10 December 2015

Platform for NGO-ECHA discussions
Meeting note

Time: Thursday 10 December, 16:00 – 17:30 Helsinki Time (EET, GMT+2)

Place: Meeting room K325, European Chemicals Agency

Participants:

NGO Representatives: BAINES Julia (Peta International Science Consortium – PISC*); BUSQUET Francois (European Consensus Platform for 3R Alternatives to Animal Experimentation – ECOPA*); HYNES Jarlath (Humane Society International - HSI); HÖK Frida (International Chemical Secretariat – ChemSec*); REINEKE Ninja (Chemicals, Health and Environment Monitoring Trust – CHEM Trust*); ROVIDA Costanza (European Consensus Platform for 3R Alternatives to Animal Experimentation – ECOPA*); SANTOS Tatiana (European Environmental Bureau – EEB*); STODDART Gilly (Peta International Science Consortium – PISC*); TAYLOR Katy (European Coalition to End Animal Experiments – ECEAE*); VAN VLIET Lisette (Health and Environmental Alliance – HEAL).

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); Jukka MALM (Deputy Executive Director); DE BRUIJN Jack (Director for Risk Management); HERDINA Andreas (Director of Cooperation); JACKSON Lindsay (Head of Unit, Communications); VAINIO Matti (Head of Unit, Risk Management Implementation); ELWAN Adam (Communications Unit); BRÄUTIGAM Tiiu (Communications Unit*).

** Attended remotely*

1. Risk management

Substitution

ECHA is involved in several activities to help gain a "bird's-eye view" of how the assessment of alternatives for substances of very high concern (SVHC) is being carried out. VAINIO Matti (MV) explained about a joint project with Dr. Joel Tickner from the University of Massachusetts Lowell who will pick real cases from the authorisation and restriction processes and draft a report on how the assessment of alternatives is being carried out in the EU regulatory environment, compared to the U.S. approach. The final report is due to be published during the summer of 2016, potentially during a workshop organised by ECHA and the OECD from 6 to 8 July. The workshop covers how regulatory impact assessment is being carried out globally, with a focus on cost-benefit analysis.

MV explained that the report has gained interest from several Member States and there is a steering group coordinating the work. MV invited any of the interested participants to join the steering group.

ECHA is planning to organise webinars on substitution in 2016. However, the number and topics are still under discussion and need to be prioritised with other topics such as REACH 2018.

Participants asked whether ECHA has plans to make already existing information about

alternatives and successful substitution cases more accessible. MV explained that the information is already published on the ECHA website, although not in a structured database which would be very time-consuming to produce. ECHA is aware of the benefits such a database would bring and is considering it in its long-term planning, most likely for after 2016.

Action points:

- ECHA will inform participants how they can sign up for the steering group working on the report on alternative assessment in the EU
- ECHA will inform participants once the topic(s) and number of webinars on substitution for 2016 will be confirmed in January
- ECHA will send the feedback report of the first webinar on substitution that took place in September to the meeting participants

Public consultations

MV explained that a document has been submitted to the ECHA Management Board in December, covering all public consultations and summarising why and how they are done for different processes. The document also covers what works and what could still be improved in terms of the process for collecting and making the input they provide more accessible to ECHA's audiences. ECHA is also looking for best practice and benchmarking from other Agencies and stakeholders on how to improve the process.

Participants explained that a structured database where all consultations and respective comments could be found and searched by external audiences would be very useful. They suggested a more proactive approach to promote the individual consultations through for example social media, advertising in sectoral magazines and reaching out to new accredited stakeholder organisations that are not yet represented in ECHA's work. They also asked that ECHA does more research for each substance to determine the actual uses and companies producing and supplying potential alternatives to target communications about public consultations directly to them.

