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General Secretariat

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2023/0453 (COD)**

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LIMITE

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CONTRIBUTION

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| From: | General Secretariat of the Council |
| To: | Ad hoc Working Party on One Substance One Assessment |
| N° prev. doc.: | WK 3157/2025 |
| N° Cion doc.: | ST 16961/23 + ADD 1 |
| Subject: | OSOA Package: Regulation on Data Platform - comments from a delegation |

Following the call for comments on the above set out with WK 3157/2025, delegations will find attached comments from BE.

| File | | 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 (Text with EEA relevance) - 2023/0453(COD) | |
|------------------------|-----------------------|--|---|
| Member State | | BELGIUM | |
| Row in table Annex III | Reference in the text | MS position | MS comment |
| 13 | Recital 1 | In favor | BE is in favour of including the wording "groups of chemicals" |
| 14 | Recital 2 | Scrutiny | The use of validated methods is necessary for well grounded decisions. BE would like to see the EP sentence on animal testing be modified: " and thereby contribute to ensuring that testing on animals only takes place as a last resort, in particular when no other relevant validated method is available to obtain the necessary information ". |
| 16 | Recital 4 | Neutral | |
| 18 | Recital 6 | Neutral | |
| 19 | Recital 7 | Scrutiny | About enforcement activities: this should be carefully evaluated: not all enforcement data can be shared, or not all is relevant. |
| 20 | Recital 8 | Object | Compared to the scope of the review in the COREPER mandate, the EP is not mentioning the "chemicals data on substances other than active substances" in recital 7 nor art.26a. Moreover, a justification of what is in/out in the present scope is needed as in COREPER mandate (in recital 8). |
| 21 | Recital 9 | Neutral | |
| 21a | Recital 9a | Object | - A list and justification of what is in/out in the present scope is needed as in COREPER mandate. - The originator principle seem quite clear, there is no need for an additional amendment by EP on confidentiality here. |
| 24 | Recital 12 | In favor | part of EP amendment is simple clarification, the other is identical to COREPER. |
| 26 | Recital 14 | Scrutiny | This proposal might entail a lot of work for the agencies. BE could have flexibility on this if this refers to a generic statement on the rights, about the entire database. If this is per dataset or study, this seems not feasible. |
| 29 | Recital 17 | Scrutiny | An estimation of resources is needed (positive that EP art.26a mention the resources issue). About the database on alternatives: 1) To be analyzed: amount of work for MS (which studies?)/COM/Agencies (including the validity assessment), confidentiality on R&D, exact scope; 2) BE is wandering on a possible link with INCITE (< JRC-Seville) from Industria Emissions Directive. https://innovation-centre-for-industrial-transformation.ec.europa.eu/ - and what about any possible future other initiatives on substitution? 3) Safer substances providers are encouraged to provide info, this is positive for innovation, often SMEs About the database on chemicals in articles: BE welcomes the inclusion of the ecodesign and waste regulations, but BE needs an estimation of the resources needed. BE is also wandering if art.22.1 wording is in fact covering articles ("products") also. |
| 30 | Recital 18 | Neutral | |
| 31 | Recital 19 | Neutral | |
| 33 | Recital 21 | In favor | Under certain conditions, BE is in favour of the possibility to deliver extra data voluntary = more data becomes available. However wording should be modified in order to take into account the following concerns: - COM or agencies can refuse on the basis of a justified lack of added value of the data - the amount of work can be enormous, a mechanism is to be foreseen to be able to select relevant data, e.g. registration of allowed users, a self-assessment questionnaire, plus a mark indicating in the metadata the source/status of this data (the later already foreseen by COREPER elsewhere). - the added value of this in comparison to published litterature is to be verified. An interest could be in collecting grey litterature containing data, or datasets that do not fit into scientific papers. |
| 34 | Recital 22 | Neutral | |
| 35 | Recital 23 | In favor | Under certain conditions, BE is in favour of the possibility to deliver extra data voluntary. See also our comments on recital 21. |
| 36 | Recital 24 | Neutral | |
| 36a | Recital 24a | Neutral | |
| 36b | Recital 24b | Object | - The COREPER text on HBM and personal data was the result of in-depth analysis of the relevant regulations and the role of data processors, data controllers, etc, we should be very careful if this is modified or deleted. - recital 24c is not in this table, while it is important. |
| 39 | Recital 27 | In favor | Under certain conditions, BE is in favour of the possibility to deliver extra data voluntary. See also our comments on recital 21. |

