NGO-ECHA Dialogue
Meeting note

Time: 09 April 2024, 14:00–16:30 Helsinki time

Place: Hybrid meeting – ECHA and online

Participants

NGO Representatives:
POCHAT Julia (Eurogroup for Animals); KJELL Theresa (Chemsec); HAIDER Sonja (Chemsec); ROMANO Dolores (EEB); McIVOR Emily (ECEAE); GRANGE Emma (Cruelty Free Europe); STODDART Gilly (PETA); DUGUY Hélène (Client Earth); ZIETEK Tamara (ECEAE); REINEKE Ninja (CHEMTrust); HOCHMUTH Jen (PETA); SHIPTON Kate (Cruelty Free Europe); ROVIDA Costanza (ECOPA); GHESQUIERE Basile (Health and Environment Alliance); RENAHAN Tess (PETA)

ECHA:
MÁK István (meeting chair, Communications); VIÑAS Mercedes (Director Submissions and Interaction); RASENBERG Mike (Director Hazard Assessment); LEFEVRE Rémi (HoU Risk Management II); KARKOLA Sampo (HoU Dossier Evaluation I); CLIFFE David (HoU Communications); BALDUYCK Bo (Governance, Strategy and Relations); FRICK Jutta (Communications); AAHAUGE Jakob (Communications); SAARI Veera (Communications); Van BROEKHUIZEN Fleur (Water, Alternative Methods and Prioritisation); BIN Essi (Risk Management I); FAST Anni (Data Availability); SOBAŃSKI Tomasz (Data Management and Analysis); RHEINBERGER Christoph (Risk Management II); ZAROGIANNIS Panagiotis (Water, Alternative Methods and Prioritisation)

Welcome

István Mák (ECHA) opened the meeting and welcomed all the attendees. The agenda for the meeting was introduced to the participants prior to the meeting. The agenda for the meeting was introduced to the participants prior to the meeting, inviting them to comment and propose agenda topics for ECHA to consider.

Mercedes Viñas (ECHA) was happy to see both known and new stakeholders joining the NGO-ECHA Dialogue. She emphasised the importance of the NGO-ECHA dialogue, highlighting its alignment with the new ECHA strategy, which places collaboration at its core alongside science and knowledge. In line with our strategy, we want to further enhance our collaboration and put even more emphasis on listening and understanding our stakeholders' needs. Therefore, it is great to see that many of the agenda points are brought up and presented by NGOs during today's Dialogue.

Integrated Regulatory Strategy

Ninja Reineke (CHEMTrust) did a short recap on the larger events organised by ECHA, where the Integrated Regulatory Strategy was also on the agenda (The Shaping Tomorrow conference and the IRS Workshop). Especially the workshop was appreciated, where the NGOs were also invited to present their views. While it is important to express satisfaction with all the work already done (e.g., groupings, assessments, reports prepared), they are concerned about the lack of follow-up (using the data for better protection of human health and environment). Ninja asked what the format of the follow-up for these meetings will be and if stakeholders will be involved with that as well.

Fleur van Broekhuizen (ECHA) responded that ECHA is very happy with the input received from NGOs. The Agency also acknowledges the concerns raised and it is also very important for ECHA that follow-up actions are taken and in a timely manner. Conclusions from the IRS workshop are still being drafted and expected to be shared soon. When planning follow-up actions, all input will be considered (Member States, NGOs, and Industry). RiME (Risk Management and Evaluation) platform was identified as a good collaboration forum between ECHA and Member States. This is only for preliminary discussion, decision-making remains in the open, public domain. The format of how NGO feedback will be collected has not been decided yet, however, the NGO input is important, and the Agency will continue to seek for it. By responding to "calls for comments", NGOs are already providing important support to ECHA. In the context of PARC, the Agency is also looking into how NAMs and read-acrosses could be optimally used.

ECHA's Relationship with External Stakeholders

Dolores Romano (EEB) opened the discussion by expressing the perception of NGOs, that there is an imbalanced representation between industry and the civil society at ECHA's working and expert groups. Some of the boards/groups have a balanced representation (e.g., management board), while others in the NGOs' view (e.g., RAC, SEAC) are tilting towards industry. NGOs would also support the idea to have representatives from Academia directly invited by ECHA, to represent Academia and not to be present as a representative of the civil society.

István Mák (ECHA) briefly responded, that many of the groups are organised based on rules of procedure, laid down by various legislations. Essi Bin (ECHA) explained the rules governing participation in RAC and SEAC meetings. Only ECHA accredited stakeholder organisations have the possibility to participate in these meetings and participation is ensured to be balanced, based on the Procedure for admission of ASO observers. István Mák (ECHA) offered to collect information on organisation, membership and voting rules for the major ECHA working and expert groups and to report back on those during the Autumn, at the next NGO-ECHA Dialogue.

