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LIMITE

ENV

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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 6848/2024
N° Cion doc.:	ST 16973/23, 16972/23, 16961/23 + ADD 1
Subject:	OSOA Package: comments from delegations

Following the call for comments on the above set out with WK 6848/2024, delegations will find attached additional comments from DK on Data platform, and comments from FR and SE.

DENMARK

Additional Remarks
Ad hoc Working Party on One Substance One Assessment - The common data platform on chemicals

Medicinal products

Denmark can support the wording of article 3(2a) in line 96.a.new, but only if it made clear that article 3(2a) a to c are cumulative by adding an "and" in the end of a and b.

We therefore suggest to amend the article 3(2a) in line 96.a.new to:
2a. The common data platform shall also provide access to data generated or submitted as part of the implementation of 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, Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3 and Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX4, as far as:
(a) they are held by EMA and submitted to EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation, **and**
(b) either relates to active substances used for other applications regulated by other Union legislation covered by 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) falls at least in one of the following category: - 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 Council XXX and Regulation (EC) No 726/2004 of the European Parliament and of the Council XXX; or - Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council XXX; or - Data used to derive Maximum residue levels ~~data~~ compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the Council XXX

Denmark have some concerns on the scope of the review clause in Article 26a in line 298.b.new, as this could endanger the confidentiality of medical products if the scope of the common data platform is extended.

FRANCE

NOTE DES AUTORITÉS FRANÇAISES

Objet : Commentaires des autorités françaises à la suite de la réunion du groupe de travail du 13 mai 2024 sur le paquet législatif « Une substance, une évaluation »

Les autorités françaises remercient la Présidence belge pour les textes de compromis proposés à la discussion lors du groupe du 13 mai dernier.

Pour ce qui concerne l'évolution des ressources et de la gouvernance de l'ECHA, les autorités françaises sont favorables aux propositions de la Présidence permettant d'introduire une clause de revoyure dans la directive RoHS[1] et dans le règlement POP[2] pour envisager de futurs développements réglementaires.

Directive modifiant la directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la réattribution de tâches scientifiques et techniques à l'Agence européenne des produits chimiques

Les autorités françaises souhaitent apporter leur soutien à la Commission sur les dispositions suivantes :

- Article 1(3)(a) : Dans un souci de rationalisation des ressources à mobiliser au sein de la Commission et de l'ECHA, une formulation plus flexible comme initialement proposée par la Commission devrait être adoptée plutôt qu'une formulation imposant un délai de réexamen fixé *a minima* tous les 5 ans par la Présidence pour la liste des substances soumises à restrictions.

- Article 1(3)(c) : L'ajout des termes « or a group of similar substances » n'est pas nécessaire.

- Article 2 : Une application du texte dans les 12 mois est l'option privilégiée par les autorités françaises et non dans les 24 mois comme proposé par la Présidence.

[1] Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS). DIRECTIVE 2011/65/UE DU PARLEMENT EUROPÉEN ET DU CONSEIL du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques.

[2] Règlement (UE) 2019/1021 du Parlement européen et du Conseil du 20 juin 2019 concernant les polluants organiques persistants (refonte) (Texte présentant de l'intérêt pour l'EEE.)

Par ailleurs, les autorités françaises souhaitent proposer un complément au considérant 5b pour faire écho au nouveau paragraphe 9 de l'article 5 (point (d) de l'article 1(1)) afin d'indiquer que les Etats membres devront être consultés avant l'adoption de toutes lignes directrices par la Commission. Ainsi elles proposent la rédaction suivante :

« (5b) Most exemption requests are expected to require the expertise of the Committee for Socio-economic Analysis set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. The Members States' representatives should be consulted by the Commission when adopting guidelines **for the purpose of granting, renewing or revoking an exemption, including** on the involvement of the Committee for Risk Assessment. »

Enfin, les autorités françaises apportent leur soutien global au compromis de la Présidence.

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

Modifications du règlement (UE) 2019/1021 (POP)

A l'article 4(4), les autorités françaises souhaitent modifier la formulation proposée par la Présidence au paragraphe 2 de l'article 15 afin de s'aligner sur la formulation du paragraphe 1 de ce même article. En particulier, l'emploi du terme « to mirror » ne leur semble pas approprié dans la mesure où les amendements des annexes IV et V ne sont pas le miroir des amendements des annexes I, II et III mais viennent en complément. Pour ce qui concerne l'ajout entre crochets de la Présidence visant à préciser sur quoi porte la délégation de pouvoir, les autorités françaises partagent la position de la Commission considérant que cet ajout n'est pas nécessaire et qu'il est important de maintenir de la flexibilité.

