Platform for NGO-ECHA discussions
Meeting note

Time: 2 July 2020, 15:30–17:00 Helsinki time

Place: Online

Participants:

NGO Representatives: Noa Simon Delso, BeeLife; Apolline Roger, ClientEarth; Katy Taylor, Cruelty Free Europe; Tamara Zietek, Eurogroup for Animals; Costanza Rovida, European Consensus Platform for Alternatives; Marina Pereira, Hannah Stuart, Humane Society International; Maike Niggemann, IndustriAll; Jerker Ligthart, International Chemical Secretariat; Gilly Stoddart, Julia Baines, PETA; International Science Consortium; Martin Dermine, Pesticide Action Network Europe; Elisabeth Ruffinengo, Women Engage for a Common Future.

ECHA: Mercedes Viñas (Head of Unit Data Availability – Meeting chair); Mike Rasenberg (Computational Assessment); Bo Balduyck (Governance, Strategy and Relations); Teodora Kateva (Data Availability); Jutta Frick, Nerija Jukniute and Veera Saari (Communications).

1. Welcome

Mercedes Viñas opened the meeting by welcoming everyone to the virtual meeting of the NGO platform. The agenda was reviewed and adopted as circulated.

2. Alternatives to animal testing

Mike Rasenberg presented ECHA's recently published report on the use of alternatives to animal testing in REACH. The report shows that adaptations continue to be used more than experimental studies, with read-across being the most popular option. One of the main observations is that in vitro non-animal test methods have seen a significant uptake.

Mike noted that despite the tools and guidance made available, such as the Framework for Read Across Assessment, there are still many incompliances and many dossiers will need to be updated. Registrants will continue to have opportunities to strengthen their alternative approaches. It was mentioned that ECHA expects companies to make use of our guidance and tools, and that ECHA would be happy to hear any ideas from NGOs on how this could be enhanced – any feedback can be emailed to stakeholder@echa.europa.eu.

Mike highlighted that the REACH registration database is a unique knowledge database that can serve the safe use of chemicals, sustainable chemistry development, circular economy and further development of alternative approaches to animal testing.

This topic raised lots of interest and questions from NGOs, followed by a discussion on compliance and testing methods.

Humane Society International (HSI) raised the issue of compliance despite the guidance available and asked whether ECHA plans to issue more case examples. ECHA explained that, at the moment, there is ongoing, focused work with some industry organisations. It is expected that these industry organisations, such as Cefic, with whom we are working on case studies, will share their learnings.

International Chemical Secretariat asked for clarification regarding incompliance: is it because the new test methods do not give good enough results, or is it related to the way registrants use alternative test methods? ECHA explained that when companies use test methods follow OECD guidelines, they provide compliant results. The issues come with adaptations particularly with higher-tier, more complex end-points. For more simple end-points companies generally know how to do it (there is also a correlation with the company or consultancy size) – it's more about being aware how to apply the adaptation. For example for read-across, the main problem is that the registrants need to explain not only chemical similarity but also the biological consequence of the chemical similarity. Especially for these more complex endpoints, companies need to make certain investments in testing to fulfil the information requirements.

Cruelty Free Europe asked about read-across: is ECHA seeing that registrants are not following the structure of its Read-Across Assessment Framework or are they just failing? ECHA responded that it is a mixture of both issues and every case is specific and it is difficult to generalise, but too often the dossiers are not very close to being compliant.

Cruelty Free Europe requested more information about specific data. ECHA suggested to have a separate discussion with interested NGOs regarding more details on the numbers in the report.

The European Consensus Platform for Alternatives asked:

1) Is ECHA requiring a 28-day study for each member in a chemical category? ECHA responded that each case is specific and that it cannot generalise.
2) Would it be possible for a company to have a discussion with ECHA before doing a test to have a better picture whether results will be accepted and to save potential costs and animals? ECHA responded that, at the moment, this is not available, but we are building experience and case studies through different industry initiatives for this purpose exactly. Through these on-going pilot cases with industry associations, we will see what we could offer in the future. There was a low number of volunteers for the specific case studies on testing strategies – ECOPA volunteered to get involved.
3) What happens if, after the final decision, a company decides to do a read-across assessment by providing a better justification? The ECHA participants were not involved in this part of the compliance check process and promised to get back to this question in writing.

HSI had a question on read-across and how to improve the registrants' compliance with the guidance available. According to HSI, examples of good approach could help companies improve, but for some reason, these are lacking from the report. They asked whether ECHA is planning to issue more formal examples. ECHA clarified that it has no new examples available at the moment, aside from the already published information in the Read-Across Assessment Framework, but hope that our work with Cefic and other industry organisations on illustrations will help companies.

HSI noted the positive trends in the report for skin and eye end-points related to in vitro tests, however, raised a concern about a moderate increase in the number of pre-natal developmental toxicity and (sub)chronic repeated dose studies. They asked what ECHA is

doing to tackle these end-points. ECHA said that it is pleased with the progress made in in vitro studies in general. The challenge is to have sufficient information to ensure safe use. ECHA is cooperating closely with the European Commission and stakeholders, investing in new approaches for the more complex endpoints.

HSI agreed that lots of work needs still to be done and asked whether ECHA's observations in terms of research needs are known to the research community to foster the development of new methods. ECHA responded that we do raise our needs within the relevant research communities and are actively working in two specific areas: projects funded by DG Research and Innovation (European Commission), and APCRA, a collaboration with the US Environmental Protection Agency, Office of Research and Development, and Health Canada. ECHA asked for support from the NGOs towards the European Commission to ensure that funding is spent in such a way that its outcome is relevant for the regulatory frameworks.

Due to the number of open technical questions on the topic, it was agreed that ECHA will organise a follow-up discussion with interested NGOs on more details on the report on alternatives to animal testing after the holiday period. An invitation will follow.

3. Transparency approach update

Bo Balduyck presented ECHA's plans for the bi-annual update of the Agency's action plan to improve its transparency. Transparency is one of the core values of ECHA and its Management Board has adopted a transparency approach. In December 2020, ECHA's management board is foreseen to come to an agreement on two streams of work related to transparency: data availability and communication and engagement. Stakeholder consultations will follow for both work streams.

Data availability

Mercedes Viñas presented ECHA's plans to build a roadmap for data availability for 2020-2024 to improve access to data on chemicals. The main blocks of the roadmap will consist of:

- A review of the publication policy, with the aim to identify possible additional publication opportunities, e.g. the technical function of a substance in a specific use.
- Regulatory visibility of substances and processes with potential transparency enhancements, e.g. registrants' view, substance evaluation outcome, and dossier evaluation status.
- Integration of (new) data sources, such as a redesign of the Classification and Labelling Inventory, and integration of information on the import and export of hazardous chemicals under the PIC Regulation.
- Exploring ways to facilitate the use of the data, e.g. through better download or web services functionalities.

BeeLife asked about the data that ECHA hosts and how it is organised. ECHA replied that its database is quite complex and contains information from several different legislations. The data comes mainly from registration dossiers from companies, but also from information generated by ECHA. ECHA aims to present all the data in a user-friendly, digestible format, and for this purpose, targeted consultations with stakeholders will follow to hear more about their use cases to be able to better serve different user groups.

ClientEarth asked about ECHA's work and role in the context of the EU's Green Deal and

Digital Policy and achieving a global chemicals database. ECHA replied that it is following the EU developments very closely and is very open to play a role and contribute to the EU projects and strategies. ECHA is actively participating for example in the project initiated by the European Parliament (and now lead by DG ENV) on looking at the feasibility of setting up a common EU chemicals data space. We are sharing our experience and knowledge with other EU institutions and EU agencies, such as EFSA, to see how to bring our data together and improve integration. In addition, one area of potential work is to improve access to data and awareness between the EU Member States about different regulatory processes so we can reach the principle of one substance – one assessment.

The International Chemical Secretariat thanked ECHA for the efforts to increase transparency on data on chemicals and asked several questions.

- **When the consultation on the dissemination roadmap will take place?** ECHA replied that that this will be done online most likely in late autumn. The timing will be communicated soon.
- **Will information regarding individual tonnage bands by companies be made public?** ECHA explained that it is reviewing its publication policy as a whole and will welcome stakeholders' views on this. ECHA mentioned that the publication of individual tonnage bands is on the list to be discussed.
- **Will there be more clarity on the so called NONS substances**, i.e. substances registered prior to the REACH Regulation under Directive 67/548/EEC: Notification of New Substances. ECHA replied that it is looking into NONS substances from a broader perspective and deciding whether to put efforts in making sure the NONS substances are updated in the latest data format, which will in turn facilitate dissemination.
- **Could ECHA's data be more easily used for API development in the future?** ECHA replied that it is looking into various ways to make data available and that it is very important to get more information on how the data accessed via API is planned to be used and what stakeholders' needs are.
- **What are ECHA's plans regarding the dissemination of classification and labelling information and is ECHA planning to improve the current search possibilities?** ECHA explained that it intends to put its efforts in the re-design of the Classification & Labelling (C&L) Inventory and is therefore not foreseeing major improvements on the current C&L Inventory in the meantime. The way C&L data are published and the available user interface have not been updated in any significant way since their first release and improving this legacy is deemed not to be efficient. Therefore, the current solution will be kept until the full re-design. Aside from the classification and labelling inventory, other improvements will continue to be made for the other features of the database for example a new release is planned for October.
- **Could ECHA publish the same information as Eurostat does on the aggregated tonnage of substances**, categorised by hazard point (e.g. for CMR substances)? ECHA clarified that it currently publishes the aggregated total tonnage band at a substance-level and that as part of the Roadmap, it will look into further ways to make the data available in consultation with stakeholders (e.g. individual tonnage bands, if not claimed confidential).
- **Where does the hazardous substances data presented in aggregated tonnages per substance on the EUROSTAT website come from?** Is ECHA contributing with data to EUROSTAT? ECHA's information on chemicals is not linked to the EUROSTAT's data and ECHA is not supplying such data to EUROSTAT. As per EUROSTAT notice on their website: Eurostat's hazardous substance indicators are based on industrial production statistics.
- **Is ECHA taking the EU open data policy into account in its data availability roadmap?** ECHA clarified that it is following the EU's data policies closely and will

definitively take them into account in its own developments.

Communication and engagement

Jutta Frick presented ECHA's plans to improve communication and engagement with its stakeholders. She mentioned three concrete projects running in 2020-2022 where stakeholders' views and feedback will be much appreciated:

- Study on the public's perception of ECHA to improve our communication – NGOs were invited to take part in the on-going survey by 17 July 2020.
- Mapping stakeholders' interests in 2020 to provide more tailor-made content.
- ECHA website revamp starting in 2021 – a customer insight survey will follow.

4. EU Chemicals Legislation Finder

The EU Chemicals Legislation Finder is a search engine for regulatory information on chemicals enabling companies, especially SMEs, to find out how their substances are being regulated in the EU and what legal obligations they have. It gives a comprehensive overview of all EU chemicals legislations in a single portal, free-of-charge and comes with a dedicated helpdesk service where you can ask questions about different EU legislations on chemicals.

There was not enough time to cover this item, so it was agreed to share the presentation after the meeting and to have NGO colleagues come back with feedback via email on their experience with this new service available on ECHA's website.

5. AOB

Clarification on 'non-governmental organisation'

In the last NGO platform meeting, it was mentioned by some of the invitees that participation to the meeting should be reconsidered for future. ECHA clarified that the intention of the platform is to engage with organisations who represent the interests of civil society and are focussed on health, the environment and animal welfare. Therefore, ECHA will pay close attention to inviting only those organisations who fit this description.

Next meeting

ECHA is planning to organise another NGO platform meeting later in the year and NGOs' topic proposals will be very much appreciated. An indicative date and request for topics will follow in the autumn.

Follow-up actions

ECHA will organise a follow-up discussion with interested NGOs on the report on alternatives to animal testing after the holiday period.

Annex I – Meeting agenda

15:30–16:05 **Report on the use of alternatives to testing on animals**
- ECHA report on animal testing, *Mike Rasenberg, ECHA*
- Discussion

16:05–16:30 **Update on transparency approach**
- Update in 2020, *Bo Balduyck, ECHA*
- Information on chemicals, *Mercedes Viñas, ECHA*
- Communications, *Jutta Frick, ECHA*
- Discussion

16:30–16:50 **Experience with EU chemicals legislation finder**
- Discussion, *Teodora Kateva, ECHA*

16:50–17:00 **Any other business**
- NGO invitees
- Next meeting

Annex II – Presentations

Presentations available here.