Fifth meeting of the NGO-ECHA discussion platform – Animal Welfare, Substitution and transparency
Meeting note

16 September 2014

Platform for NGO-ECHA discussions
Meeting note

Time: Tuesday 16/09/2014, 15:00 – 16:30 Helsinki Time (EEST, GMT+3)

Place: Meeting room K325, ECHA Conference Centre

Participants:

NGO Representatives: MCIVOR Emily (Humane Society International - HSI)* TAYLOR Katy (European Coalition to End Animal Experiments - ECEAE); WILKS Susie (Humane Society International - HSI)*.

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); DE BRUIJN Jack (Director for Risk Management); JACKSON Lindsay (Head of Unit, Communications); BANERJEE Mira (Communications Unit); ELWAN Adam (Communications Unit); VAHTERISTO Liisa (Committees Secretariat); BALDUYCK Bo (Legal Affairs Unit); IBER Andrea (Legal Affairs Unit); BIGI Elena (Legal Affairs Unit).

** Attended remotely*

1. Opening

The chair, Leena YLÄ-MONONEN (LYM) introduced the topics of the meeting: Animal testing related issues: update on cosmetics and REACH, update on the information requirements for second species related to developmental toxicity and the ECHA web page on new OECD test methods. The meeting concluded with an update on working together to promote substitution and ECHA's approach to transparency.

2. Animal Welfare

Update on cosmetics and REACH

Elena BIGI (EB) gave an update on following the CARACAL meeting that took place in April regarding on-going work to clarify the overlaps between the Cosmetics Regulation and REACH.

EB explained that ECHA has internally prepared a fact sheet to clarify the position of the Commission on the implications of the Cosmetics Regulation for animal testing requirements under REACH. The fact sheet was intended as a layman's description of the implications these overlaps have for registrants and public interest groups. In addition, ECHA has developed a more detailed and technical Q&A document intended to guide registrants in entering waivers in their IUCLID dossiers to indicate if their chemical is intended solely for cosmetics use. The content of the fact sheet and Q&A will serve as a summary of the decision taken at the previous CARACAL meeting in April.

The two documents have been under review by ECHA and the Commission but will be made public shortly.

Discussion

The NGO participants raised the following questions and comments:

- Katy TAYLOR (KT) raised questions about the cost sharing aspects for registrants that manufacture or import substances solely for cosmetics use. In particular, whether such a registrant would be exempt from paying for data being generated through tests carried out within a larger SIEF. Andrea IBER (AI) responded that cost sharing would still need to be agreed within the SIEF. Although ECHA's regulatory role does not allow it to interfere in cost sharing discussions, ECHA recommends that registrants adhere to the principle set in the REACH Regulation where registrants are not required to pay for studies that they do not need. Registrants are also encouraged to follow the instructions that will be published in the Q&A to ensure that they know how to insert a waiver for cosmetics use in their dossier to allow for ECHA to properly assess its content.

- Susie WILKS (SW) asked further clarification on how the exposure for workers impacts the information requirements for cosmetics use. EB explained that testing would be required under REACH if the absence of worker exposure cannot be proven by the registrant as the Cosmetics Regulation does not cover worker exposure but only consumer/end-user exposure. SW also asked whether IUCLID would need to be updated to accommodate the new waivers. AI replied that waivers already included in IUCLID would be used for the time being but that the possibility to include specific cosmetics waivers together with standard texts is already being discussed as a possible feature in IUCLID 6.

- KT asked how ECHA's decision-making would be influenced within the evaluation processes with the "sole use" possibility now included for cosmetics. LYM explained that this is a new aspect for ECHA and the evaluation cases so far have generally been mixed-use as opposed to sole-use cases. However, she explained that the first priority for ECHA is to get registrants to start using the waiver correctly to ensure that these cases can be clearly identified, before they are tackled in the appropriate manner in ECHA's dossier evaluation work.