Elles proposent donc la formulation suivante pour le paragraphe 2 de l'article 15 :

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

Les autorités françaises soutiennent par ailleurs la remarque de forme de la Commission sur l'article 4(5)(a). En effet, seule la première phrase du paragraphe 2 de l'article 18 est modifiée par l'ajout entre crochets. Aussi, les mots « The first sentence of » devraient être réintégrés au texte et les deux dernières phrases en rouge devraient être supprimées pour plus de clarté de ce règlement modificatif.

Les autorités françaises sont en mesure de soutenir le reste des propositions de la Présidence.

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

Les autorités françaises sont favorables à des modalités de consultation des Etats membres relativement souples et non contraignantes afin d'éviter de ralentir le processus de décision et par conséquent la mise en oeuvre du texte. Pour ce qui concerne le plan de mise en oeuvre et le schéma de gouvernance à l'article 4, elles préférent l'option A de la Présidence considérant qu'une procédure de comitologie n'est pas nécessaire. Elles soutiennent également la proposition de la Commission d'avoir de la comitologie par procédure consultative et non par procédure d'examen à l'article 20 pour la liste des produits chimiques sélectionnés pour l'observatoire.

Bloc 4 : Approche à adopter pour les données médicaments

A la suite des arguments et précisions apportés par la Commission, les autorités françaises préfèrent maintenir la proposition initiale de la Commission pour ce qui concerne la présentation des données concernant les médicaments à intégrer dans la plateforme: elles considèrent que la mention des données médicaments dans la partie 1 de l'annexe II permettra davantage de lisibilité que dans l'article 3 du texte.

Elles reconnaissent les contraintes que représenterait l'ajout d'autres types de données sur les médicaments. Toutefois, elles considérent que pour les types de données définis, ceux-ci ne doivent pas concerner uniquement les substances actives également utilisées pour d'autres applications mais aussi les substances actives qui ont des structures proches de substances qui sont évaluées dans d'autres cadres réglementaires. De manière générale, toutes les substances actives sont pertinentes puisque source de données possibles dans le cadre de lecture croisée. Les autorités françaises ne soutiennent donc pas la limitation du champ aux substances "pertinentes" comme indiqué au considérant 8 (ligne 16) et défini à l'article 3, paragraphe 2a, point b (ligne 96.a.new). Elles proposent la suppression de cette mention afin de tenir compte de l'ensemble des substances actives.

Au considérant 8a (ligne 16.a.new), les autorités françaises soutiennent l'ouverture à une possible intégration des données relatives aux substances au-delà des substances actives. Aussi, elles proposent la clarification suivante :

"(8a) Other medicinal data hold by the EMA might present an interest for other regulatory areas, such as data related to other active substances of concern, clinical data, and data related to **other substances contained in** products and not only to active substances, amongst others. However, due to their particular nature, it is not yet clear if the cost-benefits balance of including those data is favourable, in particular for the workload of the EMA and confidentiality concerns."

Les autorités françaises sont par ailleurs favorables à la clause de revoyure proposée à l'article 26a (ligne 298.b.new) afin d'évaluer dans le futur l'opportunité de bénéficier de davantage de données sur les médicaments, notamment les données détenues par les agences nationales.

Elles souhaitent également donner le pouvoir à la Commission de modifier par actes délégués les annexes I à III du règlement afin de faciliter la mise à jour du texte. Dans le cas où le service juridique du Conseil indiquerait que les éléments des annexes constituent des éléments essentiels qui ne peuvent pas bénéficier de cette procédure, les autorités françaises demandent que le raisonnement du service juridique soit partagé aux Etats membres. *A minima* elles considèrent que les types de données médicaments à intégrer à la plateforme devraient pouvoir bénéficier d'une modification par acte délégué puisque les règlementations visées sont déjà dans le champ du texte.

Bloc 5 : Définitions et champ d'application

Les autorités françaises ne sont pas favorables à l'ajout par la Présidence d'une annexe IV listant les réglementations à partir desquelles des données sur la durabilité environnementale pourraient être collectées pour intégrer la plateforme de données commune. Elles soutiennent la position de la Commission qui indiquait notamment que l'annexe I prévoit déjà de lister les réglementations pertinentes pour collecter les données à intégrer à la plateforme.

Bloc 7 : Notifications des études et contrôle

Les autorités françaises soutiennent la proposition de la Présidence à l'article 22, paragraphe 1 (ligne 275). Elles considèrent qu'une définition des études à notifier n'est pas nécessaire et souhaitent privilégier une approche similaire à celle proposée dans la législation alimentaire où les études à notifier sont précisées dans un document d'accompagnement et non dans le corps du texte. Elles trouvent par ailleurs intéressante la suggestion de l'Italie de fixer un délai pour les notifications des études qui pourrait par exemple être de 1 mois, ce qui serait de nature à faciliter les contrôles. Toutefois, elles s'interrogent sur l'opportunité de définir un point de départ de ce délai.