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| 40 | Recital 28 | Object | <p>- Scrutiny on: The sentences introduced by the EP that says "...that are not commissioned to support an application..." etc seems either superfluous with the original wording ("they commission for compliance..") or narrowing the scope of what is to be notified in an undetermined manner. BE would like to keep the scope for notifications as in the COM proposal. A clarification on the scope that the EP wants is welcomed.</p> <p>- Object on: "notification information is kept confidential". EP deletes in art 9.3 the publication of the studies in the platform for public scrutiny, this is not inline with the spirit of this regulation. The recital should be clear that the general approach is to publish the notifications, except if defined as confidential.</p> |
| 42 | Recital 30 | Scrutiny | The amendment on "respect confidentiality of relevant elements..." etc seems to be made to clarify the criteria to be used for deciding on confidentiality, which is welcomed and was missing in the COM text. It was not immediately clear to us why EP deleted parts of art9(3), but it seems that it is to clarify that there are two databases (notifications which is confidential, and the common platform were the non-confidential parts will be published). |
| 43 | Recital 31 | Object | The amendment impact on the scope is difficult to assess with more than 70 regulations. See also comments on recital 28. |
| 45 | Recital 33 | Object | Not all the information on enforcement can be published (some is confidential) |
| 48 | Recital 36 | Object | Information on the type of studies is too detailed. To keep this manageable only high level information is to be included. |
| 48a | Recital 36a | Scrutiny | <p>- See our comments in recital 17. BE is in addition wandering if this should not be placed in the recital where the chemicals in articles and safer alternatives were mentioned for the first time in the text.</p> <p>- Editorial: 2024/1781</p> |
| 50 | Recital 38 | In favor | <p>BE understands the need to stress that the identification of the substances and groups of substances is a key component for a platform having the ambition to bring together data from many regulations. While it is not feasible to use a unique chemical identifier for substances or groups, it is feasible to link to chemical products and groups, as defined in regulation and regulatory processes, i.e. the approach that ECHA is now using in their website, and for this insert that in recital (38). It is also possible to stress in recital 40 that this aspects are included in the formats and vocabularies.</p> <p>BE is thus in favour of an improvement of the EP proposal.</p> |
| 53a | Recital 41a | In favor | Under certain conditions, BE is in favour of the possibility to deliver extra data voluntary. See our comments on recital 21. |
| 54 | Recital 42 | In favor | Under certain conditions, BE is in favour of the possibility to deliver extra data voluntary, including national ones. See our comments on recital 21. |
| 55 | Recital 43 | In favor | BE sees such an aggregated risk indicator as important. A discussion on resources is welcomed. |
| 56 | Recital 44 | In favor | <p>- scrutiny on: BE as some semantic difficulties here, all the more that no definition of an emerging risk, or existing risk is provided. This might need some clarification, and the EP amendment has the merit to point to that need but does not provide a solution. If a risk is existing, it is not emerging? or emerging means existing but not still recognized risks? or risks that might come in the future? There are also other cases: e.g. a known phthalate which had been controlled, but is now on the rising. Investigations are ongoing to determine the source(s). This could be an example of existing risks? Could also be relevant for the circular economy: existing risks that were thought to be under control, but pop up again due to new uses?</p> <p>- In favour of: "risks of chemicals, groups of chemicals, and cumulative exposure to chemicals", it is indeed better to make this explicit, and "groups" is important.</p> <p>- In favour of: justification obligation was foreseen by COREPER in art.19.4, but not mentioned in the recitals, ok thus.</p> |
| 58 | Recital 46 | In favor | Good to be explicit on "groups" |
| 60 | Recital 48 | In favor | <p>- Good to be explicit on "groups"</p> <p>- about samples: this is very important to allow the future regulation to be effective, and was not foreseen until now. Support.</p> <p>- Some practicalities are to be solved: share costs and which is the responsible company (consortiums?). This is implemented by EP in Art.21.3.a new, "the relevant business operator". Which is it?</p> |
| 60a | Recital 48a | In favor | <p>- BE supports the establishment of a permanent EU framework for the biomonitoring and is ready to contribute with BE experience and current programmes. This HBM program should be as ambitious as possible.</p> <p>- However, this needs the consideration and discussion of various aspects: 1) organisation (decision making, priorities, co-decision with MS, mandatory or not for MS); 2) responsibilities (EEA role? cooperation with MS, industry and analytica samples); 3) costs, costs sharing (BE took note of the PARC estimations of the costs); 4) level of ambition (completeness, priorities, substances, cohort sizes, geographical coverage, etc); 5) purpose and link to the exposure index proposed by the EP.</p> |
| 60b | Recital 48b | In favor | in line with MS concerns on resources |
| 60c | Recital 48c | In favor | in line with MS concerns on resources |
| 67 | Article 1(1) | Neutral | |

