04 February 2015

Platform for NGO-ECHA discussions
Meeting note

Time: Wednesday 04 February, 17:00 – 19:00 Helsinki Time (EET, GMT+2)

Place: Meeting room 1050, European Chemicals Agency

Participants:

NGO Representatives: BAINES Julia (Peta International Science Consortium – PISC*); HAIDER Sonja (International Chemical Secretariat – ChemSec*); MUSU Tony (European Trade Union Confederation – ETUC); REID Kirsty (Eurogroup for Animals*); ROMANO Dolores (European Environmental Bureau – EEB*); ROVIDA Costanza (European Consensus Platform for 3R Alternatives to Animal Experimentation – ECOPA*); STODDART Gilly (Peta International Science Consortium – PISC*); TAYLOR Katy (European Coalition to End Animal Experiments – ECEAE*); WARHURST Michael (Chemicals, Health and Environment Monitoring Trust – CHEM Trust*); WILKS Susie (Humane Society International - HSI).

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); DE BRUIJN Jack (Director for Risk Management); VAINIO Matti (Head of Unit, Risk Management Implementation) JACKSON Lindsay (Head of Unit, Communications); BALDUYCK Bo (Legal Affairs Unit); BUCHLER Frank (Executive Directorate); CARTLIDGE George (Evaluation Unit); ELWAN Adam (Communications Unit).

** Attended remotely*

1. Opening

The chair, Leena YLÄ-MONONEN (LYM) introduced the participants and the topics of the meeting: Authorisation; Update on ECHA's approach to transparency and Animal welfare.

2. Approach to authorisation

Presentation of key issues

Jack DE BRUIJN (JdB) gave an update on ECHA's topical issues in relation to the applications for authorisation process. He expressed satisfaction on the current state of play and highlighted the upcoming conference on "Lessons learnt on applications for authorisation[1]" where the Commission, Member States and stakeholders discuss and reflect on past experiences. He continued by expressing concern that the NGOs had voiced critical opinions on the application for authorisation process publically without giving ECHA the opportunity to first clarify misunderstandings and align views. He reminded that all parties around the table share the same goal of making the process work.

[1] Conference on Lessons Learnt from Applications for Authorisation

NGO participants provided further explanations to their letter and expressed concerns about the way the authorisation process had started with all applications so far having received a favourable opinion from ECHA. This included chemicals such as DEHP where in their view the opinions had not been adequately prepared and failed to consider viable alternatives. They raised the concern that that such cases would remain as precedents for future applicants, resulting in more applications for authorisation and less pressure for companies to move to safer alternatives.

JdB explained that although the authorisation had been granted for cases such as DEHP, the companies using the chemical are aware that it is a short-term solution and more work will need to be done to either eventually replace them with safer alternatives or provide a sound analysis of alternatives when reapplying for authorisation. He also said that the applicants, ECHA including its committees, the Commission, the Member States and all stakeholders are learning how the authorisation system operates. The first opinions and decisions do not therefore set a precedent.

JdB concluded that the process is still new and both the applicants and the Committees have been on a steep learning curve. When the first applications were made, the applicants were not yet fully aware of the framework in which the Committees would be assessing their application or how the Commission would make their decisions on them but this has now clearly improved.

- NGO participants and ECHA expressed interest to work together to further align views on how to improve the process in the future.

The economic feasibility of alternatives in the authorisation process

Tony MUSU (TM) presented the concerns of NGOs on the interpretation of assessing the economic feasibility of alternatives by the Socio-Economic Analysis Committee (SEAC). He highlighted that in the REACH Regulation there is no definition for economic feasibility or how it should be interpreted. He gave the example of DEHP in PVC articles and HBCDD in flame retardants where in both cases the alternatives were technically available but for DEHP the applicant was not prepared to pay for the increased costs. This resulted in a longer term authorisation of 4 years for DEHP and a bridging authorisation of 2 years for HBCDD. He concluded his presentation with a disagreement with the view of the SEAC that all alternatives which lead to an increase in costs for the applicant are to be judged economically infeasible. According to him, this leads to exaggeration of costs from the applicants, delays the progressive replacement of SVHCs with safer alternatives and reduces the incentive for innovation. NGO participants proposed that in cases where an alternative already exists and is being used in the market, the decision should be that it is economically feasible and an authorisation should not be granted.

Matti Vainio (MV) said that indeed there is a risk that the applicants would exaggerate costs which was also recognised in the note on economic feasibility that SEAC agreed upon after one year of discussions on 31 January 2012[2]. The public consultation as well as SEAC's scrutiny is precisely designed to verify information submitted by the applicants.