LYM concluded the agenda point by inviting feedback and comments from the NGO participants once the fact sheet and Q&A were published.

Update on testing of second species

LYM gave a brief update on the second species testing requirement on pre-natal developmental toxicity. She explained that for higher tonnage band (over 1000 tn/year)

chemicals, the second species requirement has been confirmed, after a ruling[1] in favour of ECHA's position by the Board of Appeal earlier this year. ECHA will further explain to its stakeholders and registered audiences about the requirement, starting with an ECHA Newsletter article with the targeted publication date of 16 October. The article will summarise the issue by describing its basis and legal interpretation, concluding with the ruling of the Board of Appeal.

Discussion

The discussions covered the following aspects:

- KT raised questions about the timing of the newsletter article and announcement of the second species requirement as the animal welfare NGOs have recently escalated the decision of the Board of Appeal to the Court of Justice. LYM explained that the aim was not to carry out a larger communications campaign but rather to follow-up on the Board of Appeal decision. In line with other similar cases, ECHA does not wait for the ruling of the Court of Justice as it may take a significant amount of time before it is issued. She reassured that if a different ruling would be given, ECHA would adapt its processes accordingly. KT asked that in ECHA's communication about the second species issue, it would be made clear that the second species requirement for Annex IX (100-1000 tn/year) substances is conditional and not standard. LYM assured that this distinction between Annex IX and X would be made.

ECHA webpage on alternatives and new OECD test methods

LYM gave an update on ECHA's webpage on alternatives and new OECD test methods[2] published in the spring. She explained that ECHA received a lot of positive feedback after its publication for making information on alternative methods more easily accessible to registrants. Nevertheless, she explained that the page could still be further improved, by for example improving its linkage from other pages. She mentioned that the pages would be updated as new test methods are developed and approved. She also welcomed feedback from the NGO participants on how to best improve the page in the future.

Discussion

NGO participants discussed the web page on alternative methods and the following points were raised:

- SW asked why there had not been any reference to alternative methods in the REACH 2018 Roadmap. LYM agreed to take the suggestion up with Christel MUSSET (CM) ECHA's Director of Registration and reminded that CM would also

[1] http://echa.europa.eu/documents/10162/13575/a-004-2012_boa_decision_en.pdf
[2] http://echa.europa.eu/support/testing-methods-and-alternatives

attend the Accredited Stakeholder Workshop in Brussels on 9 October where the topic would be further discussed.

- KT reiterated the need to increase the visibility of the webpage and agreed that the support section of the ECHA website is a suitable location for the page but that there were also other locations where it should be more visible, particularly those that deal with information requirements. She reminded about the original expectations of animal welfare NGOs that ECHA would list all possible tests, including those that had been pre-validated. She also expected the page to have some indication as to whether the testing methods could be used in a weight of evidence, as a stand-alone or as part of a testing strategy. She explained that ECHA guidance only focussed on OECD approved test methods whereas she expected ECHA to clarify how the different test methods fit together and to inform registrants about test methods that were soon to be approved. LYM agreed to come back about the further development plans for the pages and the reasoning for excluding pre-validated methods from the page after the meeting.
- KT asked for an update about ECHA guidance for skin sensitisation alternatives and recommended that they would also be included in the testing methods webpage. LYM confirmed that work was on-going and that ECHA is reliant on the output from the OECD before it can be published or communicated further. She agreed to come back after the meeting with more information.

