for in Article 26a, the French authorities would like the provisions to specify all the elements to be assessed in the Commission's report, these elements being specified in recitals (8) and (9). In particular, it will be necessary to assess the appropriateness of incorporating data generated before the entry into force of the text, data on active substances other than the relevant active substances and also data on other substances contained in medicinal products which are not active substances.

Cluster 4: Entry into force in relation to data inclusion

The French authorities wish to point out an inconsistency between paragraph 1 and paragraph 4 of Article 13. Paragraph 1 refers to a decision under paragraph 4, whereas the decision procedure under paragraph 4 has been deleted.

Cluster 5: Studies notifications and enforcement

The French authorities understand that the deadline proposed by the Presidency in the last subparagraph of Article 22(1) concerns only the exchange of information between business operators and laboratories. They consider that it would be more useful to set a deadline for the notification of the studies provided for in the first subparagraph of paragraph 1 (by the business operators) and in paragraph 3 (by the laboratories) of Article 22. A period of one month could be proposed, which would facilitate enforcement and harmonise practices throughout the Union. As regards the exchange of information between business operators and laboratories, the French authorities support the Commission's proposal that this exchange should take place when the studies are commissioned. In the last sentence of paragraph 1, the French authorities also propose deleting the first part of the sentence, which is redundant with the rest of the sentence. They therefore propose the following amendments to paragraphs 1 and 3 of Article 22:

« 1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, ~~**without undue delay**~~, any studies that generate chemicals data which they commission to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment under the Union acts listed in Annex I **within one month from the date of the commissionning of studies**. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. ~~**When a study falls under the notification obligation of paragraph 3**~~ **At the time of the commissioning of studies**, business operators shall inform ~~**in this respect**~~ the laboratory or testing facility in which the study to be notified is carried out about the fact that the study falls under the notification obligation of paragraph 3. »

« 3. Laboratories and testing facilities shall also~~, without undue delay,~~ notify any study commissioned by business operators to support an application, notification or regulatory dossier on which an Agency is required to provide a scientific output, including a scientific opinion, under the Union acts listed in Annex I **within one month from the date of the commissionning of the study**. However, laboratories and testing facilities shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. »

In addition, the French authorities would like to introduce a defence exemption into Article 22 insofar as the Regulation adopts a broad definition of "business operators" likely to include public entities and could undermine the confidentiality of studies carried out by the Armed Forces. In this respect, they propose the addition of a paragraph 8 to Article 22 worded as follows:

« **8. The obligations set under this article shall not apply insofar as such requirements imply a risk to national security and defence** ».

Other comments

Contrary to the position expressed by the Commission during the last working group, the French authorities reiterate their support for the amendments to Article 19(4), which require the authorities to justify any failure to take action following early warnings issued by the European Environment Agency.

The French authorities can support the rest of the Presidency compromise.

ITALY

Steering Note – OSOA / Essential uses WK 7281/2024 INIT

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

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

Taking into account that the confidentiality of the data will be respected, the presidency's text can be accepted.

2) Involvement of the MS, delegated and implementing acts *article 4(1) and article 4(4) - line 116 and 119*

We agree with the text of Presidency (without comitology) for the establishment of the implementation plan and the governance scheme

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

We appreciate the distinction in annex 1 of the part 1 and 2. We appreciate the riformulation of art3 (2a) . In particular, for the **line 96 a news** : (Art 3 (2a) point c): we agree the proposal .

Line17b new (recital 9): we agree with the text

Line 99 b news (art 3.3.c):

- please perhaps an editorial check is necessary: the "letter c" it seems deleted
- we agree with power delegated to the Commission only to add, if necessary, new categories data on medicine product in the platform (so power delegate to amend Art.3(2a), point c).

Lines 284-285-286 . art 23: we agree with the text revised (we support the approach) we have only 2 editorial suggestion:

- paragraph 1: the number 1 has been deleted for mistake
- paragraph 3 the number 3 for the 3rd paragraph has been deleted perhaps for mistake.

line 298.b.new: Art 26a, we agree with clause review regarding medicinal products data (six year) and for the general review we agree with the period 10 years (instead 8years)

4) Entry into force in relation to data inclusion

article 3(11) line 114 : we thanks the presidency for the clarification in the steering note, anyway we think that it could be better clarified that the new data generated /submitted after the Enter in force will be add by echa without undue delay**.** So we propose the following modification in the last sentence in the line 114 "*Upon integration of those datasets of chemicals data in the common data platform, when the ECHA receives* ***new*** *chemicals data in accordance with Article 5,* ***after the enter in force of this regulation****, it shall make that data available through the common data platform without undue delay. "*

5) Studies notifications and enforcement

Linea 36 (recital 28) we agree with the text and the provision on echa guidance on the type of studies requiring notification.

line 275 (art 22.1) we appreciate the modification, anyway the timing (one month) has been modified *only* one time in particular only for the laboratory while it appears at beginning of the paragraph for the economic operator. We ask that also for the economic operator is allowed a specific time to sent the notification. It is important also from point of view of the enforcement.

OTHER OUR COMMENTS on Platform regulation :

On DATA GENERATION MECHANISM

Line 270 (article 21.5)

We appreciate the modification proposed by the Presidency anyway we deem important to involve also the stakeholders . we suggest the following modification *: "*5. The ECHA shall commission these scientific studies in an open and transparent manner*. The ECHA shall consult Member States* ***and stakeholder*** *prior to commissioning those scientific studies.*

Motivation: Before undertaking new scientific studies, it is important that all relevant information is taken into consideration, including on the methodologies of the study and to avoid potential duplication of work (incluse at global level). The industry has vast experience in designing scientific studies and with other stakeholders could share specific expertise on studies to be commissioned under the data generation mechanism

On environmental sustainability

Line 82, article 2(11) - we propose the following modification: **"***11. 'environmental sustainability related data' means any data relevant for the environmental sustainability assessment of a chemical* ~~***or material***~~ *throughout its entire life cycle, including:*" .

Motivation: This suggested amendment aims at keeping the focus on chemicals since this is the object of the Common Data Platform.

