



Submission in response to HSE statement on the use of independent scientific knowledge and advice (ISA) and transparency – March 2021

Q3. Do you think the ISA statement provides a clear explanation of how the Agency will ensure a high degree of transparency when carrying out its functions under UK REACH?

Q4. Explain why you don't think the ISA statement provides a clear explanation on how the Agency will ensure a high degree of transparency?

1. The level of transparency provided by this statement should be measured against the EU system it replaces and the European Chemical Agency's (ECHA's) decision-making structures and processes. In our view, the Independent Scientific Advice statement does not provide a comparable or equivalent level of transparency or independent oversight as this system. As currently constituted, the GB structure will result in a more closed and less transparent system than ECHA's, that could be more susceptible to industry capture and lobbying, as well as regulatory inaction.
2. Firstly, the degree of transparency of these arrangements has been largely constrained from the start by the UK REACH Regulation. This stripped away the open structure of committees of experts from EU Member States (particularly the Committees for Risk Assessment and for Socio-Economic Analysis) and replaced them with a duty to seek independent scientific advice. The committee structure within ECHA helps to ensure its decisions can be challenged and the best information is available for its discussions, helping to avoid mistakes and to ensure that decisions are made more independently and transparently. It also helps to resolve potential divergences of opinions on draft decisions, as well as to ensure that the decision-making process and scientific basis underlying it have credibility with all stakeholders and the public.
3. It is very difficult, if not impossible, to provide an equivalent level of transparency outside this committee structure. The efforts by officials to provide oversight mechanisms within this limited legislative framework is therefore very welcome, such as the use of 'challenge panels.' We set out below much-needed further changes that could improve the processes for challenging opinions and allow for better oversight by stakeholders.
4. It must be noted, however, that a statement cannot replace the legal certainty and standing of a clear legislative framework, such as that provided by the EU REACH Regulation which determines ECHA's processes. This gives stakeholders less confidence in the permanence and reliability of oversight mechanisms, which cannot be trusted in the same way as arrangements determined by legislation, and we would ask for a strengthening of the language around these mechanisms.
5. The statement is still slightly unclear how decisions previously made by ECHA committees will now be made by HSE staff and members of the new REACH Independent Scientific Expert Pool (RISEP). Our understanding is that members of RISEP might be used in case teams that will draft HSE opinions, but that these teams will primarily be drawn from HSE

staff. In addition, challenge panels that review HSE's opinions will be drawn from RISEP and Agency staff who were not part of the Case Team, as well as other experts from relevant Government scientific agencies. It seems that draft opinions written primarily by HSE staff will be scrutinised by 'challenge panels' that will provide the recommendations and endorsement of the draft opinions through seeking consensus between the experts, i.e. on authorisations and restrictions etc.

6. Stakeholder organisations should be able to fully participate in challenge panels, i.e. ask questions, raise points etc. Currently, stakeholder organisations can observe, with a limited opportunity for some technical questions and statements. Some of the wording around even this limited role for stakeholders in this process is too weak, for example: "during the opinion development a stakeholder consultation meeting **may** also be held for gathering information, as well as enabling challenge and scrutiny by stakeholders of the restriction proposal evidence". The structure should ensure that challenge panels always include stakeholders and an even balance between industry and NGOs; this should be a permanent feature and not something which can vary from case to case. This would follow equivalent processes within ECHA, whereby the committees for Risk Assessment and for Socio-economic Analysis allow for stakeholders from industry, NGOs and trade unions to help inform decisions, only without voting rights. It would also better align with commitments made by the Government [in response to a 2019 legal challenge](#) of its post-Brexit framework not to "undermine the opportunities for public participation and stakeholder engagement in the REACH system in place after exit day."¹ The processes should ensure that opinions can be independently challenged; no amount of efforts to "manage group think and/or undue influence of particular experts with strong views" will address this, unless stakeholders are embedded in this process.
7. It is right that the agendas and minutes of challenge panel meetings will be published on the Agency website. We ask for clarity that agendas and draft opinions will be published in full in adequate time ahead of these meetings, and that the recommendations of panels will also be published in full. It is necessary that all relevant paperwork is published in the same way it is within ECHA processes, including all the comments received from public consultations and the response to them. Under Article 88(1) REACH, membership of ECHA's Committees must be made public, including professional qualifications, and there should be an equivalent requirement for members of the challenge panels. While members of the RISEP will rightly be asked to make a declaration of financial interests, this declaration should be required of all those who develop opinions for the Agency and this register should also be made public. There should also be a meaningful role for devolved administrations in these opinion forming processes. The exclusion of DAs from these processes (other than the ability to get clarification on issues) in order to set a clear demarcation between the "opinion formation and decision-making functions" is not justified or explained. This is different from ECHA processes, where each member state contributes to the 'opinion-forming process' and it could create difficulties for reaching common standards, if the opinion decides against – for example – a restriction that was adopted by the EU, leaving a DA with little ability to review that decision.
8. We understand that accredited stakeholder organisations will also have the ability to invite an academic/NGO expert into a discussion, if their expertise is relevant to the topic and agreed by the secretariat beforehand. This would help to ensure that discussions are informed and enhanced by experts in the area under discussion, and we ask that this provision is also included in the ISA statement.

