NGO-ECHA Dialogue
Meeting note

Time: 08 November 2023, 14:00–16:30 Helsinki time

Place: Hybrid meeting – ECHA and online

Participants

NGO Representatives:
Christine Hermann (EEB); Cindy Adolphe (BeeLife); Costanza Rovida (ecopa); Dolores Romano (EEB); Emily McIvor (ECEAE); Emma Grange (Cruelty Free Europe); Gilly Stoddart (PETA); Hélène Duguy (Client Earth); Iiris Lamminmaki (HEAL); Jay Ingram (HIS); Jen Hochmuth (PETA); John Harkin (CEEMET); Michela Vuerich (ANEC); Sidsel Dyekjaer (ChemSec); Rebecca Ram (Eurogroup for Animals); Stefan Scheuer (ChemTrust)

ECHA:
MAK Istvan (meeting chair, Data Availability); MCGUINNESS Sharon (Executive Director); VINAS Mercedes (Director Submissions and Interaction); RASENBERG Mike (Director Hazard Assessment); LEFEVRE Remi (HoU Risk Management II); BALDUYCK Bo (Governance, Strategy and Relations); NICOT Thierry (Risk Management II); MARQUEZ-CAMACHO Mercedes (Risk Management I); PEDROSA Tiago (HoU Computational Assessment and Alternative Methods); BOUHIFD Mounir (Computational Assessment and Alternative Methods); CLIFFE David (HoU Communications); FRICK Jutta (Communications); AAHAUGE Jakob (Communications); SOUSA Sara (Communications)

Welcome

Istvan Mak (ECHA) opened the meeting with a warm welcome to all the attendees before handing over to Mercedes Viñas (ECHA). She reiterated the significance of the NGOs dialogue, emphasizing that it provides a platform where ECHA's initiatives can be shared and valuable input from NGOs can be heard as well as a place for NGOs to raise issues of interest for them.

Executive Director Sharon McGuinness (ECHA) spoke about the development of ECHA's new strategy, and incorporating internal and external inputs. The agency faces a period of transition with new mandates and tasks. The new strategy aims to address the new challenges and to enhance stakeholders' engagement. Sharon emphasized work with civil society organisations, where communication is key to understand their needs.

Consultations under authorisation and restriction

Thierry Nicot (ECHA) presented key points about consultation during the application for authorisation process and how suggestions on alternatives are considered. He explained how the consultations work, including the duration, frequency, commenters, and promotion. Additionally, he presented general observations from ECHA for Cr(VI) uses.

Afterwards, followed a discussion where Stefan Scheuer (ChemTrust) asked about the request of the Commission for preparing a dossier on Cr(VI) restriction and the impact it will have on the applications for authorisation consultations.

Mercedes Marquez–Camacho (ECHA) presented an overview on the consultations on restriction proposals with a focus on information provided on alternatives. She described the different types of third-party consultations, the interested parties, commenters, promotion, and support to stakeholders. She also showed an example of a consultation web page and stressed the importance of providing supporting evidence when submitting information on alternatives.

EEB and ChemSec expressed their concern about the lack of accessibility for alternative providers to reply to consultations. They pointed out that the website in their opinion is not user-friendly and appears to be targeted towards companies that are already familiar with ECHA. The communication needs to be improved, as these companies feel that their input is often disregarded. Mercedes Viñas (ECHA) stressed that ECHA is open to improving access and that it is in the interest of all stakeholders to engage and provide information. However, the information must be supported by evidence.

ChemSec and ChemTrust shared their concern about the misinformation surrounding the topic of PFAS. They emphasized that the communication needs to be clearer. Mercedes Marquez-Camacho (ECHA) reinforced that the agency has participated in various events to explain the restriction proposal on PFAS. In addition, ECHA has dedicated a page on its website for PFAS and is open to suggestions to make the communication clearer. She also clarified that ECHA is not the dossier submitter of PFAS but is supporting the evaluation of the proposal.

New approach methodologies Workshop Report

Tiago Pedrosa (ECHA) provided an update on the NAM workshop. The workshop was convened in response to the growing expectations of stakeholders regarding the replacement of animal testing in the regulatory setting. Its purpose was to explore opportunities for increasing the use of new approach methodologies in the short and long term.