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| 70a | Article 1(2), point (ba) | Scrutiny | Feasibility of such connections to third countries outside EU? |
| 77 | Article 2, first paragraph, point (2) | Neutral | |
| 85 | Article 2, first paragraph, point (10) | Scrutiny | - scrutiny: resources? See comments on recital 17 - in favour: ok to include "fate" - scrutiny: part of the enforcement data are confidential |
| 89a | Article 2, first paragraph, point (11a) | Neutral | |
| 92a | Article 2, first paragraph, point (14a) | In favor | Indeed a definition of data processor was missing, BE did not checked however the legal validity of the one chosen by the EP |
| 99a | Article 3(2), point (ba) | In favor | see conditions for implementing this in BE comments recital 21 |
| 99b | Article 3(2), point (bb) | In favor | see conditions for implementing this in BE comments recital 21 |
| 104a | Article 3(4a) | In favor | see however needed improvements in BE comments to recital 38 |
| 109a | Article 3(5), point (da) | Scrutiny | See our comments in recital 17 |
| 109b | Article 3(5), point (db) | Scrutiny | See our comments in recital 17 |
| 113 | Article 3(6) | In favor | In favour of EP additions, but keep also COREPER amendments on context data |
| 116 | Article 3(9) | In favor | normal but explicit security measures |
| 118 | Article 3(11) | In favor | the EP amendments goint towards ensuring that a minimal set is delivered in a predictable manner are welcomed |
| 120 | Article 4(1) | Neutral | |
| 121 | Article 4(2) | Neutral | |
| 123 | Article 4(4) | Neutral | |
| 128a | Article 4(5), point (da) | Scrutiny | feasibility? |
| 130 | Article 4(5), point (f) | In favor | reporting and transparency will make cooperation easier |
| 132 | Article 5(1) | In favor | in line with COREPER mandate |
| 133 | Article 5(2) | Object | While the EP amendments are going in the same direction than the COREPER mandate on access by the public, COREPER carefully designed a text on this in article 16 that foresees the necessary mechanisms, and takes into account some very specific legal constrains in certain MS on who decides about making information public. This equilibrium should not be modified. |
| 134 | Article 5(3) | Neutral | |
| 136 | Article 5(5) | In favor | BE si ready to submit HBM data |
| 137 | Article 5(6) | Scrutiny | While BE is in favour of the voluntary submission of national data on env. sustainability, the implications of a compulsory version are not still well evaluated. |
| 138 | Article 5(7) | Neutral | |
| 139 | Article 5(8) | Neutral | |
| 140 | Article 5(9) | In favor | BE understands that the data provided to ECHA by national authorities and agencies are to be provided in good shape. |
| 140a | Article 5(9a) | Scrutiny | This aspects of data controller/processor revealed to be very complex juridically. Any modification here is to be carefully grounded juridically. |
| 140b | Article 5(9b) | Scrutiny | This aspects of data controller/processor revealed to be very complex juridically. Any modification here is to be carefully grounded juridically. |

