10 October 2018

Platform for NGO-ECHA discussions
Meeting note

Time: Wednesday 10 October, 12:00 – 13:30 Helsinki Time

Place: Meeting room K323, European Chemicals Agency

Participants:

NGO Representatives: BERNARD Alice (ClientEarth); FASSBENDER Christopher (Peta International Science Consortium – PISC); HÖK Frida (International Chemical Secretariat – ChemSec); LOONEN Helene (European Environmental Bureau – EEB); MUSU Tony (European Trade Union Confederation – ETUC); SANTOS Tatiana (European Environmental Bureau – EEB)*; TAYLOR Katy (European Coalition to End Animal Experiments – ECEAE)*; VALERO Alana (European Consumer Voice in Standardisation – ANEC)*.

ECHA: YLÄ-MONONEN Leena (Director of Evaluation – Meeting chair); BARANSKI Maciej (Forum Secretariat); BROERE William (Legal Affairs); BRÄUTIGAM Tiiu (Communications); DE BRUIJN Jack (Director of Risk Management); ELWAN Adam (Communications); HOFFSTADT Laurence (Evaluation); HOLMQVIST Jenny (Regulatory Affairs)*; KARHU Elina (Risk Management); KOLARI Ida-Liisa (Evaluation); NICOT Thierry (Risk Management).

** Attended remotely*

1. Changes to ECHA's evaluation practice

ECHA gave an update on changes to the dossier evaluation practice. As of 1 January 2019, ECHA will send its dossier evaluation decisions to all non-compliant registrants of a substance.[1]

ECHA highlighted the recently updated PACT[2] table which now also gives an overview of the evaluation lifecycle of substances and allows you to follow substances more easily across 8 different processes.

NGO participants welcomed the change in dossier evaluation but raised concerns about the effectiveness of substance evaluation where the quality of decisions is high but the output is low and can take years before risk management measures start. ECHA explained that any missing data needs to be requested formally by an ECHA decision and registrants have a commenting period which, together with cases that require complex testing can take time. Member States who are tasked with evaluating the substances also have resource limitations and are faced with a cumulative workload from carrying out previous evaluations.

However, ECHA stressed that the integrated regulatory strategy and common screening activities have channelled several cases to compliance check and the data generated

[1] ECHA news: Member registrants will start receiving dossier evaluation decisions in 2019
[2] Public activities coordination tool (PACT)

there may help to conclude cases without having to enter into the heavier substance evaluation process.

ECHA's work together with the Member States on categorisation and grouping is expected to further reduce the overall time required before risk management activities can start.

2. Risk Management

Ensuring efficient process for identifying substances of very high concern

NGO participants asked for an update on how ECHA will ensure that expert groups deliver results for the Member State Committee to conclude substance evaluations. ECHA explained that it is working with the expert groups to determine the appropriate amount of information required to put substances forward for decision-making. ECHA highlighted that expert groups have a mandate of supporting dossier submitters who evaluate cases and stressed their importance in contributing to increased transparency on substances that are being worked on. ECHA also continues to review expert group work to make sure they meet these aims.

Public consultations for authorisation

NGO participants asked about progress made in improving public consultations for authorisation. They raised concerns on their format and felt that, in some cases, the comments were dismissed without proper justification.

ECHA explained that all comments received are made public and answered by applicants. Applicants' responses are also made public. All this information is evaluated by ECHA's Committees and, where relevant, discussed with stakeholders in the so-called trialogues. The outcome of the comments received and discussions are reflected in ECHA's opinions.

Ahead of the next wave of applications in 2019, ECHA is working to improve public consultations to attract more alternative suppliers, users and experts in different fields. ECHA is also looking into adding an ECHA contact point for those submitting comments in case they have questions on the content of the consultation.

ECHA plans to organise or support the organisation of substitution workshops with alternative suppliers, industry applicants and stakeholders to facilitate dialogue ahead of the latest authorisation application dates. ECHA is also looking into publishing a searchable database of alternatives that have been assessed in applications for authorisation.

ECHA and ChemSec communications are further discussing how to use ChemSec's marketplace as a channel for advertising public consultations for applications for authorisation.

NGOs raised concerns over a recent presentation of organisations representing the pharma industry on the use of ethoxylated nonyl- and octyl phenols to the RAC and SEAC and questioned whether this would set a precedent for others, highlighting an imbalance on how much industry applicants are heard compared to those who comment through public consultations. ECHA explained that this opportunity for the sector organisations was given as a pilot to give a better understanding in the committees of the specificities of the pharma industry. ECHA will assess whether similar opportunities will be given in the future to other sector groups. These are not planned for sectors using Coal Tar Pitch

High Temperature.