2 SEAC note on economic feasibility

MV reiterated the argumentation included in SEAC's note and said that – in the context of the applications for authorisation – it is difficult to see any other interpretation that would also be meaningful. The NGO suggestion to equate "economic feasibility" to "affordability" was discussed during the development of SEAC's note but not considered workable. In summary, it has not been possible to come up with a more operational definition of economic feasibility than what has been currently used by SEAC. NGO's are nevertheless invited to provide further suggestions that could possibly be discussed at future meetings of this forum.

3. Update on ECHA's approach to transparency

Bo BALDUYCK (BB) presented the latest developments in ECHA's approach to transparency and referred to the recent adoption of a policy paper on transparency[3] by the ECHA Management Board in December 2014. He highlighted that transparency has been on the agenda since the start of the Agency and a continuous development of that value has been undertaken. He stressed the importance of maintaining a balance between the rights of third parties and the core values of the Agency. He went on to explain that the new policy paper has been based on three main pillars:

1. Clear explanation of activities and processes;
2. Practice of open decision making;
3. Making information available, in a timely manner.

Accredited stakeholders were involved in the process through the prioritisation of six ideas for improvement which were then grouped into three main recommendations:

1. Extending the dissemination project to decisions taken by the Agency to give a start to finish picture of what is happening to dossiers and substances;
2. Rethinking the website structure and making all ECHA communication clearer;
3. More explanation and information on the processes of the Committees, decision making and reviewing observer and third party involvement.

His presentation concluded with the announcement of a new transparency section on the ECHA website including links to final regulatory decisions taken by ECHA, agenda of the Executive Director, on-going public consultations and plans and reports.

Discussion

The discussions covered the following aspects:

- Further clarification was given about speaking rights in the SEAC and Risk Assessment Committees (RAC) and whether they specifically included discussions on authorisations. The Management Board had agreed to the speaking rights for discussions on authorisation applications. However, the speaking rights were given to ensure consistency and discuss procedural matters, not specific cases.

- The numbers of potential conflicts of interest and how they had been followed-up was also discussed. The annual activity report due to be published in the coming weeks would include a standard section on the implementation of conflict of

[3] ECHA's approach to transparency - policy paper

interest policy. It was also highlighted that the minutes of the Committees include all possible conflicts of interest and the declarations of ECHA management are also publically available on the ECHA website[4].

- Participants said that more could still be done to improve the visibility and linking of alternative methods on the ECHA website. The point was taken up by LYM as a follow-up action for future development of the website.

- Concerns were expressed over the increasing number of written procedures both in RAC and SEAC and having the chance to contribute at an earlier stage. In ECHA's perspective the comment was relevant to the work of all Committees and discussions would continue on how to further develop the processes to give better access and more timely information to observers.

4. Animal Welfare

Follow-up of recent ombudsman decision on promotion of alternative methods

LYM gave an update on two ombudsman cases related to dossier evaluation. The first one is an open case on testing proposals from 2013 and is linked with the case from 2012, concluded in December 2014. The already concluded case dealt with ECHA's duties in the compliance check procedure and the "last resort" principle where animal tests should only be conducted after all other possible options had been exhausted. She informed that a confidential draft conclusion had been received by ECHA from the ombudsman for the 2013 case and that ECHA has until the end of March to provide comments.

She explained that due to the principal issues related to the dossier evaluation process raised in the two cases, a further discussion with the Commission, enforcement authorities and Member State Competent Authorities would have to take place. Regardless of the pending ombudsman case related to testing proposals, ECHA is, as a direct follow-up from the Article 117(3) report[5], actively following up with Member State enforcement authorities on cases where testing is potentially being carried out without testing proposals. Feedback on the proposed approach from the 15 Member States concerned is being sought for and the issue will also be further discussed at the next Enforcement Forum meeting in March.

Progress with guidance and web updates for skin and eye irritation, skin sensitisation and reproductive toxicity

Skin and eye irritation

George Cartlidge (GC) informed participants about the progress for updating the guidance on skin and eye irritation. He explained that the previously published guidance on skin and eye irritation was discussed during a Partner Expert Group (PEG) meeting in November 2014 and had been revised based on those discussions. The next steps involve a consultation with the Member State Committee (MSC), RAC and the Competent Authorities for REACH and CLP (CARACAL). ECHA expects to publish the updated

[4] ECHA website – independence and transparency in decision-making
[5] The Use of Alternatives to Testing on Animals for the REACH Regulation

guidance before the summer of 2015 together with an update of the test methods web pages where the test methods and their uses are put into context and further explained.

Skin sensitisation

GC went on to explain that the updating of the guidance on skin sensitisation had already started with a PEG consultation planned for the summer of 2015 and with a target publication date in summer 2016. Three new non-animal test methods make up the integrated testing strategy and IATA for skin sensitisation. ECHA is anticipating publication of two of the new test methods, the Direct Peptide Reactivity Assay (DPRA) and KeratinoSens, which have been recently adopted by the OECD. Regarding the human Cell Line Activation Test (hCLAT), ECHA is waiting for confirmation from the European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM) before moving ahead with updating the test methods webpages soon after. The ECVAM recommendation is expected as early as February 2015. The skin sensitisation workshop will be hosted at ECHA in April and the report of the workshop about 6 months later may also raise awareness of the new skin sensitisation approach.