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| 142 | Article 6(1) | Neutral | |
| 145 | Article 6, 3. | Scrutiny | in line with COREPER mandate, but the word "only" disappeared, a juridic advice is needed, as this seemed to be important to have a finite scope to the purposes. |
| 150 | Article 6, 3., point e | In favor | in line with coreper |
| 150a | Article 6(3a), first subparagraph, point (ea) | In favor | in line with coreper |
| 150b | Article 6(3a), first subparagraph, point (eb) | In favor | however, see comment on recital 43: resources to be discussed. |
| 150c | Article 6(3a), first subparagraph, point (ec) | In favor | in line with coreper |
| 150g | Article 6(4a) | In favor | in line with coreper |
| 150h | Article 6(4b) | Neutral | |
| 150i | Article 6(4c) | Neutral | |
| 150j | Article 6(4d) | Neutral | |
| 150k | Article 6(4e) | Scrutiny | Why is environment mentionned in this new para? |
| 151 | Article 6(5) | Neutral | |
| 151a | Article 6(5a) | In favor | in line with coreper |
| 152 | Article 6(6) | Neutral | |
| 152a | Article 6(6a) | In favor | in line with coreper |
| 152b | Article 6(6b) | In favor | in line with coreper |
| 164a | Article 8(4a) | In favor | however, a carefully defined scope is to be defined (all research activities?) |
| 167a | Article 9(1a) | Scrutiny | Feasibility of such connections to third countries outside EU? |
| 168 | Article 9(2) | Scrutiny | Feasibility of such connections to third countries outside EU? |
| 169 | Article 9(3) | Scrutiny | see our comments in recital 28: objection if this means that the notifications remains confidential. However if there are two separated databases, one for the full notifications, and the other being the common platform where non-confidential things are published, then BE is ok. This seems to be the case in amendment 4b from the EP. Maximal transparency is to be preserved. |
| 170a | Article 9(4a) | In favor | to clarify the criteria to be used for deciding on confidentiality, which is welcomed and was missing in the COM text. |
| 170b | Article 9(4b) | In favor | to clarify the criteria to be used for deciding on confidentiality, which is welcomed and was missing in the COM text. |
| 170c | Article 9(4c) | In favor | in line with coreper |
| 173 | Article 10(1) | Neutral | |
| 174 | Article 10(1a), first subparagraph | In favor | in line with coreper |
| 174h | Article 10(2), point (a) | In favor | in line with coreper |
| 174i | Article 10(2), point (b) | In favor | in line with coreper |
| 174j | Article 10(2), point (c) | In favor | in line with coreper |
| 174k | Article 10(2), point (d) | In favor | in line with coreper |