Line 189 (article 13.3) - Coherentely with the previous proposal on line 82, article 2(11), we add the proposal: " 3. Where researchers or research consortia funded by Union framework programmes make available to the ECHA, under Article 5(6), any environmental sustainability data on chemicals ~~**or materials**~~ they collect or generate, the ECHA shall integrate the relevant data in the database on environmental sustainability related data."

Motivation: This suggested amendment aims at keeping the focus on chemicals since this is the object of the Common Data Platform.

On format and vocabularies

Line 212 (article 14.6) – we propose the following modification: **"***The Commission and the Agencies shall cooperate when setting standard formats to ensure coherence with other formats and the interoperability of the standard formats with the common data platform and with existing data submission approaches.* ***They shall also consult stakeholders.***

Line 228 (article 15.6) – we propose the following modification: **"***The Commission and the Agencies shall cooperate with each other in setting the controlled vocabularies.* ***They shall also consult stakeholders.*****"**

On Early warning and action system for emerging chemical risks

Line 255 (article 19.5)

We would like to suggest the following modification **" 5.** The EEA shall make all ~~relevant~~ **confirmed** data on early warning signals that it holds or hosts as well as the report referred to in paragraph 4 available to the ECHA for integration in the common data platform. **To avoid confusion, data that is not a positive identification of an emerging risk as described in article 19.3 will not be included in the common data platform."**

Line 254 *(art. 19.4) on annual report we propose the following modification*

*4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, ~~relevant~~ Union agencies and Member State**s*** ~~*competent authorities*~~ *who shall undertake regulatory or policy actions accordingly**.*** ~~*or justify if they*~~ ***If Commission and Member States*** *decide not to proceed with any action related to the early warning signals* ***shall justify the inaction.***

Motivation: we agree with the Commission that the justification of regulatory inaction is a task not proportionate for the EEA. A justification on regulatory inaction is a duty of policy maker of Commission and MSs

On enforcement

Line 237 (Article 17) : we agree with the indication that the data in Common Platform can be used also for enforcement of chemicals legislation .

Motivation: In our understanding, for instance, in the enforcement on Safety data Sheet under Reach regulation often our inspectors note the absence of chemical data in different sections as n. 9, 10, 11, 12 and if it is possible to cross check with the presence of data chemical in the common platform this could be a useful lever to increase the quality of the SDSs

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PORTUGAL

"One Substance One Assessment package"

Portuguese Comments following the AHWP-OSOA 27.05.2024

Please find bellow the PT comments relating to the OSOA legislative package, following the 27th May 2024 meeting and taking into consideration the reference documents made available in this context.

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

PT have global scrutiny reservation on the PRES compromise text, as we still have some reservations, namely on block 4, and we still keep some concerns we would like to reiterate.

- ***Presidency´s compromise proposal, taking in consideration the PRES steering note***

2) Involvement of the MS, delegated and implementing acts

As transmitted in the last meeting, PT believes that it is important the clarification of the type of procedure in each relevant provision, and also the identification of the committee/expert group where the "consultation of MS" is taken place, namely if this will be in the MS committee or in the OSOA Expert Group.

Regarding implementing powers related to the MS involvement, PT have preference, in general, for Option 1 – implementing power without comitology, with "consultation of MS" for the provisions mentioned in Presidency´s compromise proposal. Notwithstanding this preference, in the spirit of compromise, PT can accept the Option 2 - Implementing power with comitology concerning the adoption, publication and revision of the selected chemical lists, as it referred in Article 20(2) – "Observatory", preferably according to paragraph 2 of Article 24a, the advisory procedure, instead of paragraph 3, the examination procedure.

4) Entry into force in relation to data inclusion

PT has some reservations on this block and would need to analyze the foreseen PRES revised proposal for this block and for block 3 (namely for article 3(2a)).

Other comments on Presidency´s compromise proposal (WK 7123/2024)

Line 128 - Article 5(1) and Line 29 - Recital 21 – we see merit in not multiplying the number of different actors, which are covered anyway by the wording "Member State". We propose the following amendment on recital 21:

" 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 or the Commission for hosting and maintenance. In such case, it should be for the Agencies or the Commission, as the case may be, to decide whether to respond positively to the offer."

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.ea.new - Article 6(6a) – we do not support the PRES proposal. We propose to delete point (c) considering that EEA is not performing risk management.

Lines 242 - Article 18 – we support the proposal. However, we would prefer the reference to "as appropriate" to be deleted.

Line 254 – Article 19(4) – we share the concerns/position of the COM regarding the additional administrative impacts resulting from this amendment. Taking into account that EEA collects and processes information to produce reports on various environmental and climate issues that are intended to inform and support policy decisions, it is questionable why in relation to this particular report there should be an obligation for MS to adopt regulatory or policy actions or justify when decide not to proceed with any action.

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~~ ~~shall undertake~~ **which can be used to support any** regulatory or policy actions ~~accordingly~~ or justify ~~if they decide~~ **a decision** not to proceed with any action related to the early warning signals."

SLOVENIA

Comments in accordance with the Presidency note (WK 7566/2024 INIT) on »One Substance One assessment« - OSOA legislative package:

- Proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (WK 7123/ 2024 INIT)

Chemicals data confidentiality and use

We support the proposal of BE Presidency to keep the "originator principle". We see it justified and this will bring more trust between authorities and data holders, which is a benefit to all.

Notification of studies - Article 22

We would suggest for the text "study falls under the notification obligation of paragraph 3" to be deleted (editorial change).

The deadline in line 275 "within one month" would in our opinion make more sense to change it in "any time during the commissioning of the study" to inform the laboratory or testing facilities. It can be even deleted, as we do not see real added value in it. It is an addition burden. Our aim should be to stimulate the operators and others to notify the studies and we believe that original text of COM is more appropriate.

Inclusion of medical devices into Annex 3

We support the COM proposal

Early warning and action system for emerging chemicals risks - Article 19

We would prefer COM proposal as we find argumentation of the COM justified.

