25 April 2017

Platform for NGO-ECHA discussions
Meeting note

Time: Tuesday 25 April, 15:30 – 17:15 Helsinki Time (EEST, GMT+3)

Place: Meeting room K325, European Chemicals Agency

Participants:

NGO Representatives: BERNARD Alice (European Environmental Bureau – EEB)*; FASSBENDER Christopher (Peta International Science Consortium – PISC)*; HYNES Jarlath (Humane Society International – HSI)*; HÖK Frida (International Chemical Secretariat – ChemSec); LOONEN Helene (European Environmental Bureau – EEB); MORGHENTI Daniela (European Federation of Allergy and Airways Diseases Patients' Association – EFA)*; ROMANO Dolores (European Environmental Bureau – EEB)*; TAYLOR Katy (Cruelty Free International).

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); BALDUYCK Bo (Executive Office); BRÄUTIGAM Tiiu (Communications Unit); DE BRUIJN Jack (Director of Risk Management); ELWAN Adam (Communications Unit); KORJUS Pia (Evaluation Unit); REGIL Pablo (Risk Management Implementation Unit); VAINIO Matti (Risk Management Implementation Unit).

** Attended remotely*

1. Animal welfare

Article 117(3) report on alternatives

Leena Ylä-Mononen (LYM) explained that the report will be published on 1 June and is in line with the messages, scope and style of previous reports. As a new element, the report now also includes data on lower tonnages.

Katy Taylor (KT) expressed particular interest in numbers of new animal tests and use of *in vitro* methods. LYM confirmed that this data will be available in the report.

ECHA's Report on the Regulatory Applicability of Alternative and Non-Animal approaches

LYM gave an overview of what the report will include and its scope. She acknowledged collective letters written by stakeholders questioning the need for the report and raising concerns about its tone and level of detail. In particular, concerns about the report giving an overly negative view on the availability of alternatives where they already exist. LYM explained that the report, commissioned by ECHA's Management Board, hopes to induce further discussion and development of the applicability of alternative and non-animal approaches where deficiencies exist. LYM assured that ECHA staff will still review the report based on stakeholder comments before publishing it by the end of 2017.

Action point

- ECHA to follow-up with responses to stakeholder concerns and comments and inform them of subsequent drafts before publication

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EOGRTS testing proposals

LYM explained that exact timelines for draft decisions for testing proposals for the extended one-generation reproductive toxicity study (EOGRTS) are not yet available. The REACH Committee is expected to vote on the decisions during the summer and registrants will have up to a further 3 months to act. The resulting dossier updates are still expected in the last quarter of 2017. ECHA has shared the list of 216 cases with Katy Taylor (KT) who was asked to share it with her network and the other NGO participants.

KT asked whether the justification form could be altered to include information on how registrants have justified their study design. LYM explained that documenting alternative considerations has been fully implemented in IUCLID 6 and it is no longer feasible to change the template in view of the 2018 registration deadline. However, registrants have been informed through guidance and other means that conclusive study design justifications should always be included with testing proposals.

Action point

- KT to share list of 216 cases with other accredited stakeholder NGOs

Update on the follow-up of the European Ombudsman decisions on compliance checks and testing proposals

LYM explained that discussions were still pending between ECHA, the Ombudsman and NGOs on whether ECHA could reject testing proposals where the considerations provided were not accurate.

The first two pilot compliance check decisions are currently at the follow up evaluation phase and the 117(3) report will include a summary of them. ECHA will follow-up the overall learnings from the pilots in CARACAL in June.

KT asked whether any follow-up of ECHA's survey to registrants who had carried out tests without submitting testing proposals would be done. She was particularly interested if Member States had carried out any enforcement actions in response to the recommendations made by the report. LYM explained that the feedback from Member States had been compiled in a report to be consulted by the Enforcement Forum and published[1]. The 117(3) report would also refer to these results.

Skin sensitisation: ECVAM Recommendations on Defined Approaches

JH gave an overview of the soon to be published ECVAM report. He asked whether ECHA would inform registrants of the recommendations and how to best do this. LYM agreed to follow-up on most appropriate way for ECHA to pass the information to registrants.

Action point

- ECHA to check how to best communicate the ECVAM recommendations to registrants

[1] Reports from Member State investigations concerning the obligation to submit testing proposals for vertebrate animal tests under REACH

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2. Transparency

NGO involvement in specific groups and collaborative work

Jack de Bruijn (JDB) explained that the expert (PBT, ED) and sector groups (PETCO) were open to NGO participants and that summaries of each meeting were published on the ECHA website. He explained that efforts are being made by ECHA to keep topics in open sessions but in some cases, Member States preferred to keep parts of the meetings closed.

Frida Hök (FH) questioned the efficiency and the need for expert groups explaining that they could often become bottlenecks for concluding on certain substances. JDB explained that the groups are found useful by Member States and almost always help to draw conclusions on cases. He acknowledged that ECHA could do more to explain what the groups were discussing and their outcomes.

FH expressed concern over the amount of groups versus the limited resources of NGOs to attend them. She reiterated the benefit of producing good, concise summaries for NGOs to follow and be alerted.

