NGO-ECHA dialogue
Meeting note

Time: 12 November 2020, 14:30–16:00 Helsinki time

Place: Online

Participants:

NGO Representatives: Apolline Roger, Hélène Duguy, 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; Gilly Stoddart, Julia Baines, Emily McIvor, Samantha Saunders, Erik Prochazka, PETA, International Science Consortium; Dorota Napierska, HCWH, Health Care Without Harm Europe (HCWH); Michela Vuerich, The European consumer voice in standardisation (ANEC); Natacha Cingotti, Health & Environment Alliance (HEAL); Kristina Wagner, European Coalition to End Animal Experiments (ECEAE), Animal Welfare Academy

ECHA: Jukka Malm (Deputy Executive Director – Meeting chair); Frank Buchler, Bo Balduyck (Governance, Strategy and Relations); Elina Karhu, Jonathan Kuster and Hannu Braunschweiler (Prioritisation), George Cartlige (Hazard III); Tomas Szobanski (Computational Assessment); Jutta Frick, Satu Kimmo and Nerija Jukniute (Communications).

1. Welcome

Jukka Malm (ECHA) opened the meeting by welcoming everyone to the virtual meeting of the NGO dialogue. The agenda was reviewed and adopted as circulated.

2. EU's new Chemicals Strategy for Sustainability and ECHA's role

Bo Balduyck (ECHA) presented the new Chemicals Strategy for Sustainability in the context of the Green Deal and reflected on ECHA's role foreseen. He also drew attention to a joint position paper of EFSA and ECHA published in October 2020: In support of the EU chemicals strategy for sustainability: One substance – one assessment

Frank Buchler (ECHA) noted that the Chemicals Strategy is addressed to the EU institutions, not ECHA: the Commission may request ECHA to support the implementation and the resourcing of such additional work will be a challenge. In general, the initiative is with the Commission. ECHA needs to be prepared to de-prioritise certain activities, to be able to adjust and meet the demand raising from the Chemicals Strategy.

Questions and answers

Jukka Malm (ECHA) thanked for the questions sent in advance and invited participants to join the discussion.

European Consensus Platform for Alternatives asked about the **open platform for accessing relevant academic data** and why is that limited to academic data. ECHA

explained that this is an initiative of the European Parliament and the feasibility study on data needs is ongoing; broader data is concerned, not limited only to academic data.

ClientEarth asked **a) to what extent ECHA may refuse to take the tasks given by the Commission and b) how ECHA is contributing to the revision of REACH**. ECHA explained that the Agency carries out the tasks requested by the Commission but expects for new tasks coming from legislative initiatives to be allocated appropriate resources. ECHA further clarified that the Agency contributes to the decision- making process via regular reporting - the next 5-year report on the operation of REACH regulation is due in June 2021.

The European consumer voice in standardisation (ANEC)) asked about the **approach to risk management and prioritisation**: will restrictions be imposed only via REACH or whether there will be changes also in the product legislation. ECHA responded that it will be up to the Commission to decide which regulation is the most effective for tackling certain products. ECHA added that a proposal for a new sustainable products regulation is coming from the Commission next year.

Humane Society International asked about **one substance on assessment and ECHA's role in reducing animal testing**. ECHA clarified that it is too early to comment on that, no deep discussions yet how to better coordinate this between different scientific agencies: a lot of work on the plate to make this principle apply in practice.

Further questions from animal welfare organisations:

ECHA's view on point 106 of the European Parliament's Resolution on the Chemicals Strategy for Sustainability: ECHA said that it welcomes that part of the resolution - it highlights the sustainability of ECHA's work and resourcing. ECHA added that the Agency's role in relation to alternatives to animal testing is clarified in the legislation. When talking about resources, ECHA said that it is more important that the Agency's staff is up-to-date on the development in the regulatory science and alternatives, instead of having separate dedicated staff working on alternatives.

What is the role of ECHA in moving away from the animal testing? ECHA clarified that a strategy is a political agenda that needs to be designed into concrete tasks. According to ECHA, in the strategy, innovation is strongly related to research and development. ECHA continues to monitor what is happening in the science and how to incorporate it into regulatory decision making.

The use of NAMs to support the 'sustainable-by-design' concept. How will ECHA take this into account? ECHA said that the strategy is rather broad in terms of development of sustainable products, it is to be seen whether ECHA will be asked to do more. ECHA is already working on NAMs and tries to promote it in priority setting and screening; ECHA keeps on communicating to the stakeholders, including industry, hoping that they can take information into account in early product development.

Founding regulation for ECHA: ECHA said that a founding regulation could help in establishing a more coherent governance and funding for the agency, as ECHA is now working on more tasks than defined initially under REACH.