SWEDEN

Comments 28 May 2024 – Common Data Platform

OSOA Package: Ad Hoc Working Party on One Substance One Assessment on 27 May 2024: Regulation establishing a common data platform on chemicals – Revised Presidency compromise text – WK 7123/2024 INIT

As stated at the WP of 27 May 2024, and as expressed in the written comments of 15 May 2024, Sweden prefers to include legacy data in Article 3(2a)(a) and in Article 3(2a)(b), include all active substances within in the scope of the Union acts listed in Annex I, part 2, by deleting the reference to Annex I part 1 in point (b)

The current wording in Article 3(2a)(b-c), where points b and c are cumulative (i.e., the word "and" is included), means in practice that very few substances will come into the scope of the Data Platform. The consequence is that ECHA will not have access to all environmental risk assessments which are held by EMA.

Sweden would, as a secondary option, prefer to expand the scope of active substances in Article 3(2a)(b) to substances with properties which may create hazards for, or through the environment, including data on hormones and antibiotics. This would enable environmental protection authorities to have access to substances which are not PBT but still have an impact on the environment.

Sweden therefore proposes an amendment to article 3(2a)(b):

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

Regarding legacy data, Article 26a should at least be made more clear, by adding a reference to Article 3(2a)(a):

[…] The review shall include an assessment of the scope regarding medicinal products data to include in the common data platform referred to in Article 3(2a), **point a and** point c, […]

COMMISSION			
Line	**COM proposal 15.05.2024**	**PRES text 17.05.2024**	**COM position**
16	*(8) While some medicinal products are also chemicals, the application and use of hazard and risk assessments performed on them under Union acts on medicinal products is different from the application and use of hazard and risk assessments performed under the main Union acts on chemicals. Because of this and in order to achieve the best possible balance between the administrative burden for the European Medicines Agency ('EMA') and the added value for Authorities of including chemicals data related to medicinal products in the common data platform, only chemicals data with the highest added value related to relevant active substances contained in medicinal products should be included. Relevant active substances concern active substances covered by the medicines legislation and also subject to regulatory procedures under other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment. The specific chemicals data to be included for those relevant active substances should cover chemicals data related to environmental risk assessments carried out under Union legislation on medicinal products for human and veterinary use, non-clinical studies carried out under*	*(8) While some medicinal products are also chemicals and could present an interest for the objectives of this Regulation, the application and use of hazard and risk assessments performed on them under Union acts on medicinal products is different from the application and use of hazard and risk assessments performed under the main Union acts on chemicals. It is thus appropriate to adopt a stepwise approach and to include at this stage, taking due account of the administrative burden for ~~EMA~~ the European Medicines Agency ('EMA'), only chemicals data related to relevant active substances contained in medicinal products with a known added value. At this stage, ~~Relevant~~ active substances identified as relevant* ~~are those covered by the medicines legislation and used for other applications regulated by~~ *concern active substances covered by the medicines legislation and also subject to regulatory procedures under other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment. The specific chemicals data to be included for those relevant active*	See COM proposal at the end of this document (COM maintains position that 'relevant substances' should only be defined in recitals)

	Union legislation on medicinal products for human use and maximum residue limit values the EMA holds, as well as specific reference values.	*substances should cover chemicals data related to environmental risk assessments carried out under Union legislation on medicinal products for human and veterinary use, non-clinical studies carried out under Union legislation on medicinal products for human use and maximum residue limit values the EMA holds, as well as specific reference values.*	
17.b. new	*Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data and data on medicinal products, held by the EMA, as well as data related to medicinal products and the active substances they contain held by Member State competent authorities. The Commission should assess in close cooperation with Member States and the Agencies whether such additional data should be included in the common data platform.* *The Commission should therefore review the scope of the data to be included in the common data platform to assess whether it should be extended to further support the objectives of this Regulation. The review should be conducted on the basis of an in-depth analysis, in close cooperation with the Member States and the Agencies.*	*Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data, and other data related to other substances contained in medicinal products besides active substances. Moreover, a relevant part of the medicinal data is held by the National Competent Authorities. The Commission should thus assess in close cooperation with Member States and the Agencies whether such additional data should be included in the common data platform.*	See COM proposal at the end of this document

32.b. new	***(24a) The EEA, ECHA, EFSA and the Commission should be able to process human biomonitoring data constituting personal data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA, the Commission, the ECHA and the EFSA should process that data only where the processing is necessary for reasons of substantial public interest, as laid out in Article 10(2)(g) and for scientific research as laid out in Article 10(2)(j) of the Regulation (EU) No 2018/1725. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data.***	***(24a) The EEA, ECHA, EFSA, EMA and the Commission should be able to process human biomonitoring data constituting personal data. To the extent that human biomonitoring data constitutes a special category of personal data, namely, health data, the EEA, the Commission, the ECHA and the EFSA should process that data only where the processing is necessary for reasons of substantial public interest, as laid out in Article 10(2)(g) and for scientific research as laid out in Article 10(2)(j) of the Regulation (EU) No 2018/1725. This Regulation lays down the cases where there is such substantial public interest in processing human biomonitoring data.***	PRES proposal is acceptable
36	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications, as a dedicated service of the common data platform, to store the	(28) In order to increase transparency, as well as to enable Authorities to have complete prior knowledge of studies commissioned by business operators, irrespective of whether such studies are carried out by the business operator itself or are outsourced, business operators and laboratories should notify to a database of study notifications established and managed by the ECHA the studies on chemicals they commission for compliance with regulatory requirements under the Union acts listed in Annex I. For this purpose, the ECHA should establish and manage a database of study notifications,	COM proposes the following: *The ECHA should also develop guidance for duty holders to facilitate the implementation of the notification obligation, including details as regards the type of studies requiring notification.* Rationale: - Guidance should potentially be broader - PRES proposal gives the impression that scope is set via guidance document

	information related to those studies. In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.	as a dedicated service of the common data platform, to store the information related to those studies. ***The ECHA should also develop guidance as to the type of studies requiring notification.*** In order to allow business operators and laboratories sufficient time to prepare the notifications of studies, the obligation to notify studies should only start to apply two years after the date of entry into force of this Regulation.	
	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I or II set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I or II, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed formats, making use of existing formats and ensuring interoperability	(38) In order to ensure the interoperability and comparability of chemicals data and to facilitate their automatic and electronic exchange, the Agencies and the Commission should store chemicals data in adequate and mutually coherent and interoperable formats and use mutually coherent and interoperable controlled vocabularies. Some Union acts listed in Annex I ~~or II~~ set procedures to establish or make available data formats, in particular for the submission of chemicals data by business operators or Member States. Where such procedures do not exist in the Union acts listed in Annex I ~~or II~~, the Agencies and the Commission should, where relevant, specify appropriate formats for chemicals data they receive and store, avoiding the use of proprietary standards while, as appropriate, using OECD or other internationally agreed	This is in line with PRES approach to move all legislation in Annex I.

