Concawe General comments

Concawe members are committed to producing high quality registration dossiers that are regularly updated. At the same time, workable solutions need to be found to handle our complex substances. The usual framework and practices for mono- and multiconstituent substances cannot always be directly applied to petroleum substances which are UVCBs under REACH.

It is apparent after nearly 10 years of dialogue that common understanding has not been achieved between the Agency and Registrants around expectations for some endpoints and acceptability of adaptations. However it is not clear if additional clarity in the text of the Annexes will resolve this in many cases. Introducing additional testing requirements and/or more stringency in the REACH Annexes will only further erode the expert judgement of the Registrant(s) (i.e. those with the greatest familiarity of the chemistry, intrinsic properties, and risks); and reduce the ability to avoid animal testing and ensure cost effectiveness in instances when risk management measures and operational conditions which are necessary to control a well-characterized risk are also sufficient to control other potential risks, which will therefore not need to be characterized precisely.

The information provided at this stage for several of the amendments (even for the priority 1 amendments) is not sufficient for industry to provide a satisfactory review of potential changes to the Annexes of REACH and have left us hypothesizing what exactly is suggested.

Example: The amendment suggested for Annex VIII. Section 9.3.1 (Clarify in which cases the Kow is a reliable predictor/when it can be used) – it is unclear whether the clarification is an alignment with the guidance document R71, and specific chemistries will be listed, or whether the definition for “low” will be expanded with a value. Better input by industry can be provided, if the information had been more specific.

Example: Some points where OECD methods are pointed out but most of points do not give us any information on which way some parameters should be developed.

A justification should be provided as to why such amendments are required – what is the issue and is not captured by the text currently in the annex. Example: The amendment suggested for Section 1.5 “Clarify requirements for Read-across adaptations”. The requirements for substance grouping are already captured in the annex. What exactly needs to be clarified, and what are the concerns from the legislator.

It is difficult to assess the consequences of the points that have been listed for modification. More discussion between experts from involved stakeholders on the details of the modifications is needed, after which, careful consideration of the impacts will be necessary before the actual modifications are incorporated into the legal text. We therefore welcome the creation of the CARACAL subgroup that will work on these amendments and volunteer two experts (human health and ecotox) to participate on behalf of Concawe.

New standards in the Annexes should apply only to new dossiers. Dossiers with data which have been generated according to previous methods should not be considered as non-compliant and tests should not have to be repeated.
We are concerned that requesting more data, data according to new (OECD) standard test methods and changes in the rules could lead to dossiers previously considered as complete, could be considered non-compliant. A waiver should be included in case data have been generated in the past according to standards that were applicable at that time.

Special attention should be given to the adaptation of standard information requirements for complex substances such as UVCBs. The practices for mono- or multiconstituent substances for e.g. read-across, weight of evidence, PBT assessment are often not applicable to UVCBs. Modifications to the Annexes should consider this, to avoid disproportionate testing being required for UVCBs as compared to mono- or multiconstituent substances. Modifications to Annex XI should ensure that read-across is allowed for UVCBs. This will allow for a considerable reduction in animal tests to be carried out as well as a faster filling of data gaps.

Some points in the current versions of the annexes that need clarification are not listed in the Commission note. Some examples (but not exhaustive) are:

Example: Improvement of consistency in the text is needed, e.g. IX.9.1 – column 2

Example: Some terms need explanation included in REACH to make it easier to apply REACH, e.g. IX.9.2.1.2 – easy biodegradable is explained in the CLP Regulation

Therefore, other parts of the Annexes VI-XI than the ones listed in the Commission note should be assessed and amended if necessary.