3. Animal-welfare

Concerns about testing cosmetics under REACH

Following a recent Board of Appeal decision[3], NGOs raised concerns over cases where cosmetic ingredients that were used solely for cosmetics received compliance check and substance evaluation decisions requesting animal testing.

NGOs also asked for clarification on how ECHA would ensure that, particularly for substance evaluation, Member States are not asking for animal testing because of concerns about wide dispersive use in cosmetics which falls under the scope of the Cosmetics Regulation.

ECHA explained that this specific Board of Appeal case found that ECHA's decision did not properly explain why a test was required and ECHA was asked to go back to the registrant to explain its reasoning. ECHA only assesses information required for REACH and if a substance is exclusively used in cosmetics, and there is no worker exposure, ECHA will not ask for more data.

ECHA reassured that evaluating Member States were well aware of what concerns they should be assessing and the borderline between REACH and the Cosmetics Regulation.

Update on the pilot study investigating use of compliance checks to assess compliance with Article 13(1): last resort principle and tests without a proposal

ECHA's Forum Secretariat gave an update on the Forum's initiatives on cases involving animal testing:

- 2015 initiative: 121 cases of tests with no testing proposals
  - Suspected non-compliance with Articles 10(a)(ix) or 22(1)(h) of REACH (no testing proposals)
  - ECHA received feedback from 7 Member States concerning 25 cases – one case of non-compliance. Report from this initiative is on the ECHA website[4]
- 2017/2018 initiative: cases related to last resort requirement under Article 13(1)
  - Forum agreed to treat these cases as "interlink" cases from ECHA in November 2017. This means national enforcement authorities will consider them and follow up, if allowed by national priorities.
  - ECHA sent 89 cases of suspected non-compliance with Art 13(1) to national enforcement authorities in early 2018. All cases addressed Annex VII dossiers (where only in vitro studies are required). The cases addressed in vivo studies for skin and/or eye irritation conducted after 2009. The cases concerned duty holders in 12 countries.
  - Most of the affected Member States indicated that they plan to follow up the cases.
  - Regarding the current status, ECHA Secretariat understands that Member States are working on the follow up of these cases. No deadline is set, as

[3] Case number A-009-2016: decision of the Board of Appeal of the European Chemicals Agency

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

enforcement depends on national priorities. So far ECHA Secretariat received responses for 15 specific cases where national enforcement authorities indicate that action has already been taken or that it will take place. In addition, one Member State indicated that some action on its cases has been taken and companies were contacted. Partial feedback received so far suggests that tests were done either outside the EU or for non-EU regulatory regimes (e.g. U.S. or China), but in general, it is too early to draw conclusions. National enforcement authorities need more time and ECHA needs more feedback to build a better picture.

- 2018 initiative
    - A new batch of cases of tests without testing proposals in preparation and communicated to the Forum by the end of 2018.

There will be an open session of the Forum in November where stakeholders can have a dialogue directly with the enforcement authorities.

4. AOB

ECHA's social media communication

NGOs expressed concerns about messages posted by ECHA in social media that, in their view, could be seen as biased towards the chemical industry. They mentioned posts highlighting the benefits of nanomaterials while dismissing their risks as well as a post on Facebook[5] that they claim suggest that apples and potatoes are as bad as man-made chemicals. NGOs also explained the importance of considering content from other sources that ECHA posts to ensure they are unbiased.

ECHA explained that it strives to maintain a balanced approach to all its communications between the wishes of different stakeholder groups. When looking at ECHA's social media channels, the overall majority of posts highlight chemical safety through, for example, restrictions and products withdrawn from the market through the Commission's Rapid Alert System (RAPEX).

ECHA acknowledged that it can do more to highlight the risks and safety concerns for consumers in its individual posts but due to the nature of social media where posts are short, it can sometimes be difficult to highlight all aspects. ECHA welcomes and encourages continued feedback from NGOs on the content it publishes and suggested more collaboration in future social media activities through for example joint campaigns or offering guest columns in ECHA's newsletter. ECHA agreed to follow-up with NGOs via a separate discussion.

[5] ECHA Facebook post: "The dose makes the poison"

10 October 2018

Annex I – Meeting Agenda

12:00 – 12:30 Changes to ECHA's evaluation practice

- Overview of upcoming changes to dossier evaluation
- Discussion

12:30 – 13:00 Risk Management

- ECHA update
  - Ensuring efficient process for identifying substances of very high concern
  - Public consultations for authorisation
- Discussion

13:00 – 13:20 Animal Testing as a last resort

- ECHA update
  - Concerns about testing cosmetics under REACH
  - Update on the pilot study investigating use of compliance checks to assess compliance with Article 13(1): last resort principle and tests without a proposal
- Discussion

13:20 – 13:30 AOB