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 13 May 2024 on the "One substance, one assessment" legislative package

The French authorities would like to thank the Belgian Presidency for the compromise texts proposed for discussion at the group meeting on 13 May.

Regarding the evolution of ECHA's resources and governance, the French authorities are in favor of the Presidency's proposals allowing the introduction of a review clause in the RoHS directive and in the POP regulation to consider future regulatory developments.

Directive amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

The French authorities wish to provide their support to the Commission on the following provisions:

- Article 1(3)(a): In order to rationalize the resources to be mobilized within the Commission and the ECHA, a more flexible formulation as initially proposed by the Commission should be adopted rather than a formulation imposing a review period set at least every 5 years by the Presidency for the list of substances subject to restrictions.

- Article 1(3)(c): The addition of the terms “or a group of similar substances” is not necessary.

- Article 2: Application of the text within 12 months is the option favored by the French authorities and not within 24 months as proposed by the Presidency.

Furthermore, the French authorities wish to propose an addition to recital 5b to echo the new paragraph 9 of Article 5 (point (d) of Article 1(1)) in order to indicate that Member States must be consulted by the Commission before the adoption of any guidelines. They therefore propose the following wording:

« (5b) Most exemption requests are expected to require the expertise of the Committee for Socio-economic Analysis set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. The Members States’ representatives should be consulted by the Commission when adopting guidelines **for the purpose of granting, renewing or revoking an exemption, including** on the involvement of the Committee for Risk Assessment. »

Finally, the French authorities provide their overall support for the Presidency's compromise.

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

Amendments of regulation (EU) 2019/1021

In Article 4(4), the French authorities wish to modify the wording proposed by the Presidency in paragraph 2 of Article 15 in order to align with the wording of paragraph 1 of the same article. In particular, the use of the term “to mirror” does not seem appropriate to them insofar as the amendments to Annexes IV and V do not mirror the amendments to Annexes I, II and III but are complementary. As regards the Presidency's bracketed addition aimed at clarifying what the delegation of power relates to, the French authorities share the Commission's position considering that this addition is not necessary and that it is important to maintain flexibility. They therefore propose the following wording for paragraph 2 of Article 15:

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

The French authorities also support the Commission's formal comment on Article 4(5)(a). Indeed, only the first sentence of paragraph 2 of Article 18 is modified by the addition in square brackets. Then, for greater clarity of this amending regulation, the words “The first sentence of” should be reinstated in the text and the last two sentences in red should be deleted.

The French authorities are able to support the rest of the Presidency's proposals.

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 3: Involvement of the Member States, delegated and implementing acts

The French authorities are in favor of relatively flexible and non-binding consultation arrangements with Member States in order to avoid slowing down the decision-making process and consequently the implementation of the text. Regarding the implementation plan and the governance plan in Article 4, they prefer option A of the Presidency considering that a comitology procedure is not necessary. They also support the Commission's proposal to have comitology by advisory procedure and not by examination procedure in Article 20 for the list of chemicals selected for the observatory.

Cluster 4: Approach to adopt for medicinal products data

Following the arguments and clarifications provided by the Commission, the French authorities prefer to maintain the Commission's initial proposal with regard to the presentation of medicines data to be integrated into the platform: they consider that the mention of medicines data in part 1 of the Annex II will allow for greater readability than in Article 3 of the text.

They recognize the constraints that adding other types of medicines data would represent. However, they consider that for the types of data defined, these must not only concern active substances also used for other applications but also active substances which have structures close to substances which are evaluated in other regulatory frameworks. Generally speaking, all active substances are relevant as possible data sources in the read-across framework. The French authorities therefore do not support limiting the scope to "relevant" substances as indicated in recital 8 (line 16) and defined in Article 3, paragraph 2a, point b (line 96.a.new). They propose the deletion of this mention in order to take into account all active substances.

In recital 8a (line 16.a.new), the French authorities support openness to possible integration of data relating to substances beyond active substances. They also propose the following clarification:

"(8a) Other medicinal data hold by the EMA might present an interest for other regulatory areas, such as data related to other active substances of concern, clinical data, and data related to **other substances contained in** products and not only to active substances, amongst others. However, due to their particular nature, it is not yet clear if the cost-benefits balance of including those data is favourable, in particular for the workload of the EMA and confidentiality concerns."