	with existing data submission approaches. ***When specifying such formats and controlled vocabularies, the Agencies and Commission should, where relevant, take into account input and contributions from Member States and stakeholders.***	formats, making use of existing formats and ensuring interoperability with existing data submission approaches. ***When specifying such formats and controlled vocabularies, the Agencies and Commission should, where relevant, take into account input and contributions from Member States and stakeholders.***	
57	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy.***Where relevant and whenever possible, information generated through studies commissioned by the ECHA should be generated by means other than***	(48) Under Regulation (EC) No 178/2002, the EFSA is able to commission, in an open and transparent manner, the scientific studies it needs to accomplish its mission, while seeking to avoid duplication with Member States or Union research programmes. The ECHA should also be able to commission studies to obtain adequate data and information on chemicals within its mission, while maintaining the principle that the burden to prove compliance with Union chemicals legislation remains on the duty holder. Furthermore, the ECHA should commission such studies out of its own initiative or at the request of the Commission, with the objective of supporting the effective and efficient implementation and evaluation of Union acts on chemicals within its mandate and contributing the development of a Union chemicals policy. ***Where relevant and whenever possible, information generated through studies commissioned by the ECHA should be generated by means other***	PRES proposal is acceptable

	vertebrate animal tests, through the use of alternative methods.	***than vertebrate animal tests*** ~~through the use of alternative methods.~~	
27	(49) In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the specific data types and reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 201649. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert	(49) ~~In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant,~~ ***In order*** to expand***, where relevant,*** the ***list of*** ~~specific~~ data types ~~and reference values~~, listed in ***Article 3, paragraph 2a, point c,*** ~~and Annex II~~, to be made available by the EMA through the common data platform, ***in order to support the achievement of the objective of this Regulation, especially to ensure the coherency and the efficiency delivery of hazard and risk assessments of chemicals, and to consider new scientific discoveries, in particular on the increase of hazard or risk to the environment or human health,*** the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending ***Article 3, paragraph 2a, point c.*** ~~Annexes I, II and III~~.	1. The PRES proposal has removed from the recitals the text that refers to **delegating powers to COM for amendments of Annexes I, II and III**. This should be brought back (elements of digitalisation and interoperability which we have proposed in the enacting terms for the addition of medicinal acts and other active substances could also be added) *In order to adjust the contents of Annexes I and III to technical and scientific progress in the field of chemicals and to bring in the scope of this Regulation new Union acts under which relevant chemicals data and information is generated or submitted, and, where relevant, to expand the reference values, listed in Annex II, to be made available by the EMA through the common data platform, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes I, II and III.*

	groups dealing with the preparation of delegated acts.		2. COM does not support the inclusion of **point (b)** in Article 3(2a) and suggests deleting it, referring to relevant active substances in the chapeau of the paragraph, and retain the description of relevant active substances in the recital. 3. COM suggests delegating power to COM to amend scope via delegated act (the current wording implies that legacy data and other active substances can only be included through OLP). 4. Drafting suggestion for empowerment to amend Article 3(2a)(c) *In order to expand, where relevant, the list of data types listed in Article 3, paragraph 2a, point c, to be made available by the EMA through the common data platform, to support the achievement of the objectives of this Regulation, in particular to ensure coherent and efficient chemicals assessments, and to consider new scientific developments, especially with regard to hazards or risks to the environment of human health, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission*

			in respect of amending Article 3, paragraph 2a, point c.
57.a. new		***(49anew)*** It is of particular importance that the Commission carry out appropriate consultations during its preparatory work in relation to the amendment of the Annexes by delegated act, including at expert level through the One-Substance One-Assessment Expert Group, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 201649. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	We had this text in the original version, but this only works if the above text on amending Annexes I – III is brought back
69	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2).	The provisions laid down in this Regulation apply to chemicals data as laid out in Article 3(2) and ***(2a)***.	PRES proposal is acceptable
96.a. new	**Article 3** 1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform'). 2. The common data platform shall provide access to all chemicals data: (a) generated or submitted as part of the implementation of the Union acts listed in Annex I to	***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, part2, as far as:*** ***(a) they are held by EMA and submitted to EMA in the context of the relevant***	See COM proposal at the end of this document

	this Regulation and held by the Agencies or the Commission; (b) generated as part of Union, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission; ***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 listed in Annex II and held by the EMA.*** 3. The following information shall not be included in the common data platform: (a) the information referred to in Article 45 of Regulation (EC) No 1272/2008[1]; (b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/2009[2] of the European Parliament and of the Council. [1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending	***procedures that are concluded after the date of entry into force of this Regulation, and*** ***(b) they either relates to active substances subject to regulatory procedures under other Union acts listed in Annex I part 1 to this Regulation,*** ***or is related to other 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*** ***footnotes*** ***XXX1 Directive 2001/83/EC of the European Parliament and of the Council of***	

	and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1). [2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (OJ L 342 22.12.2009, p. 59).	***6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).*** ***XXX2 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).*** ***XXX3 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).*** ***XXX4 Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).***	
99.b. new	N/A	***The Commission is empowered to adopt delegated acts in accordance with Article***	This provision should go to the article on delegation of powers.