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| 174l | Article 10(2), point € | In favor | in line with coreper |
| 174m | Article 10(2), point (f) | In favor | in line with coreper |
| 174n | Article 10(2), point (g) | Object | Information on the type of studies is too detailed. To keep this manageable only high level information is to be included. |
| 176 | Article 10(3), point (a) | Neutral | |
| 181a | Article 10(3), point (fa) | Object | Information on the type of studies is too detailed. To keep this manageable only high level information is to be included. |
| 182 | Article 10(4) | Object | communicating to the public on things that are not started and might be later abandoned will create confusion. |
| 182a | Article 10a | Scrutiny | See our comments in recital 17 |
| 182b | Article 10a(1) | Scrutiny | See our comments in recital 17 |
| 182c | Article 10a(2) | Scrutiny | See our comments in recital 17 |
| 182s | Article 10a(3) | Scrutiny | See our comments in recital 17 |
| 182e | Article 10b | Scrutiny | See our comments in recital 17 |
| 182f | Article 10b(1) | Scrutiny | See our comments in recital 17 |
| 182g | Article 10b(2) | Scrutiny | See our comments in recital 17 |
| 182h | Article 10b(3) | Scrutiny | See our comments in recital 17 |
| 182i | Article 10b(4) | Scrutiny | See our comments in recital 17 |
| 185 | Article 11(2) | In favor | allows predictability |
| 191 | Article 13(1) | Neutral | |
| 192 | Article 13(2) | Scrutiny | While BE is in favour of the voluntary submission of national data on env. sustainability, the implications of a compulsory version are not still well evaluated. |
| 193 | Article 13(3) | Scrutiny | While BE is in favour of the voluntary submission of national data on env. sustainability, the implications of a compulsory version are not still well evaluated. |
| 194 | Article 13(4) | Neutral | |
| 205 | Article 14(4) | Object | If the formats are compulsory for national agencies, then art.14(1) and 14(8) should involve MS in the definition of the formats. |
| 215a | Article 14(5), point (ia) | Neutral | |
| 215b | Article 14(5), point (ib) | Neutral | |
| 218 | Article 14(8) | Object | If the formats are compulsory for national agencies, then art.14(1) and 14(8) should involve MS in the definition of the formats. |
| 229 | Article 15(5), point (a) | Neutral | |
| 234 | Article 15(8) | | |
| 234a | Article 15a | In favor | however, see our comments in recital 21 + there should be a mechanism for ECHA to refuse on the basis of the added value and not only on quality. |
| 234b | Article 15a(1) | | |
| 234c | Article 15a(2) | | |
| 234d | Article 15a(3) | | |

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| 234e | Article 15a(4) | | |
| 234f | Article 15a(5) | | |
| 237 | Article 16(1) | Neutral | |
| 238 | Article 16(2) | Object | the wording "second sentence" is to be maintained along with COREPER agreement on art. 5(2) as this was for taking into account the juridic constrains in some MS about who decides what can be made public. |
| 239 | Article 16(3) | Scrutiny | redundant? |
| 241 | Article 17(1) | In favor | only clarification |
| 242 | Article 17(2) | Neutral | |
| 243a | Article 17(3a) | Scrutiny | This proposal might entail a lot of work for the agencies. BE could have flexibility on this if this refers to a generic statement on the rights, about the entire database. If this is per dataset or study, this seems not feasible. |
| 246 | Article 18(1) | In favor | ok to add "fate" |
| 246a | Article 18(1a) | In favor | BE sees such an aggregated risk indicator as important. A discussion on resources is welcomed. |
| 247 | Article 18(2) | In favor | |
| 252 | Article 19(2), first subparagraph, point (b) | In favor | |
| 253 | Article 19(2), first subparagraph, point (c) | In favor | logical to take the relevant info into account |
| 255a | Article 19(2), first subparagraph, point (ea) | Neutral | |
| 255b | Article 19(2), first subparagraph, point (eb) | In favor | See our comment on recital 21 |
| 255c | Article 19(2), first subparagraph, point (ec) | In favor | |
| 257 | Article 19(3) | In favor | |
| 258 | Article 19(4) | Scrutiny | BE is in favour if the EP amendment, but fears that sometimes 6 months is not enough. Thus BE suggests the following compromise text: Within six months of the presentation of the report, the Authorities shall undertake regulatory, policy or enforcement actions accordingly, or provide either an operational action plan , or a justification if they decide not to proceed with any action related to any of the early warning signals identified by the report, including an assessment of the possible consequences of non-action. |
| 258a | Article 19(4a) | In favor | |
| 259 | Article 19(5) | Neutral | |
| 259a | Article 19(5a) | Neutral | |
| 261 | Article 20(1) | In favor | |
| 262 | Article 20(2) | In favor | |
| 267 | Article 20(4), point (c) | Neutral | |
| 270 | Article 21(1) | In favor | |
| 270a | Article 21(1), point (a) | Scrutiny | depending the structure of the final text, mantaining reference to annex I , part I is necessary. |
| 270b | Article 21(1), point (b) | In favor | |
| 270c | Article 21(1), point (c) | In favor | |
| 271 | Article 21(2) | In favor | BE is in favour, but not a blocking point |