Concawe comments human health			
Annex	**Issue**	**Priority**	**Comment**
Annex VI	Clarify substance identity issues.	1	We need more information on what needs to be clarified to ensure that the modifications are still workable for UVCBs in particular
Annex VII Section 8.1 and 8.2	Clarify registrants' obligation if the in vitro studies under points 8.1.1 and 8.1.2 in Annex VII are not applicable to the substance, or if the results of these studies are not adequate for classification and risk assessment.	1	Related to the first intent of this change (i.e. clarify registrants obligation if the tests are not applicable to the substance), any modifications should not negate the ability to rely on the Annex XI adaptation 'Testing is Technically Not Possible', (i.e. cannot conduct study based on the properties of the substance). It should be acknowledged that relevant in-vitro/ex-vivo OECD TG meant to answer specific questions related to potential hazards indicated in Section 8.1 and 8.2 are validated for certain chemical domains. Testing beyond the bounds of these chemical domains compromises the validity and integrity of the output. Alternatively, any changes should not limit the appropriate use of other scientifically validated non-OECD TG methods or non-testing methods (such as QSAR, read-across) that do offer information on chemicals outside of these assay applicability domains and which could inform a weight of evidence approach.
Annex VII Section 8.3	Ensure consistency with the latest developments under OECD test guidelines.	1	Any changes to align the language within the REACH Annexes and OECD developments should continue to allow for expert judgment of the registrants (i.e. those with the greatest familiarity of the chemistry, and intrinsic properties) in determining a hazard classification decision.
Annex VII and VIII Section 8.4	Clarify mutagenicity testing strategy for all registrants regardless of their tonnage. Specify whether/what further studies must be done in case in vitro test is not negative, to resolve the mutagenicity concern.	2	In general the type of in vivo follow-up assays should consider the nature of the substance, uses and relevant routes of exposure. While premature to comment at this time due to lack of detail, it is problematic to specify specific tests generically to all cases, particularly for in vivo tests. The necessity of the information for all animal tests should be carefully considered.
Annex VII and VIII Section 8.4	Clarify mutagenicity testing strategy for all registrants regardless of their tonnage. Specify whether/what further studies must be done in case in vitro test is not negative, to resolve the mutagenicity concern.	2	It is not clear what needs to be clarified "regardless of the tonnage band", the requirements on mutagenicity tests should be different for Annex VII and Annex VIII dossiers?
Annex VIII Section 8.6.1	List DNT and DIT tests under "specific toxicological studies" that can be requested under Column 2 of Section 8.6.1. of Annex VIII (last indent)	1	The necessity for this modification is not clear at this time. The text in Annex VIII 8.6.1 already specifies the opportunity for the Registrant to propose or for the Agency to require additional, i.e. "indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects"
Annex VIII Section 8.7.1	Delete the adaptation based on availability of PNDT study (OECD TG 414)..	1	Introducing this change is not without impact. Clarity on a 'grandfathering' statute should be provided as well as a justification for why the Agency considers such a change is warranted generically for all substances.
Annex IX and X Section 8.4	Clarify the conditions when to perform an in vivo somatic cell genotoxicity study as well as a germ cell study.	1	It may be premature to comment before seeing the details. However testing all substances by the same testing paradigm is not clearly considering the need to avoid animal testing and to ensure cost effectiveness. The nature of the substance, its uses, routes of exposure, and existing RMMs should be considered when establishing the necessity for any additional animal testing.
Annex VIII Section 8.7.1	In case of concern for sexual function and fertility, clarify what tests shall be performed. This could also be discussed as part of updating standard requirements for endocrine disruptors.	2	This seems unwarranted, unless of course appropriate RMMs are not in place. If there is a concern it is very likely the risk can be well managed without the need for generating additional data. Care should be taken to avoid confusing hazard identification with risk management. If proposed, it should be specified what constitutes a 'concern'.