		24 to amend Art.3(2a), point c, by adding new categories of data types presenting an interest for the objectives of this Regulation or, in view of developed scientific knowledge, there is evidence of an increased hazard or risk to the environment or human health.	In addition, drafting suggestion: *The Commission is empowered to adopt delegated acts in accordance with Article 24 to amend Art.3(2a), ~~point c~~, by adding new categories of data types presenting an interest for the objectives of this Regulation or if, in view of scientific developments, there is new knowledge on the hazards or risks to the environment or human health.*
113	10. The Commission or ~~Agencies y~~ agency under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001 ***of the European Parliament and of the Council***.	10. The Commission or Agencies ~~y~~ under whose authority chemicals data is included in the common data platform on chemicals shall remain responsible for handling any requests for access to documents made under Regulation (EC) No 1049/2001 ***of the European Parliament and of the Council***[52].	It is not clear what the PRES proposal is here.
114	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant ~~datasets~~ ***datasets of chemicals data, including, where applicable, chemicals data generated or submitted before the entry into force of this Regulation, ~~, according to paragraphs 2, 2a, 3 and 3a,~~*** ~~submitted under any of the Union acts listed in Annex I, including chemicals data~~	11. The common data platform and its dedicated services shall be established by [OP: please insert date: three years after the date of entry into force of this Regulation], unless specified otherwise. The relevant datasets ***of chemicals data,*** ~~according to paragraphs 2 and 2a, 3 and 3a, submitted under any of the Union acts listed in Annex I, including chemicals data submitted before the entry into force of this Regulation,~~ ***including, ~~where~~***	PRES proposal is acceptable

	~~submitted before the entry into force of this Regulation,~~ shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those ***datasets*** ~~datasets~~ ***~~chemicals data~~*** in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	***~~applicable~~, chemicals data generated or submitted before the entry into force of this Regulation, unless specified otherwise,*** shall be integrated progressively into the common data platform by [OP please insert date: ten years from the date of entry into force of this Regulation] according to the implementation plan referred to in Article 4 (1), first sentence. Upon integration of those datasets ***of chemicals data*** in the common data platform, when the ECHA receives chemicals data in accordance with Article 5, it shall make that data available through the common data platform without undue delay.	
116	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall ***by means of an implementing*** ~~decision~~ ***act,*** adopt ~~and publish~~ an implementation plan identifying ~~datasets~~ ***chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion ~~by means of an implementing decision~~. ***[That implementing act shall be adopted in accordance with the procedure referred to in paragraph 2*** ~~3~~ ***of Article 24a.]*** Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3. COM proposal: implementing act without comitology control, i.e. delete sentence referring to Article 24a	1. By [OP please insert date: 6 months after the date of entry into force of this Regulation] the Commission shall ***by means of an implementing*** ~~decision~~ ***act, in consultation with Member States,*** adopt ~~and publish~~ an implementation plan identifying ~~datasets~~ ***chemicals data*** for inclusion in the common data platform together with a timeline for their inclusion ~~by means of an implementing decision~~. ~~[That implementing act shall be adopted in accordance with the procedure referred to in paragraph 2 3 of Article 24a.]~~ Subsequent rolling implementation plans shall be adopted in line with the governance scheme referred to in paragraph 3.	Addition of 'in consultation with MS' implies comitology control. This should be deleted

119	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing ~~decision~~ ***act. [These implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 ~~3~~ of Article 24a.]*** COM proposal: implementing act without comitology control, i.e. delete sentence referring to Article 24a	4. The Commission shall adopt and publish the governance scheme referred to in paragraph 3 and any revision thereof by means of an implementing ~~decision~~ ***act, in consultation with Member States.*** ~~[These implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 3 of Article 24a.]~~	Addition of 'in consultation with MS' implies comitology control. This should be deleted
128	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes, research, corresponding to their mandate and the type of data they already hold. ~~***Upon suggestion of a Member State,*** a national Authority or a scientific body of a Member State~~~~***, after approval of by the Commission, the Agencies shall host and maintain chemical data which are additional to the data mentioned in the first sentence.***~~ ***In addition, Agencies may host and maintain chemicals data offered to them by Member States.***	1. At the Commission's request, the Agencies shall host and maintain chemicals data generated as part of Union, national or international legislation, programmes or research activities, corresponding to their mandate and the type of data they already hold. ~~Upon suggestion of a Member State, a national Authority or a scientific body of a Member State, after approval of the Commission, the Agencies shall host and maintain chemical data which are additional to the data mentioned in the first sentence.~~ ***In addition, Agencies may host and maintain chemicals data*** ~~offered to them by Member States~~ ***according to their mandate and offered to them by Member States or other parties.***	PRES proposal is acceptable
129	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in Article 4(4), point (c).~~	2. Where the Commission or the Agencies hold data or information referred to in Article 3(2), ***or 3(2a),*** they shall make that data available to the ECHA, in a standard format, where available, together with the relevant context data as ~~referred to in~~	PRES proposal is acceptable (first comma to be deleted: ...in Article 3(2) or 3(2a))

	referred to in Article 4(5), point (c). ~~2a.~~ The Commission and the Agencies shall indicate whether that data or information ~~is made available to the public under the originating Union act~~ ~~shall not be made available to the public in accordance with provisions on confidentiality under the originating Union act.~~ is confidential in accordance with provisions on confidentiality under the originating Union act.	~~Article 4(4), point (c).~~ ***referred to in Article 4(5), point (c).*** ~~2a.~~ The Commission and the Agencies shall indicate whether that data or information ~~is made available to the public under the originating Union act~~ ~~shall not be made available to the public in accordance with provisions on confidentiality under the originating Union act.~~ ***is confidential in accordance with provisions on confidentiality under the originating Union act.***	
146.b.new	***(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.***~~	***(g) supporting policy making and legislative processes.*** ~~***the adoption by the European Parliament, the Council of the European Union and the European Commission of a legally binding act.***~~	COM drafting suggestion: ***(g) supporting policy making and legislative developments at Union level***
146.ea.new	N/A	***6a. The EMA may process human biomonitoring data constituting personal data for the following purposes:*** ***(a) Evaluating and prioritising required regulatory action;*** ***(b) Performing assessments of chemicals*** ***(c) Supporting regulatory risk management.***	COM proposes to have the same text (and processing purposes) as for EFSA and ECHA
146.f.new	7. Any processing of human biomonitoring data constituting personal data by the EEA,	***7.*** Any processing of human biomonitoring data constituting personal data by the EEA,	PRES proposal is acceptable