The materials are now available on the website. Key takeaways from the workshop include a strong commitment from all stakeholders to replace animal testing, although there were differing opinions on the speed and readiness for full replacement.

Mounir Bouhifd (ECHA) briefly talked about the 117(3) report, which outlines the status of the implementation and use of non-animal test methods in generating data for REACH registration. NGO feedback was considered in the development of the report. The report enables us to conclude that alternative methods are widely employed when available. Mounir also explained ECHA's ongoing activities related to NAMs, with a special focus on omics. He presented a potential way forward, involving the identification of critical needs, the application of NAMs within the current system, and a subsequent redesign. Additionally, he explained how to integrate omics into regulatory science.

In July, TEAM Mastery published estimates of the number of animals used for REACH purposes. Currently, they are undertaking a similar effort focused on fish, although this presents greater challenges due to less comprehensive reporting. Constanza Rovida (ecopa) inquired about the relevance of this information for ECHA. She also underlined that animal testing often yields limited results, with many cases failing to provide results on toxicological effects of chemicals.

Tiago Pedrosa (ECHA) responded that it is aware of the paper. However, counting the number of animals tested is not the goal of the 117(3) report, which focuses on the uptake of alternative methods. Other initiatives and European statistics serve that purpose. He also acknowledged that while animal testing has limitations, it is the system used and it has contributed to achieving a good level of safety and protection.

In connection with the 117(3) report, Emma Grange (Cruelty Free Europe) inquired whether ECHA is considering the inclusion of an analysis regarding the acceptability of adaptations in future reports, with the objective of helping registrants. Tiago Pedrosa (ECHA) indicated that they offer guidelines and examples of effective adaptations through frameworks such as Read-Across Assessment Framework, and the Evaluation Report, which includes analyses of the quality of the information received.

Dolores Romano and Christine Hermann (EEB) expressed concern about how industries might exploit the topic of animal testing to withhold proper information and avoid classification. They inquired about the internal progress on non-animal methods, particularly with the RAC. Additionally, they emphasized the importance of advancing the use of non-animal testing for classification purposes. Tiago Pedrosa (ECHA) reassured that, regarding the RAC, they are collaboratively exploring with Member States how to incorporate NAMs.

Emily McIvor (ECEAE) inquired about how ECHA assesses the data quality of incoming animal study data, and asked for more information on the frequency with which ECHA reviews the raw data and the level of scrutiny applied. McIvor highlighted that the belief that it is possible to determine the number of animal tests by examining EU statistics is a myth, as it does not account for tests conducted outside the EU. A substantial amount of animal testing for REACH data occurs beyond EU borders. McIvor questioned whether ECHA is overseeing the compliance of non-EU laboratories. Mike Rasenberg (ECHA) provided a brief explanation of the criteria for accepting information, emphasizing compliance with guidelines and GLP. He reassured that ECHA maintains strict standards and diligently follows up on compliance.

New tasks allocated to ECHA

Bo Balduyck (ECHA) presented the new responsibilities assigned to the agency, in the context of the European Commission's Chemicals Strategy for Sustainability. He elaborated on the status of the REACH and CLP revision, and detailed the new legal mandates for ECHA, including the Drinking Water Directive, Cross-border Threats to Health Regulation, and Battery Regulation. Additionally, he highlighted some pending (but announced) Commission proposals on the table. The upcoming additions to ECHA's legal mandate indicate a transition to a "chemical agency" in the wider sense, moving beyond REACH and CLP.

Future of NGO-ECHA Dialogue

Istvan Mak (ECHA) initiated a discussion on the future of the NGO-ECHA dialogue. NGOs expressed interest in adopting a hybrid format, incorporating both virtual and physical meetings. They suggested coordinating physical meetings with other events taking place in Helsinki and increase the frequency to approximately twice a year. Proposed initiatives were discussed like AMA (Ask Me Anything) sessions, breakout groups, and the involvement of NGOs in presentations, not solely ECHA. Additionally, the preferred communication channel between meetings could involve assigning a dedicated contact point for the NGO-ECHA dialogue, such as a functional mailbox.