3. Substitution

Mira BANERJEE (MB) gave an update on future joint communications projects with accredited stakeholders on the promotion of substitution. She explained that although substitution is not an ECHA process as such, we are committed to making substitution more visible and increasing its awareness among registrants and the general public. She highlighted ECHA's recent communications activities on substitution including a dedicated newsletter issue which dealt entirely with substitution and was published in April[3]. She went on to explain the plans for future projects including a video for raising awareness among consumers, following the same style as ECHA's video on the Price You Pay[4]. The video is planned to be launched at the end of 2014 or early 2015. The storyline is currently being developed and ECHA plans to discuss it with the Communicators' Network of accredited stakeholders during their next meeting in Brussels on 10 October. ECHA is also planning to publish a dedicated webpage on substitution intended for industry. The page would be developed together with accredited stakeholders. ECHA also plans to work together with accredited stakeholders to launch a webinar or possibly a webinar series on substitution topics. The webinar(s) would start either very late in 2014 or early 2015 and, as with the webpage, the content would primarily come from the accredited stakeholders. All of the substitution projects will be under discussion at the October Communicators' Network meeting.

[3] http://newsletter.echa.europa.eu/home/-/newsletter/2/2014
[4] https://www.youtube.com/watch?v=WSWIAEDJfSg

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4. Transparency

LJ gave an update on ECHA's approach to transparency, a project that was established in response to a shared recommendation that was made by accredited stakeholders during the 2013 Accredited Stakeholder Workshop. The feedback then was that ECHA was doing well in terms of transparency when compared with other EU institutions but that more could be done to improve. LJ explained that ECHA has produced a draft approach paper for discussion and comments at the workshop. The first document covers 3 pillars:

1. Transparent processes – improving the clarity of the different processes within ECHA and how they impact stakeholders
2. Transparent decision-making – clarity about how decisions are taken, who is involved and who can contribute to them including for example declarations of conflicts of interest
3. Transparency of data – making full use of the data collected by ECHA and making it available in raw format to allow for its reuse

Participants at the 2014 Accredited Stakeholder Workshop will receive two documents from ECHA. The first explaining the 3 pillars and the work done so far and the second asking for feedback about how they could be further developed before the approach is finalised.

Discussion

The following points were raised:

- KT suggested the UK's Freedom of Information Act as a model for how public bodies should proactively advertise where and how their information is made available and how the public can make a formal request to access information that has not been published. Bo BALDUYCK (BB) explained that ECHA has a public register of documents on the ECHA website. He explained that the registry does not include all the documents published by ECHA but already includes many publications and documents accessible to all. ECHA also complies with EU legislation on the access to documents which allows members of the public to request access to any document that ECHA holds, unless exceptions set out by the legislation apply.

- KT appreciated the improvements already made in the availability of data through the E-CHEM portal and the timely publication of ECHA decisions but was concerned about their visibility on the website. LYM explained that ECHA is working on the development of the dissemination website and looking into better ways of publishing its decisions. ECHA aims to publish them within three months but as this is not a legal requirement, they have had to be deprioritised due to other commitments. Jack DE BRUIJN (JDB) mentioned that although ECHA is currently looking into revamping the dissemination website with the first significant improvements in 2015, other improvements are already under way through for example improving the search features of the website to allow for decisions and other documents to be found more easily.

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5. AOB and Agenda setting

Meeting participants agreed that the next meeting could be in conjunction with the Member State Committee meeting in December, depending on the needs of the participants. If no need is identified, the next meeting would take place during the first Member State Committee meeting in February 2015. A detailed agenda and timing would be agreed later by email.

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Annex I – Meeting Agenda

Date & Time:
Tuesday 16 September
15:00 - 16:30 Helsinki Time
Location: Meeting Room K325

15:00 – 15:05 **Opening of the meeting**

15:05 – 16:00 **Animal Welfare**

- Update on cosmetics and REACH
  Elena Bigi, ECHA
- Update on testing of second species
  Leena Ylä-Mononen, ECHA
- ECHA webpage on alternatives and new OECD test methods
  Leena Ylä-Mononen, ECHA
- Discussion

16:00 – 16:15 **Substitution**

- Joint projects on substitution – webpage, webinars and consumer video
  Mira Banerjee, ECHA
- Discussion

16:15 – 16:25 **Transparency**

- Update on ECHA's approach to transparency
  Lindsay Jackson, ECHA
- Discussion

16:25 – 16:30 **AOB & Agenda setting**