Action points:

- ECHA will look into improving the format of the public consultations in the regular news products (e-News, Stakeholder Update and website) to see if they could be presented in a more accessible and visible way
- ECHA will look into using social media to reach out to new audiences for public consultations, for example through paid advertising
- ECHA will collect suggestions for improving the public consultation process, for instance through the Accredited Stakeholder Workshop in October 2016
- Stakeholder participants invited to share good examples of public consultation practices with ECHA

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Benefits of REACH

MV explained that from a risk management perspective, ECHA is planning to carry out the following two studies:

1. **Meta-analysis of restrictions**
   Overview of restriction cases to derive aggregates for costs and benefits. A draft report of the findings will be presented in the upcoming workshop on restrictions organised in Brussels in January

2. **Authorisations**
   A meta-analysis of the benefits and health risks of authorisations

Participants discussed a study being carried out by the European Commission on the benefits of the chemicals legislations and MV explained that ECHA's planned work will complement a part of the Commission's study.

2. Alternatives to animal testing

Follow-up of Ombudsman cases

ECHA gave a short update on the follow-up of two EU Ombudsman cases, the first on compliance check from 2014[1] and the second on testing proposals from September 2015[2].

Participants voiced concerns over the template for considerations of alternatives to a testing proposal to be used by registrants which they thought is essentially a checklist. They expressed interest to have more leading questions and to signpost specific endpoints for registrants with the need to justify their proposal in more detail. LYM explained that NGOs are welcome to send comments also on the template, before it is implemented in IUCLID. Participants also asked ECHA to consider a paid scientific advice service where registrants could contact ECHA for guidance on filling in their IUCLID endpoints, a similar service already offered by the European Medicines Agency (EMA).

Action points:

- ECHA to look into the implementation of the testing proposal template in IUCLID, based on comments received from participants (preferably by end of January) and the CARACAL meeting in March

- ECHA to consider whether offering a paid scientific advice service for registrants could be a future possibility

Promoting alternative methods to animal testing

ECHA gave an update on the planned actions for promoting alternative methods in 2016 which resulted from the shared recommendations of the 2015 Accredited Stakeholder

[1] 1568/2012/(FOR)AN – Compliance check, animal testing
[2] 1606/2013/AN – Animal testing, alternative methods

Workshop[3] that took place in October. The recommendations were to simplify and streamline guidance on alternative methods for REACH 2018 registrants, target consultants and inform them about alternatives and to ensure ECHA staff is up-to-date with the latest scientific methods.

LYM explained that guidance updates were on-going and the deadline for their implementation is in mid-2016. In addition, a workshop on new approach methodologies in regulatory science[4] will be organised by ECHA in April where new methods will be further discussed. She continued with examples of how ECHA staff were being trained and kept up-to-date on the latest methods which included various scientific events, working groups and journals.

Participants explained that the guidance ECHA is preparing for registrants, may also be relevant in other fields such as occupational health and that these should also be considered when making updates. They also suggested that ECHA should encourage registrants to use in vitro methods for justifying read-across or grouping, for ECHA to validate and use test methods approved by the Toxic Substances Control Act (TSCA) and to participate in the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) staff meeting in October 2016 to keep up-to-date with the latest developments. ROVIDA Costanza (CR) highlighted another workshop being planned by the European Commission in November 2016 on the development of scientifically valid non-animal approaches.

Action points:

- ECHA to update all accredited stakeholders about the follow-up of the shared recommendations of the 2015 Accredited Stakeholder Workshop in upcoming issues of the Stakeholder Update news bulletin. A report back on all follow-up actions will be presented in the 2016 Accredited Stakeholder Workshop
- CR to send further information about the workshop on the development of scientifically valid non-animal approaches to ECHA

3. AOB & agenda setting

Action point:

- ECHA to approach participants for topics and timing of the next meeting at the start of 2016

[3] Accredited Stakeholder Workshop - proceedings
[4] Topical Scientific Workshop – New approach methodologies in regulatory science

Seventh meeting of the NGO-ECHA discussion platform
Meeting note

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Annex I – Meeting Agenda

Date & Time:
Thursday 10 December
16:00 - 17:25 Helsinki Time
Location: Meeting Room K325

16:00 – 16:05 **Opening of the meeting**

16:05 – 16:35 **Risk management**
- Update from ECHA
- Discussion

16:35 – 17:15 **Animal Welfare**
- Follow-up of ombudsman cases
  Leena Ylä-Mononen, ECHA
- Promoting alternative methods to animal testing
  Leena Ylä-Mononen, ECHA
- Discussion

17:15 – 17:25 **AOB & Agenda setting**