Action point

- ECHA to start communicating outcomes from the various groups in the Stakeholder Update

LYM gave a short update on the collaborative approach pilot discussed also in the March CARACAL. She highlighted an online meeting targeted at registrants whose substances have been flagged for follow-up actions by Member States. The meeting would identify whether registrants are willing to collaborate with Member State competent authorities, ECHA and other registrants on groups of substances to bring faster results and more insightful conclusions. She welcomed NGO stakeholders to join the meeting.

Action point

- ECHA to send invitation to online meeting to participants

NGO access to Conflict of Interest Advisory Committee (CoIAC)

Bo Balduyck (BB) gave an introduction to the topic explaining that CoIAC was set up as an internal body to give advice to the Executive Director, Committee Chairs and members of the Management Board. Alice Bernard (AB) asked whether NGOs could also have access to the CoIAC to increase stakeholder confidence in ECHA's transparency and to be able to consult the CoIAC before sending formal letters directly to the Executive Director. BB explained that the current mandate of CoIAC does not allow for direct external consultation. NGOs can still raise any questions about potential conflicts of interest to the Committee through their representation in the Management Board.

Dolores Romano (DR) expressed the need for more transparency in the activities of Committee members. She explained that their declarations were often insufficient. LYM reiterated that transparency is very much a core value of ECHA and the feedback received would be considered carefully.

3. Risk management

Improving alternative provider considerations in SEAC opinions

FH explained that in a recent case, the ECHA Committee had sent an opinion to the Commission where alternative providers were not taken into account.

Pablo Regil (PR) explained that in general but also in this specific case alternative providers that provided comments were brought in contact with the applicant as part of the trialogue discussion and members of the Committee also challenged the draft opinion with possible alternatives. However, when the applicant was asked to document that they had considered the alternatives, it showed that the specifications of the proposed alternatives did not meet the requirements of the applicant.

NGO participants concluded with a request to see more progress and actions from ECHA in finding and involving alternative providers in the application process. LYM explained that ECHA is open to developing new ways of reaching out to alternative providers and hopes that together with stakeholders, this on-going development work can continue.

4. Information requests under substance evaluation

Three-step process developed in A-005-2014[2] Board of Appeal case

Pia Korjus (PK) explained how ECHA has been following-up the Board of Appeal (BoA) decision. She explained that ECHA prepared a template for Member States for substance evaluation draft decisions with subheadings per endpoint to help them address all the points of the BoA decision.

Christopher Fassbender (CF) referred to BoA case A-004-2015[3] on MHHPA compliance check decision where the appellant was asked to perform 90-day study. According to CF, the scientific case against performing the tests was strong and he said the three-step process developed in the previous BoA case should have been applied. The NGO participants concluded that ECHA should apply the three-step process to every evaluation case. LYM clarified that the BoA decision A-005-2014 is not directly applicable to dossier evaluation decisions and that ECHA still abides by the "animal testing as a last resort" and 3Rs principles in all its decisions. LYM concluded that the decision-making system involving the Member States is in place to challenge any omitted information or aspects.

5. AOB & agenda setting

JH followed-up on data sharing with third countries from the previous platform meeting. He asked whether ECHA would be willing to participate in discussions with Korean regulators and industry to develop guidelines for Korean industry for using data from REACH for their own regulation. LYM asked for more information about the level and means of expected involvement from ECHA before being able to commit. She also mentioned that the Commission would need to be informed and suggested NGO actions towards more international bodies such as the Strategic Approach to International

[2] A-005-2014 Decision of the Board of Appeal
[3] A-004-2015 Decision of the Board of Appeal

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Chemicals Management (SAICM) meeting.

Action point

- JH to send more details about what is expected of ECHA in discussions with Korean regulators and industry

Participants agreed that the next meeting could take place in the autumn. Adam Elwan (AE) to propose possible dates during the summer.

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Annex I – Meeting Agenda

Date & Time:
Tuesday 25 April
15:30 - 17:10 Helsinki Time (EEST, GMT +3)
Location: Meeting Room K325

15:30 – 15:35 **Opening of the meeting**

15:35 – 16:15 **Animal Welfare**

- Article 117(3) report on alternatives
- ECHA's Report on the Regulatory Applicability of Alternative and Non-Animal approaches
- EOGRTS Testing proposals
- Update on the follow-up of the European Ombudsman decisions on compliance checks and testing proposals
- Skin sensitisation: ECVAM Recommendations on Defined Approaches

16:15 – 16:35 **Transparency**

- NGO involvement in specific groups and collaborative work:
  - Transparency and communication of ECHA expert groups (PBT, ED)
  - Sector groups (i.a. PETCO)
  - Update on collaborative approach pilot (CARACAL follow-up)
- NGO access to Conflict of Interest Advisory Committee (CoIAC)

16:35 – 16:45 **Risk management**

- Improving alternative provider considerations in SEAC opinions

16:45 – 16:55 **Information requests under substance evaluation**

- Three-step process developed in A-005-2014 Board of Appeal case

16:55 – 17:05 **Follow-up from previous meetings**
17:05 – 17:10 **AOB & Agenda setting**