	the ECHA, the EFSA or the Commission for the abovementioned purposes shall not entail the sharing of such data with third parties.	the ECHA, the EFSA, the EMA or the Commission for ***the abovementioned*** purposes shall not entail the sharing of such data with third parties.	
148	***9.*** The EEA ***, Commission, ECHA and EFSA*** shall act as ~~joint~~ data controller~~s~~ for the human biomonitoring ***data constituting*** personal data ~~it~~***they*** hold~~s~~ or host~~s~~ and processe~~s~~ for the purposes referred to ~~in paragraph 2.~~ ***in paragraphs*** ~~4~~ ***3,4,5,6,8.***	***9.*** The EEA ***, Commission, ECHA, EMA and EFSA*** shall act as ~~joint~~ data controller~~s~~ for the human biomonitoring ***data constituting*** personal data ~~it~~***they*** hold~~s~~ or host~~s~~ and processe~~s~~ for the purposes referred to ~~in paragraph 2.~~ ***in paragraphs*** ~~4~~ ***3,4,5,6,8.***	PRES proposal is acceptable
148. b	10. The Commission, EEA, ECHA and EFSA shall define the storage period and any review thereof for the human biomonitoring data constituting personal data they hold as well as the criteria used to define the storage period.	***The Commission, EEA, ECHA, EFSA and EMA shall define the storage period and any review thereof for the human biomonitoring data constituting personal data they hold as well as the criteria used to define the storage period.***	PRES proposal is acceptable
190	4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall, ***in consultation with Member States***, ~~adopt an implementing decision~~ ***act*** identify~~ing~~ existing datasets ***of chemicals data*** on environmental sustainability related data, other than those referred to in paragraph 2***, and request the Agencies to host and maintain them in accordance with Article 5(1)***.	***4. By [OP please insert date: three years after the date of entry into force of this Regulation], the Commission shall, in consultation with Member States, identify existing datasets of chemicals data on environmental sustainability related data, other than those referred to in paragraphs 2 and 3, and request the ECHA to host and maintain them in accordance with Article 5(1).***	PRES proposal is acceptable
193	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission and	1. Without prejudice to Union provisions providing for the development or making available of data formats, the Commission	PRES proposal is acceptable

	the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.	and the Agencies shall specify, where relevant, for the data referred to in Article 3 (2) and ***(2a)*** falling within their mandate, standard formats and software packages and make them available free of charge through the common data platform.	
214	8. The Commission shall adopt an implementing ~~decision~~ ***act*** to remedy the divergence	8. The Commission shall adopt an implementing ~~decision~~ ***act, in consultation with Member States,*** to remedy the divergence.	Addition of 'in consultation with MS' implies comitology control. This should be deleted
216	1. The Commission and the Agencies~~, after consulting the experts designated by each Member States referred to in article 24(4),~~ shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2), where relevant.	1. The Commission and the Agencies~~, after consulting the experts designated by each Member States referred to in article 24(4),~~ shall specify and regularly update controlled vocabularies within their mandate for the data referred to in Article 3(2) ***and 3(2a)***, where relevant.	PRES proposal is acceptable
230	8. The Commission shall adopt an implementing ~~decision~~ ***act*** to remedy the divergence. ~~Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.~~	8. The Commission shall adopt an implementing ~~decision~~ ***act, in consultation with Member States,*** to remedy the divergence. ~~Those implementing acts shall be adopted in accordance with the procedure referred to in paragraph 2 of Article 24a.~~	Addition of 'in consultation with MS' implies comitology control. This should be deleted
232.a.new	XXX. The public shall have access to all chemicals data contained in the common data platform, with the exception of data which is deemed to be confidential under Article 5(2), second sentence.	***XXX. The public shall have access to all the chemicals data contained in the common data platform, except data which is deemed to be confidential under Article 5(2), second sentence.*** ~~***To help the public understand the content of the data, the***~~	PRES proposal is acceptable (it is the same as the COM proposal)

		~~***Commission can provide references to scientific publications and outreach***~~.	
234	2. The Authorities shall take the necessary measures to ensure that information contained in the common data platform marked as confidential in accordance with 5(2~~a~~)***, second sentence*** is not made ***available to the*** public.	2. The Authorities shall take the necessary ~~security~~ measures, ***including security measures***, to ensure that information contained in the common data platform marked as confidential in accordance with 5(2~~a~~)***, second sentence*** is not made ***available to the*** public	PRES proposal is acceptable
242	1. The EEA, in collaboration with the ECHA, the EFSA, the EMA, ~~and~~ the EU-OSHA ***and the Commission***, shall, ***in consultation with the Member States, establish, operate, ~~and~~ maintain and update as appropriate*** ~~present a report to the Commission and the experts designated by each Member State. The report shall contain a proposal for~~ a***n indicative*** framework of indicators to monitor ***chemical pollution and occurrence,*** the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.	The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall, ***in consultation with the Member States,*** establish, operate, ~~and~~ maintain ***and update as appropriate*** ~~present a report to the Commission and the experts designated by each Member State. The report shall contain a proposal for~~ a~~n indicative~~ framework of indicators to monitor ***chemical pollution along the chemical's lifecycle, including emissions occurrence,*** the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.	Drafting suggestion (green highlight): The EEA, in collaboration with the ECHA, the EFSA, the EMA, the EU-OSHA and the Commission, shall, ***in consultation with the Member States,*** establish, operate, ~~and~~ maintain ***and update as appropriate*** ~~present a report to the Commission and the experts designated by each Member State. The report shall contain a proposal for~~ a~~n indicative~~ framework of indicators to monitor ***chemical pollution along the chemical's lifecycle, including emissions AND occurrence,*** TO MONITOR the drivers and impacts of exposure to chemicals, AND TO measure the effectiveness of chemicals legislation and ~~[measure[~~ the transition towards the production of safe and sustainable chemicals.

254	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. ~~[~~The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities ~~for consideration of the need for regulatory or policy~~ ***who shall undertake regulatory or policy actions accordingly or justify if they decide not to proceed with any*** action related to the early warning signals. COM proposal: propose to delete the PRES proposal. The impact of the proposal is disproportionate: it will put an obligation on MS, agencies and COM to justify for each signal that was identified why they did not take regulatory action (if they did not take such action) without having much added value. The mere publication of the report will already put enough pressure on the actors.	4. The EEA shall draw up an annual report, compiling and analysing the data on early warning signals gathered in accordance with paragraphs 2 and 3. ~~[~~The first report shall be prepared by [OP: please insert date: 6 months after the end of the first calendar year after entry into force of this Regulation]. The EEA shall present this report to the Commission, relevant Union agencies and Member State competent authorities ~~for consideration of the need for regulatory or policy~~ ***who shall undertake regulatory or policy actions accordingly or justify if they decide not to proceed with any*** action related to the early warning signals.	COM does not support proposal: The impact of the proposal is disproportionate: it will put an obligation on MS, agencies and COM to justify for each signal that was identified why they did not take regulatory action (if they did not take such action) without having much added value. The mere publication of the report will already put enough pressure on the actors.