¹ <https://chemtrust.org/wp-content/uploads/20190702-Letter-to-Leigh-Day-PAP-full-response.pdf>

Q1. Do you think the ISA statement provides a clear explanation on how ISA will be used by the Agency?

Q2. Why don't you think the statement is clear regarding how ISA will be used by the Agency?

Q5. What else should be included in the statement in terms of ISA?

10. A vital issue in relation to how ISA will be used by the Agency relates to HSE's capacity to consider EU controls on hazardous chemicals at the same pace as they are getting implemented at EU level. If the UK does not keep step with and closely align with EU controls on chemicals, this will result in chemical dumping of products that do not meet EU regulations and in UK consumers and our environment receiving less protection than in the EU.
11. There is not even currently a process for systematically considering EU decisions at pace. This is a huge oversight as it's an issue of considerable concern to NGOs and indeed to industry, which wants to avoid the added cost and complexity of divergence on businesses which export to the EU. It also doesn't square with reassurances given by the Government to Parliamentarians, which suggest the UK will not diverge significantly. For example, the Government has said "it would not be appropriate to *automatically* implement future EU decisions under UK REACH" in response to the Secondary Legislation Scrutiny Committee,² and it has also said it is working hard to prevent chemical dumping from happening.³ A lack of capacity in the British system could see it fall rapidly behind EU controls. For example, it is likely that GB REACH will have to regulate a similar number of substances on an [anticipated annual budget of £13m](#) with [around 40 staff in HSE](#) – in comparison to €100 million and 400 ECHA staff who work specifically on EU REACH.
12. The Regulator should therefore not waste its limited capacity developing opinions in areas where ECHA has already adopted an opinion. It should therefore be made explicit that the Agency does not need to commission ISA if it is already in existence and that specifically includes - in the words of the explanatory memorandum to the REACH Regulation – "where ECHA has already published a robust opinion on a substance."
13. The clarification that independent scientific advice will not be needed where an EU restriction opinion can be used (and is assessed as applicable to GB) is very welcome. This should also be the case for substance evaluation, identification of substances of very high concern (SVHCs) and proposals to add SVHCs to the authorisation list. Indeed, Chemical Watch recently found that HSE's Rolling Action Plan, by which substances will be screened over a period of three years for the SVHC Candidate List, will not undertake any evaluations in 2021 or 2022.⁴ If this is indeed the case, presumably because industry has been given extended deadlines for submitting full chemical safety dossiers staged over a period of 6 years from October, it would be inconceivable for the UK not to automatically adopt the ECHA decision – otherwise the UK will fall behind EU controls very comprehensively and very quickly.
14. It is disappointing that a process for considering EU controls at pace was not been set out in legislation, in the same way as in the GB CLP legislation, which transposes the EC Regulation on classification, labelling and packaging of substances. According to this process, HSE is under a duty to consider EU opinions on harmonised classification and labelling requirements published by the Committee for Risk Assessment and within 6

² <https://committees.parliament.uk/publications/3557/documents/34373/default/>

³ <https://hansard.parliament.uk/Lords/2020-09-17/debates/09B9BD20-431D-497A-8338-B3DF9394C125/REACHAndCE#contribution-3FFE69AD-C1BC-420A-8C8A-C391F4AFACC2>

⁴ <https://chemicalwatch.com/223738/uk-hse-will-not-use-independent-experts-routinely-under-clp>

months publish its own opinion, then within 12 months of publishing its own opinion, make a recommendation to Ministers. We ask that Defra introduces legislative changes to embed such processes within GB REACH, to meet consumer expectations of getting as high protection as the EU and to minimise trade barriers with the EU.