Emily McIvor (ECEAE) confirmed that NGO participation in PEG (Partner Expert Group) meetings is possible. She asked ECHA, in case a specific NGO is interested in joining a PEG, but it doesn't have an in-house expert within that field, they are allowed to have a consultant representing them during the PEG. István Mák (ECHA) offered to provide an answer on this question during the Autumn NGO-ECHA Dialogue. David Cliffe (ECHA) highlighted that information on the functioning and organisation of the various groups should all be available on ECHA's website. If certain groups cannot be found there, feedback from NGOs is highly appreciated.

Ninja Reineke (CHEMTrust) commented that the real issue is not about access to the various groups, but instead whether there is a limit in the "number of seats". If not, industry will always have more resources to participate in these groups, tilting the balance.

István Mák (ECHA) requested NGO representatives to provide examples for those groups where imbalance is perceived, so that the Agency could investigate those.

Hélène Duguy (Client Earth) asked about the rules governing European Commission (COM) participation in RAC/SEAC. Bo Balduyck (ECHA) explained that COM and/or other EU agencies can participate in RAC/SEAC meetings as observers, based on their interest, but they are not required to be present.

Dolores Romano (EEB) thanked ECHA for their commitment to investigate the organisation and voting mechanisms of the various groups and have promised to provide examples on the perceived imbalance in the decision-making.

Transparency in the work of ECHA

Eurogroup for Animals, Cruelty Free Europe, Humane Society International, PETA and European Coalition to End Animal Experiments had prepared a joint presentation to start a discussion under the main theme of "transparency".

Julia Pochat (Eurogroup for Animals) explained that they are aware and happy that one of ECHA's aims is to reduce animal testing. A lot has been done already, however in certain areas there is still a perceived lack of transparency (e.g., the number of animals used to fulfil REACH data requirements). NGOs would like to have a better understanding of the quality of data reported by industry. They hope to explore the quantitative data in ECHA's reports in relation to the use of alternatives.

Emily McIvor (ECEAE) reiterated that the objective to move away from animal testing is both a regulatory requirement and need from animal welfare's side. ECHA has analysed submitted EOGRTS (Extended One Generation Reproductive Toxicity Study) and the accuracy of robust study summaries. ECEAE is grateful that ECHA has carried out both studies. Useful conclusions and areas of improvements have been reached and identified. Both projects revealed that results of these tests/studies can have shortcomings. Regarding the proficiency of test labs, according to ECEAE a lot can be improved. GLP compliance is required both in and outside of the EU for tests carried out for REACH purposes. Emily McIvor thanked ECHA for following up on the question from the previous NGO-ECHA Dialogue, on the percentage of in-vivo testing done outside of the EU (~40%). NGOs are welcoming the upcoming GLP Directive evaluation, hoping that it will eliminate/reduce the possibility of fraudulent study reports. In the meantime, NGOs are requesting ECHA to publish the list of GLP monitoring authorities per country. Emily McIvor also highlighted that the Common Data Platform Proposal provides further improvement in transparency.

Jen Hochmuth (PETA) thanked ECHA for organising the Dialogue and providing the opportunity to raise areas of concern from the NGOs side. PETA would like ECHA to offer a shared space for discussion, where dossier update, testing proposal and other adaption to standard requirements issues could be discussed. This would be similar to what other agencies (e.g., EMA) are providing. In this context, Jen Hochmuth asked what registrants could do to have a discussion with ECHA if they wish to make an adaptation to standard data requirements, what is the supported communication process for this and how is ECHA disseminating this information. PETA also asked the Agency how it is

planning to integrate the SCCS (Scientific Committee on Consumer Safety) into its work/organisation, when tasks under the Cosmetics Regulation would be coming to ECHA. Furthermore, Jen Hochmuth was asking, if a higher degree of transparency under the Art 117 report could be achieved, as according to her, currently in vivo, adaptation and non-experimental methods are all listed under one number.

Emma Grange (Cruelty Free Europe) had three questions on ECHA's ECHA CHEM portal: 1, There seems to be more clicks needed to reach the same information now as before. Is ECHA preparing any further update to its database and if there is any possibility to provide feedback on ECHA CHEM? 2, Some information that was not considered confidential earlier, seems no longer available (e.g., the author of a study). Was this change intentional, or have they just been running into "glitches"? 3, Cruelty Free Europe has a perception, that fewer dossiers are present in ECHA CHEM, than before. Could ECHA confirm, whether all previously performed test data should remain visible, even in case of a cease of manufacture, or a tonnage downgrade?

Mike Rasenberg (ECHA) answered most of the questions raised under this topic:

On transparency, related to GLP and the study authors reported in the registration dossiers, nothing has changed on ECHA's side. The Agency is looking into, how the information on the test labs could be published. This is expected to be a longer process. Once the testing laboratories are available to be disseminated, it becomes easy for anyone to find the relevant GLP compliance authority.

The Agency rarely sees cases, where there would be an indication of falsification of the studies. It happens, but it is rare. It is important that all parties keep an eye for these, including Industry.

ECHA does not have a formal "shared space" to discuss adaptations, etc., but informal discussions are available to all those registrants, who wish to include those alternatives in their registrations. For the time being they are few, but the Agency is open to have discussions on those with the registrants. Testing proposal evaluations are all publicly available on ECHA's website and the related registration dossiers in ECHA CHEM. There has been a recent study on ECHA decisions on read acrosses, which will soon be published. The finding is that if there is enough toxico-kinetic type of data in the argumentation, ECHA is likely to accept it. Additionally, there are several projects, where ECHA is working together with industry on test cases. E.g., people can propose categories, ECHA provides feedback on those proposals, so dossier quality can be improved.

The impact of the cosmetics legislation tasks potentially coming to ECHA can mean that lessons learned under those, could potentially be implemented under REACH as well and vice versa. Under "cosmetics", risk assessment is more targeted. Therefore, good to remember that the two are not the same. However, the ambition is really to learn from "each other".

The currently available ECHA CHEM is an MVP, minimum viable product, thus, it is a starting point. Any feedback is welcome. ECHA will continue the development of ECHA CHEM. There should be no dossiers missing, but if any concrete case is found by NGOs, please inform ECHA about it. All data available is published and a change in the registration's status should not affect the availability. This is also true in case of tonnage downgrade, as industry is required to submit all available information.

Tomasz Sobański (ECHA) provided an answer on the question of providing more detailed

information on the number of non-animal tests. He explained how information is provided under the current setup and that in the past it was more detailed, but for most people it was confusing. Mike Rasenberg (ECHA) also explained the difficulties in providing statistics on the use of alternatives. Many of the older dossiers contain multiple endpoints of different source (QSAR, read across, etc.) to fulfil the data requirements. Therefore, it is easy to count the number of e.g., QSARs used, but difficult to count, how many times a QSAR is used to fulfil the endpoint.

Anni Fast (ECHA) provided further clarifications on ECHA CHEM. The aim with the MVP was to simply publish registration dossiers again. ECHA believes that the separately published registration dossiers (as opposed to the aggregated ones before), provides better transparency. Currently ECHA CHEM only allows a basic substance search, but analysis of other functionalities to interact with the data is ongoing and further development will follow. Feedback is constantly welcome, though more structured forums will be organised later. All dossiers should be available, nothing is deleted. In ECHA CHEM active dossiers and inactive ones are shown separately in different tabs for clarity.

Bo Balduyck (ECHA) provided an answer for the question on whether the author of a study will be published or not. Following the policy review at the entry into force of the GDPR, ECHA is only publishing the name of a study author, if is considered as a publicly available data. Thus, if the study is in the public domain, the author can be published. If it is not the case, the author's name cannot be published either. This is in line with the policy of other Agencies. Mike Rasenberg (ECHA) has reiterated, that regardless, whether the information can be made public, or not, having that information is important for ECHA.

Theresa Kjell (ChemSec) commented on the importance of ECHA's data being available, as they are relying on it with their tools. Thus, they appreciate all the work done.

Update on ECHA's activities related to Alternative Methods

Tomasz Sobański (ECHA) provided a proactive update on what has happened since the last NGO-ECHA Dialogue, where NAMs have been also discussed. He started with a recap of 2023 and what has taken place with NAMs. He clarified the critical needs of moving to a non-animal testing method and provided explanation on what are the areas, where we can already now demonstrate refinement and reduction of animal tests. The presentation provided detailed information on ECHA's 2024 plans related to NAMs. This included detailed explanation on what is being done on ECHA and international level for both lower tier and higher tier endpoints.
In a report released June 2023 (The use of alternatives to testing on animals for the REACH Regulation) it has been revealed, that only 2.8% of endpoints are fulfilled using QSAR, there is room for more effective use of QSARs under REACH. However, the big picture is a lot more positive, as adaptations are used more often than experimental studies to fulfil the data requirements. ECHA is focusing in QAF (QSAR Assessment Framework) on the validity criteria for prediction. This also includes development of clear and transparent criteria for acceptance, working on wider acceptance, which could lead to new regulatory application.
Tomasz Sobański (ECHA) also introduced ECHA's NAMs collaboration network, where the Agency is working together with other EU and international organisations.

Emily McIvor (ECEAE) thanked Tomasz and ECHA for the work done so far.

Socio-Economic Assessment

Hélène Duguy (ClientEarth) presented on the background of socio-economic assessment and its current use in the EU legislative framework, with emphasis on its use under REACH. She compared the original purpose of such assessment with the perception of NGOs on how the process is running. Hélène Duguy stated that SEA is a resource intensive process that, unlike its original intention, slows down the decision-making process.

Several NGO reports (ChemTrust, Chemsec and ClientEarth), policy makers (MEPs), SEAC discussions and academia have all raised concerns about the process. These studies/discussions have raised structural concerns, which seem to stem from the regulation itself and are thus beyond the control of ECHA, but also areas where ECHA could introduce changes.

NGOs believe that the SEA is a very important tool, but they perceive that its use makes the public and decision makers lose the full picture. They believe that there is a discrepancy between the priorities (health and environmental protection, tackle chemical pollution, safe chemicals) and the tools (focus on quantifiable costs, underestimation of other key impacts).

NGOs hope that some of the proposed legislative changes under the CSS and in a possible REACH review will address part of their concerns (more information available, essential use concept, improved assessment of alternatives). In the meantime, they would like to start a conversation with ECHA to improve the current process. NGOs have asked for a dedicated workshop, with participants from e.g., academia. Theresa Kjell (Chemsec) has agreed with the concerns brought up by ClientEarth. She also wanted to highlight that in their opinion quantitative estimations are often misleading. E.g., costs are often looked at as a static value, while the cost of an alternative changes over time. As such, they support the idea of organising a dedicated workshop on SEA.

Christoph Rheinberger (ECHA) acknowledged that not everything has been perfect with the application of SEA but stressed that the Agency has been trying to better incorporate many of the elements mentioned by NGOs. Most of the elements on calculating gains/losses with the use/avoidance of alternatives are already (indirectly) considered. However, he also stressed that any model can never be 100% accurate. If desired by the legislator, certain policy preferences could be incorporated into the current decision-making process. E.g., the legislator could decide if they want to have a higher importance related to factors of human health and the environment compared to effects on industry.

Sonja Haider (Chemsec) was asking whether the process has changed in the last five years, allowing more opportunities for alternatives providers?

Christoph Rheinberger (ECHA) responded that the authorisation process has shifted, and that applicants are more assessed based on their substitution plans, instead of the actual socio-economic assessment.

Rémi Lefèvre (ECHA) reiterated that the basis for further discussion needs to be concrete examples in which NGOs perceive that by using different methods/models in the assessment, the conclusion on the SEA presented would have been different.

Agreement on a follow-up workshop was reached under the condition that NGOs should

provide concrete examples ahead of the meeting.

Drinking Water Directive

Panagiotis Zarogiannis (ECHA) explained what the goals of the recast of the Drinking Water Directive are and what is ECHA's task under it. The legislation established 4 European positive lists, provides risk assessment methodologies, and defines information requirements and procedures for updating the positive lists. He provided detailed overview of the number of substances on the positive lists, the review process and information requirements.

Applications under this legislation can be three distinct types: new (adding a new substance to the list), review (a review of an existing substance, so that at expiration it can remain on the list) and removal.

Panagiotis Zarogiannis (ECHA) also explained in high level the differences between the "Notify intention to apply" and the "Approve entry on the European Positive List" processes.

Information was provided on areas, where NGOs could be involved in the Drinking Water Directive. Different level of involvement is possible until the end of 2026 than the level afterwards, when ECHA will start receiving applications.

Gilly Stoddart (PETA) asked how much new animal testing is expected due to the Drinking Water Directive. Panagiotis Zarogiannis (ECHA) explained that the legislation makes aims at the minimisation of animal testing and the general expectation is that most applications will be for substances already registered under REACH, therefore the required data may already exist for those.

Ninja Reineke (CHEMTrust) asked how the issue of non-threshold substances will be dealt with. Panagiotis Zarogiannis (ECHA) provided that answer that Annex VI of the first implementing act (Commission Implementing Regulation (EU) 2024/365) provides information on risk acceptance of substances with significant hazards.

Dolores Romano (EEB) asked if ECHA will automatically consider all other information available on the substance, which were generated under other processes? Panagiotis Zarogiannis (ECHA) has responded that the Agency is looking into how this could be done, but it is the intention to use all data; the legislation allows RAC, if it considers necessary, to refer to any relevant information submitted to ECHA, the Commission, other Union bodies and agencies or Member States for the purpose of other Regulations or Directives. However, industry needs to meet the information requirements, as ECHA will not use existing data to fill in the gaps of missing data in the applications.

Closing the meeting

István Mák (ECHA) thanked all participants to join the event and for the lively discussion throughout the meeting. The next NGO-ECHA Dialogue is planned as an in-person meeting and will take place in the autumn (September/October). One person per organisation can be reimbursed by ECHA for their participation.