'Horizontal proposal for reallocation of EU technical and scientific work on chemicals to the EU agencies'. What EU technical and scientific work on chemicals is expected to be reallocated to ECHA, if any? ECHA responded that the Agency is waiting for more details on that and in the strategy this could be interpreted

that the Commission is looking into ways how to centralise certain assessments to fewer bodies to make the decision making more efficient.

3. Grouping of chemicals

Jonathan Kuster (ECHA) talked about the grouping of chemicals: why the grouping is done and how, and what is the progress made so far. Grouping is central in achieving the goals of the Integrated Regulatory Strategy, helping to identify substances of potential concern and initiate adequate regulatory action as quick as possible. Good progress is made in this regard and the results after ca. 1,5 years of working with this new approach are positive: speeding up the chemical universe mapping, identifying (groups of) substances for regulatory action and identifying substances without current need for further EU regulatory action.

ECHA's integrated regulatory strategy - check our new infographics

Questions and answers

ClientEarth asked **a) about other types of grouping applied to complement the approach and b) criteria helping to define the need for regulatory action**. ECHA responded that grouping structurally similar substances ensures that potential substitution candidates are included in the group from the start, to ensure that such substances are considered for relevant regulatory actions. Other aspects like use or function, as well as exposure potential, are considered additionally and play a role when prioritising groups for further work. Regarding the decision whether to initiate regulatory actions or not, ECHA further clarified that this decision remains with the respective regulatory processes.

Further questions from animal welfare organisations:

Grouping process and reducing animal testing / Does ECHA expect more or less animal testing to occur as part of hazard assessment that will result from the proposed grouping approach will be reduced? ECHA responded that the objective of REACH is to promote alternatives to animal testing and testing is identified as the last resort; the aim of grouping is to address the larger number of chemicals quicker, so that hazards are sufficiently understood, and regulatory actions can be taken faster. According to ECHA, the process allows to pool all available information so that there is no need to generate information for all substances individually.

UVCBs and relevant information requirements: ECHA is looking into UVCBs but it is not limited to those – also mono- and multi- constituent substances may be of concern due to constituents or impurities.

Grouping and nanomaterials: ECHA clarified that with the grouping approach ECHA is not differentiating nanomaterials, nanomaterials guidance for registration is being prepared.

4. AOB

More questions received beforehand from the animal welfare organisations were addressed under AOB.

Exposure-based waiving / acceptance of exposure-based adaptations (EBAs) to

standard information requirements. ECHA explained that a) future polymer registration requirements are under discussion at the CARACAL subgroup (outcome to be seen) and b) current EBA process is working in accordance with REACH Annex XI and ECHA Guidance. ECHA said that vast majority of unsuccessful adaptations are due to registrants being far from meeting the legislative requirements.

'Cocktail effects': what are ECHA's thoughts on possible solutions for the implementation of the mixture assessment factor? ECHA responded that it is too early to say more about this: it is one of the options that industry will may have to adapt their CSA but probably not the most likely one they will follow in many cases.

How does ECHA explain EFSA undertaking significant attempts for replacement of animal experiments, having a comparable mandate to ECHA? ECHA said that it cannot speak on behalf of ECHA but ECHA is doing already a lot of work: ECHA is covering wide spectrum of activities from contribution to OECD test guideline development program, and DA development through setting up the reporting standards for NAMs (like active contribution to OECD working groups on Transcriptomics and Metabolomics Reporting formats), development of the tools and methods (like QSAR Toolbox, Reach datasets) to exploring the possibilities for new applications of NAM/Alternatives in the future (APCRA) in the context of higher tier endpoints. ECHA amended that all these activities are complemented with online trainings, dedicated sessions on major scientific and regulatory events and other support materials (practical guides and illustrative examples) on proper use of adaptations.

Humane Society International reflected on **EFSA's and ECHA's actions in promoting alternative testing**. She said that ECHA could do much more on the strategic level to promote alternatives and could clearly set the goals and milestones. ECHA referred to above and took note of the expectation.

Updated figures – particularly figure 14 – from the ECHA Article 117(3). ECHA clarified that the report was updated and the updated figures sent to interested NGOs by email on 3 November.

In closing the meeting Jukka Malm noted that NGOs is a very important group of stakeholders for ECHA and thanked everybody for their participation. The next meeting will take place in 2021.

Annex I – Meeting agenda

14:30 – 14:45 **Welcome**

Jukka Malm, ECHA

14:45 – 15:15 **EU's new Chemicals strategy for Sustainability and ECHA's role**

- *Frank Buchler* and *Bo Balduyck, ECHA*
- Discussion

15:15 – 15:45 **Grouping of chemicals**

- *Elina Karhu* and *Jonathan Kuster, ECHA*
- Discussion

15:45 – 16:00 **AOB**

Annex II – Presentations

Presentations available here.