The French authorities are also in favor of the review clause proposed in article 26a (line 298.b.new) in order to evaluate in the future the opportunity to benefit from more data on medicines, in particular the data held by national agencies.

They also wish to give the Commission the power to modify Annexes I to III of the regulation by delegated acts in order to facilitate updating the text. In the event that the Council's legal service indicates that the elements of the annexes constitute essential elements which cannot benefit from this procedure, the French authorities ask for the reasoning of the legal service be shared with the Member States. At a minimum, they consider that the types of medicines data to be integrated into the platform should be able to benefit from a modification by delegated act since the regulations concerned are already within the scope of the text.

Cluster 5: Definitions and scope

The French authorities are not in favor of adding an Annex IV listing the regulations from which data on environmental sustainability could be collected to integrate the common data platform. They support the position of the Commission which indicated in particular that Annex I already provides for listing the relevant regulations for collecting the data to be integrated into the platform.

Cluster 7: Studies notifications and enforcement

The French authorities support the Presidency's proposal in Article 22, paragraph 1 (line 275). They consider that a definition of the studies to be notified is not necessary and wish to favor an approach similar to that proposed in food legislation where the studies to be notified are specified in an accompanying document and not in the body of the text. They also find interesting Italy's suggestion to set a deadline for notifications of studies which could, for example, be 1 month, which would facilitate controls. However, they question the advisability of defining a starting point for this deadline.

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

SWEDEN

Comments 15 May 2024 - Annex III – Common Data Platform (ST 16961/23)

		Sweden comments
		SE sees a need to ensure EMA's responsibility for biomonitoring. It is important that the text in the recital does not interfere with EMA:s responsibilities within the pharmaceutical legislation, etc. **For example, in article 6 EHCA shall be given responsibility for regulatory issues, e.g. (f) supporting regulatory risk management.** **Here it is important to ensure that EMA:s responsibilities in this field is considered.**
32.a 32.b	Skäl 24 a och b	**SE suggests that EMA should be included the group of concerned agencies with regard to biomonitoring of human data in this context, since this is what the regulatory authorities already work with under EU legislation. EMA should be included in the information loops wherever suited in this regulation.**
91	Article 3 Common Data Platform on Chemicals	
92	1. The ECHA shall establish and manage a common data platform on chemicals ('the common data platform').	
93	2. The common data platform shall provide access to all chemicals data:	
94	(a) generated or submitted as part of the implementation of the Union acts listed in Annex I to this Regulation and held by the Agencies or the Commission;	
95	(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;.	
96	~~(c) listed in Annex II and held by the EMA;~~	
96.a.new	(ca)~~ as well as to~~ (d)~~ the available context data of the data mentioned in the preceding paragraphs a, b~~ and c, ~~to the extent that it is relevant for the purposes of the present regulation.~~ **2a. The common data platform shall also provide access to data generated or submitted as part of the implementation of 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, Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3 and Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX4, as far as:** **(a) they are held by EMA and submitted to EMA in the context of the relevant procedures that are concluded after the date of entry into force of this Regulation,** **(b) either relates to active substances used for other applications regulated by other Union legislation covered by 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,** **(c) falls at least in one of the following category:** **- Non-clinical safety data, including data related to environmental risk assessments, compiled**	**2a. The common data platform shall also provide access to data generated or submitted as part of the implementation of 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, Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3 and Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX4, as far as:** **(a) they are held by EMA ~~and submitted to EMA in the context of the relevant procedures that are concluded~~ ~~after the date of entry into force of this Regulation,~~** **(b) ~~either~~ they relate~~s~~ to active substances within in the scope of the legislation as listed in the first subparagraph of Article 3(2a), ~~used for other applications regulated by other Union legislation covered by 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**