Reproductive toxicity

LYM explained that the REACH Annex VIII, IX and X changes to incorporate the EOGRTS test guideline had already gone through the voting committee in September 2014 and adoption of the changes for the Annex was pending in the Commission. The respective guidance update is also ongoing. Some information about the upcoming changes have been published on the Commission website[6] and ECHA plans to issue an e-News item in the coming weeks to raise awareness of the changes to registrants planning to submit testing proposals for these cases.

- Participants agreed that the continuous promotion of the use of in vitro tests and other alternative or refined methods for REACH purposes should continue in order to support the last resort principle.

Discussion

The following points were raised:

- Susie Wilks (SW) raised concerns that the existing guidance was severely out of date and that the guidance update process was taking a long time, particularly in view of the REACH 2018 registration deadline for which companies are already planning their testing strategy and may already start testing in 2016. LYM explained that ECHA will for example use written procedures for guidance updates where possible to save time.

- SW went on to question if the test methods web pages could still be updated together with a disclaimer and asked if there were any other ways of flagging to REACH 2018 registrants about the new methods and their uses before they have been formally adopted. LYM explained that the ECHA news products such as the Newsletter and e-News are an ideal vehicle for raising awareness about alternative methods. Lindsay Jackson (LJ) proposed to carry out interviews during an upcoming workshop organised by the European Partnership for Alternative

[6] European Commission – REACH implementation

Approaches, CEFIC and Cosmetics Europe in April 2015 for publication in the Newsletter. The workshop will discuss among others, how to develop skin sensitisation testing with a plan to produce a report with recommendations within 6 months of the event. ECHA would aim to publish the interviews together with the updated test guidelines web pages to generate a more comprehensive package and more interest.

- Gilly Stoddart (GS) asked about ECHA's position on the test guidelines for the fish embryo test which was already adopted in 2013 and wondered when ECHA guidance would be updated. LYM explained that the topic is under discussion in ECHA's internal regulatory science group where a project had been set up to analyse the applicability of the method under REACH. The aim is to conclude on this swiftly after which the normal guidance update procedure will be initiated.

- SW raised an issue which was presented at the previous MSC meeting concerning testing proposal updates and how the timelines could be expanded in cases where vertebrate animal testing was involved. LYM explained that in case of complex testing proposals relying on category or read-across adaptations, more time than the now regular 30+30 days can be granted, on the registrant's request, to improve the testing strategy based on the feedback given in the ECHA draft decision. With regard to compliance checks, ECHA no longer takes any dossier updates after a draft decision has been issued into account before proceeding to decision-making. However, informal interaction still takes place and ECHA gives a detailed explanation for the rationale of the decision. ECHA decisions are now also more explicit in explaining to the registrant that they can comply with the decision by opting for adaptations, provided that they are in line with Annex XI requirements. Some cases where registrants have made good adaptations and avoided unnecessary animal testing have already been concluded in follow-up evaluation.

5. AOB and Agenda setting

Meeting participants agreed that more meetings could be held remotely and that sufficient time should be dedicated for priority topics. Participants felt that at least one face-to-face meeting a year would still be useful although pairing them with the MSC was not ideal as NGO participants may miss agenda points that overrun. Other events are also possible to use for face-to-face meetings, for example in conjunction with the annual strategic workshop for accredited stakeholders, taking place in Q4. The proposal will be presented to all participants via email where the date and topics for the next meeting would also be agreed.

04 February 2015

Annex I – Meeting Agenda

Date & Time:
Wednesday 04 February
17:00 - 19:00 Helsinki Time
Location: Meeting Room 1050

17:00 – 17:05 **Opening of the meeting**

17:05 – 17:50 **Approach to authorisation**

- Presentation of key issues
  Jack De Bruijn, ECHA
- The economic feasibility of alternatives in the authorisation process
  Tony MUSU, ETUC
- Discussion

17:50 – 18:10 **Transparency**

- Update on ECHA's approach to transparency
  Bo BALDUYCK, ECHA
- Discussion

18:10 – 18:40 **Animal Welfare**

- Follow-up of recent ombudsman decision on promotion of alternative methods
  Leena YLÄ-MONONEN, ECHA
- Progress with guidance and web updates for skin and eye irritation, skin sensitisation and reproductive toxicity
  George CARTLIDGE, ECHA
- Discussion

18:40 – 19:00 **AOB & Agenda setting**

Annex II – Presentations

Click on the images below to open the presentation