Concawe comments human health			
Annex	**Issue**	**Priority**	**Comment**
Annex IX and X Section 8.7.2	Modify the SIR to ensure information generated is sufficient for classification and RA: Reconsider number of species in the PNDT requested at Annex IX. This could also be discussed as part of updating standard requirements for endocrine disruptors. This may create additional testing requirements which should be assessed.	2	In favour of reconsidering the need to test 2 species at Annex IX and Annex X. However, the scope should be clarified, or what is meant by, 'sufficient for classification'. Classification is meant to address normal conditions of use. Therefore data do not necessarily need to be generated by the seemingly most conservative route of exposure and at excessively high dose limits to be sufficient for classification.
Annex IX and X Section 8.7.3	Modify the SIR to ensure information generated is sufficient for classification and RA. This could also be discussed as part of updating standard requirements for endocrine disruptors. This may create additional testing requirements which should be assessed.	2	As above, the scope should be clarified, or what is meant by, 'sufficient for classification'. Classification is meant to address normal conditions of use. Therefore data do not necessarily need to be generated by the seemingly most conservative route of exposure and at excessively high dose limits to be sufficient for classification. Any proposals to require additional testing must be carefully considered particularly with respect to their ability to inform and improve risk assessment and risk management measures.

Concawe comments environmental safety			
Annex	**Issue**	**Priority**	**Comment**
Annex VII Section 9.1.1	Clarify conditions for performing the long-term tests for poorly water-soluble (organic) substances; i.e. long-term testing must be conducted when a substance poorly water-soluble.	1	The change being proposed is from “shall be considered” to “must be conducted”. We do not agree that this change should take place, however would recommend “must be considered” - additional lines of evidence may be available, since this endpoint may be covered by different types of information, and other issues should drive a mandatory test from a higher tonnage band, rather than solely the water solubility.
Annex VIII Section 9.1.3	Clarify conditions for performing the long-term study	1	The conditions that require clarification have not been given, therefore it is not possible to comment on this. However, we think that additional factors should be taken into consideration before requiring long term fish studies – such test should be the last tier of testing required due to animal welfare reasons. This is not in line with the general principles of REACH. According to the amendment suggested for Annex VII- Section 9.1.1, long term toxicity study on Daphnia will be available for substances highlighted here. If short term toxicity data on fish is available, and there is no indication that fish have a higher sensitivity than invertebrates, then this should be sufficient in place of the long-term fish test. Additional information could also be supplied through QSARs. Nevertheless, it is unclear what “clarifying conditions” are planned.
Annex VIII Section 9.3.1	Column 2 allows waiving the Koc if a low potential for adsorption can be expected. Low Kow is given as an example of forecasting this. Clarify in which cases the Kow is a reliable predictor/ when it can be used.	1	It is unclear whether the recommendation provided is for alignment with the REACH guidance, and specific chemistries will be listed, or whether a cut-off for “low octanol water partition coefficient” will be provided. More information is on the recommended amendment is needed.
Annex IX, Section 9.1.6.2, 9.1.6.3	Clarify what information needs to be provided. Delete points 9.1.6.2 and 9.1.6.3 as the tests described are outdated. OECD TG 212 is advised against due to animal welfare reasons; the OECD 215 can be only accepted if growth is a dominant effect.	1	It is not clear what needs to be clarified "regardless of the tonnage band", the requirements on mutagenicity tests should be different for Annex VII and Annex VIII dossiers?
Annex IX, Section 9.3.2	Clarify in which cases log Kow is not applicable as screening criterion for substances for which the bioaccumulation is not driven by lipophilicity.	2	It is unclear whether the recommendation provided is an alignment with REACH guidance, and specific chemistries will be listed, or whether the cut-off for “log Kow<3” will be adjusted. Since this has been assigned priority 2, it would seem that the “clarification” required is not merely an alignment, and therefore more information is required on which clarification is needed
Annex IX & X, Section 9.2	Clarify wording of column 2 which is unclear and should be modified to put the burden of proof on the registrant.	2	It is not indicated which aspect of column 2 “is unclear” and hence requires clarification. It is also unclear why the text “should be modified to put the burden of proof on the registrant”. It is our understanding that the burden of proof is already on the registrant. However, we agree that clarity is needed to allow registrant to waive testing based on the output of the CSA – this is currently unclear. More information is requested on the recommended amendment.
Annex X, Section 9.2	Degradation tests: clarify that the intention is to cover abiotic and biotic degradation products.	1	It is unclear what the recommendation is.
Annex IX Section 9.1, 9.1.5, 9.1.6	Clarify wording of column 2 which is unclear and should be modified to put the burden of proof on the registrant.	2	It is not indicated which aspect of column 2 “is unclear” and hence requires clarification. It is also unclear why the text “should be modified to put the burden of proof on the registrant”. It is our understanding that the burden of proof is already on the registrant. However, we agree that clarity is needed to allow registrant to waive testing based on the output of the CSA – this is currently unclear. More information is requested on the recommended amendment.
Annex VIII Section 9.2	Clarify the conditions to request or to waive further degradation testing in column 2, i.e. that Section 2.1 of Annex XIII Section 2.1 applies.	2	It is unclear what clarifications will be recommended. More information is required. However it would seem appropriate that this also be applied to Annex VII, since Section 2.1 of Annex XIII refers to both Annex VII and Annex VIII
Annex IX Section 9.3	Clarify the link between Section 4 (PBT assessment) of Annex I and Section 2.1. of Annex XIII. Specify what needs to be done if according to Section 2.1 of Annex XIII screening criteria are met.	2	It is unclear what clarifications will be recommended. More information is required. . However it would seem appropriate that this also be applied to Annex X, since Section 2.1 of Annex XIII refers to both Annex IX and Annex X

