20 October 2021

Questions and answers from the Compliance session at ECHA Safer Chemicals Conference, 6 October 2021

Question	Response
Here are so many REACH chemicals with no data available against several serious GHS Hazards. Does this mean no market for these chemicals?	When technical completeness of a registration is fulfilled, market access is granted upon registration. The compliance with production-volume dependent information requirements is checked later.
Will Grouping of Substances be used to fill the Data Lacking serious GHS Hazards in the ECHA REACH Registered Substances Database?	If an information requirement is adapted, then it is the registrants obligation to provide ensure the validity of the adaptation; e.g. according to REACH Annex XI, 1.5 (grouping and read-across).
If Technical Completeness includes Data Lacking against serious GHS Hazards how is it that this chemical is able to continue to be used as though these endpoints are Not GHS Hazardous?	When the annual production volume is low, then this hazard endpoint could be not required as part of the standard information requirements.
I am intrigued by the obligation to use "the most severe test result" for classification. Could you please clarify? How does this match with a weight-of-evidence approach for data-rich substances?	According to the CLP regulation (Title II) and its criteria, registrants have the obligation to self-classify, reflecting the intrinsic properties of the Substance (Article 5). Registrants must rely on all "relevant information" and ensure the strictest classification resulting of their assessment of the results, including if the source is WoE information
SEv - who will do the tests? Do you mean which registrant will take the lead or which test lab will do the tests?	Art 50(3) requires the registrants to agree who will perform the requested test (s) and inform ECHA- we need to know the company name not the test lab
What happens to non-compliant online sales? consumers become importers then	I'm afraid we are only able to answer questions related to this session. Please use our contact form to send your question: echa.europa.eu/contact
Is it possible to specify	Your question requires some further consultation and Im afraid cannot be answered during this session. Please

"zero tolerance"?	send us your question using our contact form: echa.europa.eu/contact
Is there any General BRcode Manual for iuclid validation assistant?	This question is related to technical completeness check. Please use our contact form to send your question: echa.europa.eu/contact
Under which conditions can a registration (number) be withdrawn at the moment? Are there already concrete proposals or considerations for stipulations in a review of the REACH regulation?	It could be as an example where there is a ceased of manufacture.
I'm wondering, that ECHA still states testing on (vertebrate) animal only as last resort and the test requests (especially in the extended Generation studies) increase?	REACH sets out the information requirements to be fulfilled. It also requires that alternative methods are considered and applied were possible. If an alternative method cannot be applied then the animal test may still be necessary. Experience suggests that the alternative methods applied by registrants are not compliant. That is one reason we wish to support the correct use of read across
What is ECHA doing to ensure that vertebrate animal testing are really done only as last resort?	This will be answered in parallel to similar questions concerning animal testing as last resort. Registrants must provide consideration of alt methods for every Testing Proposal. We analysed were TPs might have been expected and the MS enforcement authorities were informed. We raised awareness of these issues for animal testing with the MSCA and the national enforcement authorities who inspect the CROs.
Is the dossier improvement programme aimed at the lead registrant or the co-registrants?	Usually the lead registrants coordinate the work for the joint submission. Decisions within the JS to generate further information should of course be agreed together in the JS.
In case a substance is registered as a transported isolated intermediate, can a downstream user dilute it and place the product in the market making sure the downstream users implement SCC?	Placing on the market requires a (full) registration, according to REACH Article 10. If the downstream users can demonstrate SCC, they may be able to fulfil REACH Annex XI Section 3.
Will the list numbers have official status? ECHA website states "	Your question requires some further consultation and I'm afraid cannot be answered during this session. Please send us your question using our contact form:

should not be used in SDSs, or for any similar documents." However, companies use the list numbers in the same way as EINECS numbers.	echa.europa.eu/contact The list numbers were introduced at the entry of REACH when substances registered were not identifiable by any EC numbers. There was a practical need, and they cannot be considered as 'official'. ECHA has no insight on whether the list numbers will become official, as this is the responsibility of the European Commission.
We've so far heard a lot about support and "carrots" provided by ECHA. What are the "sticks" that ECHA applies or plans to start applying/implementing in order to ensure compliance?	Your question requires some further consultation and I'm afraid cannot be answered during this session. Please send us your question using our contact form: echa.europa.eu/contact
what does "Ceased registration number" mean? Is a substance under ceased registration number compliant with Reach or not?	The information "ceased registration number" gives no information to the compliance of a dossier.
What happens to non-compliant chemicals bought on line and accessing the EU market? who is responsible for compliance? and how can we be sure they comply?	If an EU-based company buys chemicals from outside EU, they are the importer and obliged to comply with REACH. If an EU-consumer buys from outside the EU and the exporting company does not comply with REACH, it is a case for customs enforcement.
The proactive dossier update is very useful but it's quite difficult for LRs to have all registrants agree to cooperate (especially ORs for foreign manufacturers): how to change this?	This goes beyond ECHA's remit, and falls under the agreements within the joint submission, including the data and cost sharing agreements.
You mentioned a "reasonable group size" is 5-15 substances. When it comes to risk management measures (e.g. REACH restrictions) we see a trend towards much larger groups. What is ECHA's view?	This programme is meant to help companies to reach compliance and for that work 5-15 is most efficient. EU RRM are a different process with different criteria and approach.
I wish that the high quality	This is beyond the scope of this session and ECHAs

data generated by industry (and in some cases under the revision of ECHA) would be acknowledged by other regulatory bodies worldwide. Can we expect here an improvement?	"powers". However, we have seen that other regions have used certain principles and parts of the regulatory toolbox to improve their legislations.
If new substances are placed on the market or 'discovered' in a company's portfolio after designating a category, can the category be amended ?	The registrant responsible on the category is also responsible on all the changes linked on it.
We agree on reduced animal experimentation, but there is little validated in vitro alternatives, is ECHA considering new approaches coming out from EU initiatives? these are not validated	We have welcomed and supported the introduction of alternative methods to replace animal methods in the REACH legal text, e.g. from 2015-2017 for irritation or sensitisation testing. And we follow the ongoing developments for alternative methods for other endpoints. ECHA is following closely the developments in the New Approach Methodologies For higher endpoints which are even more complex, these alternative approaches may not fully substitute existing test-guidelines, but instead be useful to support adaptations through e.g. grouping and read-across, or weight of evidence. To fulfil requirements at tonnages 1-10 and 10-100 tpa, some in vitro guidelines are already the standard requirements. For the higher tonnage bands, and under compliance check, ECHA checks that the information provided fulfills the Article13(3) and Annex XI in combination.
Can the hazard of persistency as such be used as argument for grouping of certain classes of chemicals like with PFAS?	Persistence can be a similar property as the basis for grouping - you will always additional supporting information to support your hypothesis.
Can you comment on the collaborative projects between ECHA and the OECD to promote accepted Non-Animal Methods (ie TGs published) and to bring these to Regulatory acceptability (eg OECD	We have welcomed and supported the introduction of alternative methods to replace animal methods in the REACH legal text, e.g. from 2015-2017 for irritation or sensitisation testing. Please, see also question (BS-M) and discussion below on in vitro alternatives

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319, OECD 249)	
As it was stated, that the Read acorss justifications are often to weak, could echa support with more details in their RA document for example what data is not weak?	1) Which data best supports a hypothesis is often case-specific. 2) However, when results from a lower-tier study (e.g. 28day) show similar type and potency of effects as the (28d/90day) data from the source substance, this may be a robust indication that 3) properties of the target substance can be predicted from the source substance.
Animal testing as a last resort. In the final CCH no time buffer is given to consider any alternatives. Is there any plan to promote and support the complinace of this perspective for CCH cases?	Decisions often reject an adaptation, and therefore ECHA must request a standard test for legal certainty (REGs must know how to secure compliance, hence a std test). These tests have std timelines. Any adaptations should be carefully developed before a CCH process is launched.
On the question of strictest test: what if there is reason to believe that the strictest test was somehow wrong?	Usually, studies that are conforming to GLP and validated test-guidelines are the basis for classification. If you consider that another study should have been used as basis for the classification, you may submit a CLH proposal with scientific justification to change the classification.
I've asked about ceased registration number. If "ceased" has nothing to do with compliance what this status "ceased" does exactly mean. Thank you for the previous answer but still unclear	A common reason for ceased registration numbers is a cease of manufacture by the registrant.
Under which conditions can a registration (number) be withdrawn at the moment? Are there already concrete proposals or considerations for stipulations in a review of the REACH regulation?	A registration number can be no longer valid when ECHA discovers that the registration was granted based on erroneous or incomplete information, or when the registrant notifies a cease of manufacture after the receipt of a draft decision (according to Article 50). In both cases the registration cannot be used to cover the manufacture and import of the substance.