275	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any ***studies*** ~~on~~ ***that generate chemicals data which they commission*** ~~to be notified s as defined in Article 2. any studies on chemicals they commission~~ to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products ***they commission as part of a risk or safety assessment*** ~~, prior to placing on the market~~***, under the Union acts listed in Annex I.*** However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. study falls under the notification obligation of paragraph 3. ***When a study falls under the notification obligation of paragraph 3, business operators shall inform in this respect the laboratory or testing facility in which the study to be notified is carried out, without undue delay.*** ~~,~~ about the fact that the study falls under the notification obligation of paragraph 3.	1. Business operators shall notify to the Database of Study Notifications referred to in Article 9, without undue delay, any ***studies*** ~~on~~ ***that generate chemicals data which they commission*** ~~and that are commissioned to be notified s as defined in Article 2. any studies on chemicals they commission~~ to support an application, notification or regulatory dossier notified or submitted to an Authority, as well as any studies on chemicals on their own or in products they commission as part of a risk or safety assessment ~~, prior to placing on the market,~~ under the Union acts listed in Annex I. However, business operators shall not notify to the Database of Study Notifications referred to in Article 9 studies that are to be notified under Article 32b of Regulation (EC) No 178/2002. study falls under the notification obligation of paragraph 3. ***When a study falls under the notification obligation of paragraph 3, business operators shall inform in this respect the laboratory or testing facility in which the study to be notified is carried out,*** ~~without undue delay~~ ***within one month of the commissioning of the study, about the fact that the study falls under the notification obligation of paragraph 3.***	It should be without undue delay: it does not make sense to commission the study with a lab and then after one month come back to them that the study should be notified. Alternative COM proposal (green highlight): ***...business operators shall, at the time of commissioning the study, in this*** ~~***respect,***~~ ***inform the laboratory or testing facility in which the study to be notified is carried out,*** ~~***without undue delay.***~~ ~~,~~ about the fact that the study falls under the notification obligation of paragraph 3.
283	Amendment of Annexes I, II and III	Amendment of Annexs	Editorial mistake: an ‘e’ is missing
284	1. Annex I shall list all the Union acts under which chemicals data, as defined under this Regulation, is generated or submitted to the	***1. In order to keep Annex I complete, since it lists all the Union acts under which chemicals data, is***	COM agrees on substance (delegated act), but suggests rephrasing as below. In addition, we need this rule that

	ECHA, EEA, EFSA, EU-OSHA and to the Commission. In order to keep this list complete and the common data platform up to date, as soon as new Union acts under which chemicals data is generated or submitted enter into force or are revised, the Commission shall adopt delegated acts in accordance with Article 24 to amend Annex I in order to list those new Union acts.	***generated or submitted to the ECHA, EEA, EFSA, EU-OSHA and to the Commission and the common data platform up to date, as soon as new Union acts under which chemicals data is generated or submitted enter into force or an existing Union act is amended to the extent of introducing provisions on the generation or submission of data , the Commission shall adopt delegated acts in accordance with Article 24 to amend Annex I in order to list those new Union acts, if the new Union act did not amend Annex I.***	Annex I shall contain all Union acts, i.e. we take the political decision now in this regulation. It is exactly this decision here and now that allows COM to amend the Annexes through delegated acts. So, the first sentence needs to stay and the last part of the last sentence should be deleted (in order not to create the impression that the political decision is still taken elsewhere). ***Annex I shall list all the Union acts under which chemicals data, as defined under this Regulation, is generated or submitted to the ECHA, EEA, EFSA, EMA, EU-OSHA and to the Commission.*** In order to keep Annex I complete~~, since it lists all the Union acts under which chemicals data, is generated or submitted to the ECHA, EEA, EFSA, EU-OSHA and to the Commission~~ and the common data platform up to date, as soon as new Union acts under which chemicals data is generated or submitted enter into force or an existing Union act is amended to the extent of introducing or revising provisions on the generation or submission of chemicals data , the Commission shall adopt delegated acts in accordance with Article 24 to amend Annex I in order to list those new or revised Union acts.~~, if the new Union act did not amend~~

			~~Annex I.~~
285	2. Annex II shall list chemicals data on human and veterinary medicinal products held by the EMA to be made available to the common data platform. Taking into account the advances in digitalisation and interoperability of the data held by the EMA, the data's relevance to chemicals assessments, as well as advances in knowledge relating to risks to the environment posed by human and veterinary medicinal products, the Commission may adopt delegated acts in accordance with Article 24 to amend Annex II in order to list additional data types.	***2. The Commission*** is empowered to adopt delegated acts in accordance with Article 24 to amend Annex II ***of this Regulation*** by adding~~, where relevant,~~ ***new reference values when, in view of developed scientific knowledge, there is evidence of an increased hazard or risk to the environment or human health.***~~categories of data types.~~	Drafting suggestion: *Annex II shall list reference values related to chemicals data on human and veterinary medicinal products held by the EMA to be made available to the common data platform. Taking into account the advances in digitalisation and interoperability of the reference values held by the EMA as well as the values' usefulness for other policy areas and for the implementation of the EU acquis, the Commission may adopt delegated acts in accordance with Article 24 to amend Annex II in order to list additional reference values.* COM's original proposal was applying to the original Annex II, and the reference to scientific developments was relating to 'relevant' substances and not to the reference values. Since Annex II has changed and only covers reference values, the argument of scientific development applies less. It is rather the usefulness of other reference values and considerations relating to digitalisation and interoperability that are relevant for the reference values.