	pursuant to Directive 2001/83/EC of the European Parliament and of the CouncilXXX and Regulation (EC) No 726/2004 of the European Parliament and of the CouncilXXX; or **- Data related to environmental risk assessments, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX; or** **- Data used to derive Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX** **footnotes** **XXX1 Directive 2001/83/EC of the European Parliament and of the Council of 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).**	**(c) they falls into at least in one of the following categoryies:** **- Non-clinical safety data, including data related to environmental risk assessments data, compiled pursuant to Directive 2001/83/EC of the European Parliament and of the CouncilXXX and Regulation (EC) No 726/2004 of the European Parliament and of the CouncilXXX; or** **- Data related to environmental risk assessment data, compiled pursuant to Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX; or** **- Data used to derive Maximum residue levels data compiled pursuant to Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX** Justification: The reference in Article 3(2a)(a) to procedures that are concluded should be deleted to allow for planning of the inclusion of historical data on active substances to be included in the implementation plans without having to go through the Ordinary Legislative Procedure. The criteria for relevant active substances should be deleted from Article 3(2a)(b). This is because it is important that the scope of the Data Regulation includes active substances for human and veterinary medicines as regulated in Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Regulation (EC) No 470/2009 from the date of the entry into force of the Regulation. It should be noted that: i. The environmental data on these substances will be able to be used in the application of environmental legislation such as the Water Framework Directive as it becomes available in the EPAR of centrally approved medicinal products, and submitted ERA from medicinal products approved by decentralized and mutual recognition procedures. ii. The initiative will contribute to improve competition by increasing access to data or information and thereby levelling the conditions especially for SMEs. iii. It is desirable to avoid that an extension in scope has to be made later by the Ordinary Legislative Procedure in Council and the Parliament. This would be resource intensive and incur unnecessary delay. iv. Problems regarding the practicalities of making the information can be addressed in the implementation plan. Including data on all the substances in scope does not mean that it is expected that it will all be available immediately. v. There is a distinction between including all active substances in scope in contrast to including all types of data on those substances in scope from the date of entry into force. The types of data included from entry into force can be restricted until the consequences of loading up different sorts of data on to the platform have been analysed. The

		data included from the outset must include, as a minimum, those data that are needed for the environmental risk assessment data, including for secondary poisoning. It should be noted that: The environmental risk assessment data on these substances will be able to be used as it becomes available in the EPAR of centrally approved medicinal products and submitted ERA from medicinal products approved by decentralized and mutual recognition procedures. Further comments: In the proposal it must be clarified that the requirements in a, b and c are cumulative. Since the four regulations are listed in Annex I, it needs to be clarified in the proposal how this provision relates to Article (3)(2)(a).
97	3. The following information shall not be included in the common data platform:	
98	(a) the information referred to in Article 45 of Regulation (EC) No 1272/200850; Footnote: 50 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 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).	
99	(b) the information related to cosmetic products and notified to the Cosmetic Product Notification Portal under Article 13 of Regulation (EC) No 1223/200951 of the European Parliament and of the Council. Footnote: 51 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November **2009** on cosmetic products (OJ L 342 22.12.2009, p. 59).	

99.a.new	~~(c) clinical data held by EMA under 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, Regulation (EU) 2019/6 of the European Parliament and of the CouncilXXX3 and Regulation (EC) No 470/2009 of the European Parliament and of the CouncilXXX4~~ ~~Where relevant, by derogation to paragraph (a), data held by the EMA resulting from procedures concluded before the entry into force of this Regulation may also be considered for inclusion into the common data platform.~~ **3a. The common data platform shall also provide access to data submitted before the entry into force of this Regulation.**	
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~~ **chemicals data, according to paragraphs 2, 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,~~ 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~~ **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.	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~~ **chemicals data, according to paragraphs 2, 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,~~ shall be integrated … Justification: We do not see the need for the references to paragraph 3.
16	~~(8) Due to the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals, for medicinal products, only chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit values the European Medicines Agency ('EMA') holds, as well as specific reference values, should be included in the common data platform.~~ ~~For medicinal active substances, only data on relevant substances should be included. These concern active substances covered by the medicines legislation and also used for other applications regulated by 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 following chemicals data that the European Medicines Agency ('EMA') holds, related to active substances subject to Union acts on medicinal products present an interest for the objectives of this regulation: chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines, maximum residue limit values, as well as specific reference values, and should~~	

	~~thus be included in the common data platform. These concern active substances covered by the medicines legislation and also used for other applications regulated by 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. These data should also be limited to data submitted to the EMA in the context of the relevant procedures that are finalised or submitted after the entry into force of this Regulation. At a later stage, it should also be possible to include in the common data platform, where relevant, data the EMA holds on procedures concluded before the entry into force of this Regulation.~~ ~~Medicinal data might present an interest for other regulatory areas. However, due to their particular nature, it is not yet clear if the cost-benefits balance of including those data is favourable, and thus clinical data should not be included in the common data platform. In order to further clarify this, the Commission should review the scope of the data to be included in the common data platform to assess whether it should be extended, and in particular for clinical data, 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.~~ **(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, only chemicals data related to active substances contained in medicinal products with a known added value. Relevant active substances are those covered by the medicines legislation and used for other applications regulated by 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.**	**(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, only chemicals data related to active substances contained in approved medicinal products with a known added value.** ~~**Relevant active substances are those covered by the medicines legislation and used for other applications regulated by 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 the environmental risk assessments (ERA) 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 critical for the environmental risk assessment and maximum residue limit values the EMA holds, as well as specific reference values.**