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| 272 | Article 21(3) | Scrutiny | BE would like the wording " validated non-animal testing methods" to be added. |
| 272a | Article 21(3a) | In favor | However, "the relevant business operator". Which is it? |
| 274 | Article 21(5) | Scrutiny | neutral but maintain MS consultation as in coreper mandate |
| 275a | Article 21(6a) | In favor | BE ok with a EU HBM permanent framework |
| 275b | Article 21(6b) | In favor | see comments on recital 48a for the practicabilities to be defined |
| 275c | Article 21(6c) | In favor | - see our comments in recital 48a - about the "organisation of any human biomonitoring study", since there are national or regional monitorings that might not be relevant for the purposes, the wording should say that it refers to monitoring initiated by ECHA/EFSA - moreover, we see as important that EEA is involved at the same level than ECHA/EFSA |
| 279 | Article 22(1) | Object | For enforcement, a clear notification time is needed. Moreover, COREPER provided for a mechanism of information from the business operators towards the laboratories and testing facilities that ensures also who is responsible in case of enforcement. This should be maintained. |
| 279a | Article 22(-1), second subparagraph | Neutral | |
| 279b | Article 22(-1), second subparagraph, point (a) | Neutral | |
| 279c | Article 22(-1), second subparagraph, point (b) | Scrutiny | - Scrutiny on: The sentences introduced by the EP that says "...that are not commissioned to support an application..." etc seems either superfluous with the original wording ("they commission for compliance..") or narrowing the scope of what is to be notified in an undetermined manner. BE would like to keep the scope for notifications as in the COM proposal. A clarification on the scope that the EP wants is welcomed. |
| 279d | Article 22(-1), third subparagraph | Object | this is not enforceable |
| 280 | Article 22(2) | Neutral | |
| 281 | Article 22(3) | Neutral | |
| 282 | Article 22(4) | Neutral | |
| 284 | Article 22(6) | Object | 18 months might be short to establish and enforce at national level. |
| 285 | Article 22(7) | Neutral | |
| 286 | Chapter VIII | In favor | is there an error in the 3 columns table? The wording "and committee procedure" was in the coreper mandate |
| 289 | Article 23(2) | Scrutiny | BE would like that the restructuring of the text as in the COREPER is maintained (annex II was modified) |
| 297a | Article 24a | In favor | identical to coreper mandate |
| 297b | Article 24a(1) | In favor | identical to coreper mandate |
| 297c | Article 24a(2) | In favor | identical to coreper mandate |
| 299 | Article 25 | Object | enforcement is in art.26 |
| 303a | Article 26a | | |
| 303b | Article 26a, first paragraph | Scrutiny | 18 months might be too soon |
| 303c | Article 26a, second paragraph | Object | Compared to the scope of the review in the COREPER mandate, the EP is not mentioning the "chemicals data on substances other than active substances" in recital 7 nor art.26a. This should be included. |
| 303d | Article 26a, third paragraph | In favor | assessing the feasibility is certainly welcomed |
| 303e | Article 26a, fourth paragraph | Scrutiny | BE does not see the scope of this |
| 303f | Article 26a, fifth paragraph | Neutral | |

| MS | Position |
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| Austria | - |
| Belgium | In favor |
| Bulgaria | Object |
| Croatia | Neutral |
| Republic of Cyprus | Scrutiny |
| Czech Republic | |
| Denmark | |
| Estonia | |
| Finland | |
| France | |
| Germany | |
| Greece | |
| Hungary | |
| Ireland | |
| Italy | |
| Latvia | |
| Lithuania | |
| Luxembourg | |
| Malta | |
| Netherlands | |
| Poland | |
| Portugal | |
| Romania | |
| Slovakia | |
| Slovenia | |
| Spain | |
| Sweden | |
| Select delegation | |