286	3. Annex III shall list all the Union acts under which regulatory processes on chemicals or groups of chemicals are undertaken by Member States competent authorities, ECHA, EEA, EFSA, EU-OSHA, or any of their committees and the Commission. In order to keep this list complete and the common data platform up to date, as soon as new Union acts under which new regulatory processes are established, the Commission shall adopt delegated acts in accordance with Article 24 to amend Annex III in order to list those new Union acts.	***3. In order to keep Annex III complete, since it lists all the Union acts under which regulatory processes on chemicals or groups of chemicals are undertaken by Member States competent authorities, ECHA, EEA, EFSA, EU-OSHA, and the Commission, and the common data platform up to date, as soon as new Union acts under which new regulatory processes are established enter into force or an existing Union act is amended to the extent of establishing new regulatory procedures, the Commission shall adopt delegated acts in accordance with Article 24 to amend Annex III in order to list those new Union acts, if the new Union act did not amend Annex III.***	Ok on substance, but drafting suggestions in line with para 1 above (line 284)
298. b.new	***1. No later than … [OP: please insert six years after the entry into force of this Regulation], the Commission shall adopt a report accompanied, if appropriate, [by a legislative proposal][by a delegated act] to extend the scope of the chemicals data related to medicinal products referred to in [Article 3(2)(c)] [Article 3(2a)] to be included in the common data platform. The Commission shall assess whether additional data types are to be included, as well as data related to medicinal products collected and submitted in the context of [relevant] Union acts listed in [Annex I][Annex II] and held by Member States and not by the Agencies.***	***1. No later than … [OP: please insert ~~three~~ six years after the entry into force of this Regulation], the Commission shall adopt ~~present~~ a report ~~an impact assessment~~ accompanied, if appropriate, by a legislative proposal to extend the scope of the data to be included in the common data platform pursuant Article 3 of this Regulation ~~to notably cover medicinal data and in particular clinical data~~ to further support the objectives ~~of this Regulation~~thereof. The review shall include an assessment of the scope regarding medicinal products data to include in the common data platform referred to in Article 3(2a), point c, as well***	1. the PRES review clause requires a review of the scope with regard to 'all chemicals data' and not just 'medicinal data'. Suggest to refer directly to Article 3(2a)(c) instead of first to Article 3. 2. the proposed wording with regard to data held by National Competent Authorities is not unequivocal in that it refers only to medicinal data held at national level. The current wording encompasses all chemicals data held at national level

		as the relevancy of data collected and submitted in the context of Union acts listed in Annex I and held by National Competent Authorities and not by the Agencies. ~~relevance to maintain the exclusion of the clinical data from the scope by identifying t~~The cost-benefit balance of incorporating ~~such~~ additional data in the common database platform shall be assessed.	Drafting suggestions (green highlight): *1. No later than … [OP: please insert ~~three~~ six years after the entry into force of this Regulation], the Commission shall adopt ~~present~~ a report ~~an impact assessment~~ accompanied, if appropriate, by a legislative proposal to extend the scope of the data to be included in the common data platform pursuant Article 3(2a), point (c), of this Regulation ~~to notably cover medicinal data and in particular clinical data~~ to further support the objectives ~~of this Regulation~~thereof. The review shall include an assessment of the scope regarding medicinal products data to include in the common data platform referred to in Article 3(2a), point c, as well as the relevancy of chemicals data related to medicinal products collected and submitted in the context of Union acts listed in Annex I and held by National Competent Authorities and not by the Agencies. ~~relevance to maintain the exclusion of the clinical data from the scope by identifying t~~The cost-benefit balance of incorporating ~~such~~ additional data in the common data~~base~~ platform shall be assessed.*

301	Annex I UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.	Annex I Part 1 UNION ACTS REFERRED TO IN ARTICLES 2, 3, 8, 11, 12, 15, 17, 21, 22 AND 23 Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.	PRES proposal is acceptable
371.0.new	N/A	***Part 2 Union acts referred to in article 3(2a)*** ***Reference to each Union act listed herein should be understood also as reference to all implementing and delegated acts adopted under that Union act, where relevant.***	PRES proposal is acceptable
372.e.new	N/A	***75. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p.176)"***	COM does not agree with inclusion of the regulation on in vitro diagnostic medical devices. There are no chemicals data held by the COM or Agencies under this regulation. Although the regulation (Annex I, section 10.3) requires the manufacturer to assess the risks of CMR and ED substances, there are no obligations on labelling or reporting to COM or Agencies on the presence of CMRs in the in vitro diagnostic medical devices and hence the EUDAMED database does not contain any chemicals data on in vitro diagnostic medical devices. Any information on

			the assessment of risks of use of CMR/ED substances are in the technical documentation held by the notified bodies designated by designated authorities of Member States. For medical devices (MDR), there actually is data at EU level: there is information on the presence of CMRs in medical devices in EUDAMED. That is why we included MDR and not in vitro MDR

COM proposal for medicinal data:

(8) While some medicinal products are also chemicals, the application and use of hazard and risk assessments performed on them under Union acts on medicinal products is different from the application and use of hazard and risk assessments performed under the main Union acts on chemicals. Because of this and in order to achieve the best possible balance between the administrative burden for the European Medicines Agency ('EMA') and the added value for Authorities of including chemicals data related to medicinal products in the common data platform, only chemicals data with the highest added value related to relevant active substances contained in medicinal products should be included. Relevant active substances concern active substances covered by the medicines legislation and also subject to regulatory procedures under other Union legislation identified in this Regulation, as well as other active substances with particular persistent, bio-accumulative and toxic properties or with a known high level of residues in the environment. The specific chemicals data to be included for those relevant active substances should cover chemicals data related to environmental risk assessments carried out under Union legislation on medicinal products for human and veterinary use, non-clinical studies carried out under Union legislation on medicinal products for human use and maximum residue limit values the EMA holds, as well as specific reference values.

(8a)Other chemicals data submitted or generated under Union legislation on medicinal products may also be of interest to chemicals regulatory areas, such as data related to other active substances contained in medicinal products, clinical data and data on medicinal products, held by the EMA, as well as data related to medicinal products and the active substances they contain held by Member State competent authorities. The Commission should assess in close cooperation with Member States and the Agencies whether such additional data should be included in the common data platform.

Article 3

[...]

2a. By way of derogation from paragraph 2, the common data platform shall only provide access to the chemicals data for relevant active substances submitted to and held by the EMA as part of the implementation of the Union acts listed in Annex I, part2, as far as:

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

(b) 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 compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX3