# Platform for NGO-ECHA discussions
Meeting note

**Time:** Tuesday 12 November, 17:00–18:30 Helsinki time

**Place:** Online

**Participants:**

**NGO Representatives:** TAYLOR Katy (Cruelty Free Europe); SANTOS Tatiana (European Environmental Bureau); STODDART Gilly (Peta International Science Consortium); CHASLARIDIS Panagiotis (European Federation of Allergy and Airways Diseases Patients' Associations); ROVIDA Costanza (European Consensus Platform for Alternatives); PEREIRA Marina (Humane Society International); DE MATOS Olivier (ECETOC).

**ECHA:** VIÑAS Mercedes (Head of Unit Data Availability – Meeting chair); DE BRUIJN Jack (Director of Prioritisation and Integration); DE COEN Wim (Hazard Assessment); KARHU Elina (Prioritisation); KUSTER Jonathan (Prioritisation); ATLASON Palmi (Prioritisation); RASENBERG Mike (Computational Assessment); SOBANSKI Tomasz (Computational assessment); ELWAN Adam (Communications).

## 1. Animal welfare

### Update on new approach methods

Mike Rasenberg (ECHA) gave an update on ECHA's activities on new approach methods. He stressed two areas of work: the development of methods and knowledge.

When it comes to testing requirements, ECHA is actively involved in the OECD's extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST). This group develops new adverse outcome pathways, different kinds of high throughput screenings, as well as omics technologies. These concepts are tested out at the OECD Working Party on Hazard Assessment (WPEA), for example with larger case studies of substances. If an agreement is reached at OECD level that these concepts have enough maturity, the work to build these into new test guidelines starts at the OECD's National Coordinators of the Test Guidelines Programme (WNT).

All this activity is also coordinated and worked on collaboratively with the European Commission's Directorate-General for Environment and Joint Research Centre. This is the formal route for the development of new approach methods.

To stimulate the development of new approach methods, ECHA is also active in the following European and international platforms:

- European Partnership for Alternative Approaches to Animal Testing (EPAA)
- Integrated European 'Flagship' Programme Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st century (EU-ToxRisk)
- Accelerating the Pace of Chemical Risk Assessment (APCRA)

Another area of ECHA's work on new approach methods is the development of further knowledge. This work bases largely on the chemicals data collected so far, and an

important aspect is exchanging this data with other authorities, like the US EPA and Health Canada, with the aim to increase efficiency and to avoid the need for testing.

ECHA also collaborates with the US EPA's Office of Research and Development and with the US National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) to share data in a targeted manner to feed different projects. For example, NICEATM is in the process of launching an improved model to predict acute toxicity, where ECHA's data has been used.

The data is also used by ECHA to develop the OECD QSAR Toolbox – a free software designed to support hazard assessment of chemicals, where its use reduces dependency on animal testing.

These international activities are not necessarily targeted to changing the requirements for testing but to enhancing and speeding up the processes in other areas, for example in prioritising chemicals as low or high priority and in accelerating ECHA's decision-making – which both have an indirect effect on avoiding unnecessary testing on animals.

ECOPA asked what ECHA does to invite registrants to use new approach methods. ECHA responded that it is in discussions with a number of bigger industries who are looking at different alternative techniques, notably metabolomics and bioactivity. It was mentioned that there are some promising results with these approaches.

Cruelty Free Europe asked whether ECHA shares information with the US National Toxicological Program (NTP). ECHA replied that it collaborates and shares data also with NTP on specific projects, but that it could discuss further ways to collaborate.

Cruelty Free International also asked about a new vacancy at ECHA on new approach methods. ECHA explained that the post will contribute to the ongoing work on the development of new approach methods and will be a temporary contract (like all contracts at ECHA).

## ECHA's approach to managing requests for *in vivo* tests for registered substances

Wim De Coen (ECHA) gave an overall context for the topic by briefly discussing ECHA's recently adopted action plan with the European Commission to improve compliance of REACH registration dossiers. The action plan increases the compliance check target from 5 % to 20 % of the registration dossiers, and has 15 actions over 5 different areas. One of the main actions is to increase the evaluation outputs.

ECHA regularly updates the dossier evaluation status web page so that registrants can follow to see whether their substances are under compliance checking. ECHA also engages with industry sector associations, so that the relevant associations can alert their members to look into their dossiers and come forward with a testing strategy.

ECHA tries to engage with the registrants continuously, but once the compliance process starts on a substance, by law, ECHA has no discretion: if a data gap is identified, it instructs the registrants what they have to do to bring their dossier to compliance.

ECOPA asked about compliance decision letters that are sent by ECHA to registrants, in particular, whether it would be possible to refine the letter to highlight even more clearly the need to first apply any possible means to fulfil the requirement without vertebrate animal tests, and only if not possible, to move to an *in vivo* test. ECHA responded that,

when a non-compliance is spotted, ECHA explains in full detail for example why a read-across has failed, why a structural similarity may not be appropriately described, why exclusion or inclusion criteria are missing, and why a final hypothesis has failed. All this information is available for the registrant if they wish to improve their read across and to come back with a new adaptation instead of performing a test. It was also highlighted that ECHA has made lots of support material available on this topic. It was stressed that it is the responsibility of the registrant to define their testing strategy and that ECHA is not in a position to do that on behalf of the registrant. According to ECHA, a number of registrants are in fact applying read-across and are coming back with improved adaptations following the compliance process.

Cruelty Free International also flagged to ECHA that some stakeholders might have concerns over the revision of the REACH annexes, which is now under a commenting period following CARACAL – the meeting for competent authorities for REACH and CLP.

Humane Society International requested for more flexibility in the process to give companies more time to bring their adaptations into compliance, particularly those who registered before the Read-across assessment framework was published by ECHA in 2016. ECHA responded that all the support material has been available for companies for years to make sure their registration dossier is up-to-date and compliant. It was also mentioned that ECHA engages with sectors to encourage companies to revisit their dossier to make sure they are compliant. Over 100 Cefic members have signed this agreement and there is ongoing work with Concawe as well.

## 2. Nanomaterials

### Revised REACH annexes for nano forms

Mercedes Viñas highlighted that the REACH annexes have been updated with specific information requirements for nano forms of substances and that the deadline for compliance is 1 January 2020.

Wim De Coen then summarised what ECHA is doing in the run up to the deadline to support registrants. ECHA is currently updating the *Guidance for nanoforms and the Guidance on grouping and read-across for nanoforms* in light of these new information requirements. The guidance will be published still in 2019. ECHA has also organised a webinar and held workshops and bilateral discussions with industry associations and registrants who have raised specific questions.

Compliance checking after the deadline will start from those substances, which have been flagged to be of concern, i.e. those that are included in the community rolling action plan and which have nano form characteristics.

The European Union observatory on nanomaterials (EUON) is the main channel for information on nano activities, including substances that are registered with nano forms. It was also highlighted that the information on dossier updates on these substances with nano forms is available through this website.

PETA International asked for more detail on the guidance updates. ECHA responded that it will update the existing guidance for human health and environmental information requirements during 2020. The human health part is expected to be provided for consultation in the first quarter of 2020, and the update of the environment part will start towards the second quarter of 2020. For both updates, the nanomaterials expert group will be involved. ECHA also highlighted that the role of the nanomaterials expert group will change to support all the regulatory aspects of nanomaterials.

European Environment Bureau expressed a concern that the updated guidance arriving so close to the deadline could be used as a reason for not meeting the deadline. ECHA replied that we believe there is enough support material and guidance available for companies to be able to register a nano form of a substance. ECHA also mentioned that it has emailed approximately 3 000 potential registrants of 300 substances, which are listed in the EUON as potentially existing in nano form in the EEA market, with the purpose of encouraging the registrants to look into their portfolio to see whether they, in fact, have substances in nano form and proceed with updating their dossiers.

## 3. Risk Management

### Chemicals universe: mapping registered substances

Jonathan Kuster (ECHA) gave an update on ECHA's chemical universe project, which is a mapping tool to support authorities' work related to the risk management goals. The tool helps to build a view of the planned, ongoing and completed regulatory action for each substance registered under REACH and to visualise the ongoing and remaining work.

In early December, ECHA will publish a list of all the REACH registered substances, divided into five pools:

1. Regulatory risk management ongoing (e.g. Candidate List)
2. Regulatory risk management under consideration (e.g. proposed for restriction)
3. Data generation (e.g. substance under evaluation)
4. Currently no further action proposed (review took place, no action proposed)
5. Not yet assigned (not yet reviewed)

The aim is to contribute to better transparency and increased visibility for all stakeholders.

European Environmental Bureau mentioned that the reference to "low priority" for substances for which currently no additional regulatory actions are expected to be identified could be misunderstood as the substance being of low hazard, though risk management actions could be under way for the substance. ECHA clarified that the pools are displayed according to priority for further action (low and high), i.e. what is meant in this context is low priority for additional regulatory action at this point in time. This will be stressed in ECHA's communication.

## 4. AOB

### Future of the NGO-ECHA platform

Mercedes Viñas summarised the results of a survey run over the summer with the NGO participants on the usefulness, frequency and content of the NGO-ECHA platform. The conclusion is that the platform is found useful and should therefore be maintained. With regards to frequency, it was highlighted by the participants that twice a year would be a good frequency for the platform.

It was also mentioned by one of the participants that the definition of NGO could be reconsidered for the future platform meetings to make the discussions more useful. ECHA clarified that the intention of the platform is to engage with organisations representing the interests of civil society and environment. ECHA promised to reflect on this and come back before the next platform meeting.

# Annex I – Meeting agenda

**17:00–17:30 Animal welfare**

- ECHA update on new approach methods
- ECHA's approach to managing in vivo studies for registered substances
- Discussion

**17:30–17:50 Nanomaterials**

- Revised REACH Annexes for nanoforms
- Discussion

**17:50–18:15 Risk Management**

- Chemicals universe: mapping registered substances
- ChemSec SIN List update (cancelled)
- Discussion

**18:15–18:30 AOB**

# Annex II – Presentations

Mapping the chemical universe