Platform for NGO-ECHA Dialogue
Meeting note

Time: 09 September 2022, 10:30–12:00 Helsinki time

Place: Hybrid meeting – ECHA and online.

Participants

NGO Representatives:
Michela Vuerich (ANEC); Julia Baines and Vera Engelbrecht (PETA); Natacha Cingotti, (HEAL); Sascha Gabizon (WECF); Simon Delso (BeeLife); Ana Fernandez Agudo, Tatiana Santos (EEB); Tamara Zietek (Eurogroup); Emma Grange (CrueltyFree); Frida Hök (ChemSec); Apolline Roger (Client Earth); Tony Musu (ETUI); Kuhlmann Janna (FoEE); Marina Pereira (HSI) Marton Kottmayer (EUChems); Helene Loonen and Jean-Luc Wietor (EEB)

ECHA:

VINAS Mercedes (meeting chair, Director Submissions and Interaction); BERCARU Ofelia (Director Prioritisation and Integration); MALKIA Annika (HoU, Data Availablity); BOUHIFD Mounir (Computational Assessment); SOBANSKI Tomasz (Computational Assessment); BOWMER Tim (Chairman of the RAC); RASENBERG Mike (Director Hazard Assessment); VAN DER ZANDT Peter (Director, Risk Management); DOYLE Simone (HoU, Risk Management I); David CLIFFE (HoU Communications); RYAN Paul (HoU, Hazard I); PEDROSA Tiago (HoU Computational Assessment); AAHAUGE Jakob (Communications)

Welcome

Mercedes opened the meeting by welcoming everyone and presenting the agenda and topics of discussion. Mercedes also introduced our new Head of Unit of Communication, David Cliffe.

The use of alternatives to testing on animals for the REACH Regulation, early key messages of the 117 (3) report

Mounir Bouhifd presented the key points of content (Implementation of NAMs in ECHA's integrated regulatory strategy; External activities promoting alternatives; Data availability), how the report will be organised and the intention of the report on the 'The use of alternatives to testing on animals for the REACH Regulation' that ECHA will publish next year.

Afterwards followed a discussion on the most effective approach to limit animal testing.

NGOs support and are encouraged with the approach to focus on the promotion of alternatives

to animal testing but highlighted that it is important not to overlook the value of analysis of the data that ECHA holds on REACH registered substances as it might reveal why animal testing has been used instead of NAMs. Mounir reassured that data analysis remains part of the report pointing out how resource intensive data mining is. He also mentioned ECHA's collaboration with other organisations also outside Europe to develop new NAMs.

It was also mentioned that avoiding animal testing is essential but that it should not be at the expense of wildlife and human health. **Amended to include HEAL's comment**: HEAL appreciated ECHA's efforts to limit animal testing in the context of regulatory requirements, also considering that some testing is still necessary for clarifying human health endpoints, such as carcinogenicity or endocrine disruption.

It was suggested that to accelerate the process of NAMs, regulatory acceptance for classification and hazard identification is needed. PETA asked whether the report would also include steps to overcome the challenges in developing NAMs. Ofelia confirmed that discussion points on how we could move towards more NAMs for regulatory purposes will be part of the report.

Changing the definition of end points to be more suitable for NAMs was also briefly touched and it was mentioned that this falls under the remit of the Commission and not ECHA.

HSI was concerned to see that a recent report on the grouping work that has been done identified data needs on the grouping approach which potentially could lead to more testing for substances where data needs were identified. If ECHA therefore could point to how alternatives could help avoid animal testing being conducted where data needs are identified. And additionally, if ECHA could expand guidance on how to better use NAMs and make them accepted. Mounir mentioned that guidance and advice are continuously provided to registrants on how to reliably use different sources of alternative data.

A discussion on how to avoid repetition of tests and issues with dosing then followed. NGOs argued that the problem lies with top dosing, whereas ECHA argued that the issue in focus is rather with inefficient too low dosing. Tim Bowmer suggested that purposely irregular dosing to avoid classification is an issue that needs attention. **Amended to include HEAL's comment**: HEAL joined in the discussion about industry testing compounds at low doses and agreed that it makes it difficult to use the results in an efficient way for the purpose of hazard classification. They suggested that this issue be brought up with industry directly.

Glyphosate

Mike Rasenberg mentioned ECHA's reaction to the HEAL report, and Tim Bowmer reminded on the magnitude of the assessment of glyphosate and on what data it was based (hazards and not risks) and which MSs initiated the dossier. In the evaluation of the dossier, focus was on the weight of the evidence, the negative and the positive studies and the animal and the human data. That led to a consensus on no classification for all three CMR endpoints. Tim also explained the functioning of the RAC committee, its members and how and on which principles they are nominated.

HEAL highlighted that they appreciate ECHA's proactiveness on this topic, and the comprehensive reply to their report to which they expect to respond soon.

Restriction process

Simone Doyle went through the restriction process; the definition of a restriction; how the

process works and which steps it entails; where and to what it applies (presentation attached).

BeeLife asked how ECHA and EFSA deal with incoherencies in the restriction process. A dialogue then followed on the difference between the regulatory frameworks, the committees and the decision makers and how the two agencies cooperate on the same type of substances. Peter van der Zandt made the point that the limits to which extent the two agencies can align has to do with the differences in the regulatory frameworks. Peter also highlighted that more regulatory alignment would be needed in order to be more efficient in the one-substance-one-assessment approach.

Update on the dissemination platform

Annika Malkia closed the meeting with an update on the dissemination of public data. She went through the main objectives with the design of the new data availability system and the next steps and timeline with a launch in early 2025. Stakeholder input is essential in the process and Annika encouraged NGOs to contribute to the further upcoming consultation on the topic.

Tony Musu asked about the current status of dissemination of the information in the Chemical Safety Report and whether there was any progress in terms of making all the data public. Annika explained that while a large part of the CSR is already published via the IUCLID dossier, the exposure scenarios are still not received in a format that fits dissemination. Instead, ECHA started to completeness check the CSRs last year, with the aim of improving the exposure information and thereby creating a better starting point for communication of safety information downstream.

Mercedes closed the meeting thanking everyone for their participation and encouraged further dialogue.