Concawe comments Annex XI			
Annex	**Issue**	**Priority**	**Comment**
Annex XI Section 1.1.2	Clarify what is meant by 'existing data.'	1	Is it unclear to us what the issue is around the meaning of "existing data". Data either exists or it does not. This is an example where more information should be provided as to why "clarification" is needed in the Annex.
Annex XI Section 3.2.(a) (ii)	Delete the footnote associated with this section and insert the content of the footnote into the legal text for s.3.2. (a)(ii).	1	Moving the footnote into the legal text is inconsequential. It would be more meaningful to review how the footnote prevents the use of exposure-based adaptations by preventing registrants from using lower tier studies such as the 28d and reproductive screen as the basis of deriving a DNEL for a risk-based approach to waiving. Currently, for a substance registered at 10-100t, irrespective of the nature of exposure and use, a DNEL generated using a 28-day study or a Reproductive screening study is considered sufficient to support a risk assessment – even for a very sensitive use. It is therefore not clear why for an exposure-based adaptation in the registration tonnage band > 100 t, a DNEL derived using a 28-day or reproductive screening study is considered to be insufficient. A DNEL derived from a 28-day study with full investigation in combination with the article 3.2.(a) (iii) « …well below » an exposure based waiving is scientifically justified. However, vagueness of terms (e.g. no significant exposure, and specifically exposure well below the DNEL/PNEC) further limit the use of this adaptation as a mechanism to avoid unnecessary animal testing to all but the most extreme cases. As such, rather than simply move the text from a footnote to the main body of the text we recommend opening a review of exposure-based adaptations set out in Annex XI section 3.2 and consider updating the text to make these adaptations clear, workable and a more meaningful to avoid unnecessary animal testing. Concawe and ECETOC have been in parallel reviewing technical challenges of Exposure Based Adaptations under REACH. The output of these reviews could feed into a discussion of a revision to the legal text. Further information on these projects can be provided upon request (please contact Marilena Trantallidi - marilena.trantallidi@concawe.eu).
Annex XI Section 1.2	Clarify weight of evidence (WoE) requirement as to the nature of documentation and justification required.	2	Given the nature of WoE as expert judgement, we agree that clarity on justification is required. However at this point, comments are limited since it is unclear on what document and justification may be recommended as part of Annex XI Section 1.2. Would prefer to improve he ECHA guidance document rather than impose legislative mandates. WoE is case specific, the nature and extent of documentation will vary based on the case. Would equally want MS and the Agency to follow any clarifications provided here for when they perform WoE as part of substance evaluation.
Annex XI Section 1.5	Clarify requirements for Read-across adaptations.	2	The requirements for substance grouping are already captured in the annex. However, it should be highlighted that RA is currently never accepted, and so clarification on RA requirements are needed.