

26 October 2016

## Platform for NGO-ECHA discussions

### Meeting note

**Time:** Wednesday 26 October, 16:00 – 17:25 Helsinki Time (EET, GMT+2)

**Place:** Meeting room 184, European Chemicals Agency

#### Participants:

**NGO Representatives:** BAINES Julia (Peta International Science Consortium – PISC\*); HYNES Jarlath (Humane Society International – HSI); REGO Laura (Cruelty Free International); REID Kirsty (Eurogroup for Animals\*); ROVIDA Costanza (European Consensus Platform for 3R Alternatives to Animal Experimentation – ECOPA\*); STODDART Gilly (Peta International Science Consortium – PISC\*); TAYLOR Katy (Cruelty Free International\*).

**ECHA:** YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); BUCHLER Frank (Executive Office); CARTLIDGE George (Evaluation Unit); HOFFSTADT Laurence (Evaluation Unit); ROSSI Laura (Evaluation Unit); SOBANSKA Marta (Evaluation Unit); SOBANSKI Tomasz (Computational Assessment and Dissemination Unit); ELWAN Adam (Communications Unit).

\* Attended remotely

## 1. Alternatives to animal testing

### Feedback on 2018 alternatives guidance and 2016 webinar

Jarlath Hynes (JH) welcomed the new approach of highlighting the type and level of expertise required in the practical guide for SME managers on meeting their information requirements for 2018 registration<sup>1</sup>.

Participants also welcomed the webinar<sup>2</sup> on using alternative methods for REACH registration and the accompanying case studies. They were pleased that the bar of acceptability for some of the cases presented in the webinar were lower than they had expected. However, participants expressed concern that case studies would not be applicable by default as the Member State Committee will have the final decision on their acceptability on a case-by-case basis.

### Fish Embryo Acute Toxicity (FET) test status

ECHA gave a short update on the applicability of the Fish Embryo Acute Toxicity (FET) test for REACH purposes. In 2015, ECHA contracted a study<sup>3</sup> on the use of FET for REACH information requirements. The report concluded that it could not be used as a direct replacement since the test conditions used by OECD when validating the method had

<sup>1</sup> [Practical guide for SME managers and REACH coordinators: How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year](#)

<sup>2</sup> [Webinar: Use of alternative methods to animal testing in your REACH registration](#)

<sup>3</sup> [Analysis of the relevance and adequateness of using Fish Embryo Acute Toxicity \(FET\) Test Guidance \(OECD 236\) to fulfil information requirements and address concerns under REACH](#)

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significantly changed. It is possible to use it as a part of a weight of evidence approach. Brief description of the test guideline and of its use under REACH<sup>4</sup> have also been published by ECHA.

#### Status of expected testing proposals for EOGRTS

The Commission has prepared draft decisions for testing proposals for the extended one-generation reproductive toxicity study (EOGRTS). They have not yet been voted on in the REACH Committee and it is expected to take still approximately 5 months before the decisions will be issued. Registrants will then have up to a further 3 months to act. Therefore the resubmitted testing proposals are only expected for third party consultation in 2017 at the earliest.

YLÄ-MONONEN Leena (LYM) explained that an inventory of EOGRTS testing proposal cases that have been referred to the Commission already exists. As all the cases have gone through the Member State Committee this information is not confidential. The list could be shared with the interested organisations so that they can better prepare for the possible third party consultations which will have to be launched in a relatively short period of time.

#### **Action point**

- ECHA to send list of cases to accredited stakeholders during the autumn to prepare for 2017 public consultations.

#### Update on ECHA's preparation of the alternatives to animal testing report (Article 117(3))

ECHA gave an update on the 117(3) report which is due to be published at the end of May 2017.

Two major differences were highlighted:

1. The report now covers all REACH annexes
2. The report presents a trend analysis of how registrants' behaviour has changed throughout the years

SOBANSKI Tomasz (TS) explained that the cut-off date for the report analysis is the end of April 2016 due to release of IUCLID 6. He also explained that ECHA does not expect a big difference in projections based on previous reports. He clarified that no significant drops in data submission were noted following the new release of IUCLID 6 and that the data from 2018 registrations will be presented in the 2020 report.

ROVIDA Costanza (CR) asked whether the report would include a section on ECHA's inquiry to companies who performed in vivo testing without a testing proposal when alternatives were already available. ROSSI Laura (LR) explained that ECHA has conducted two compliance check pilots asking registrants why additional tests were performed without justification. Depending on the outcome of the pilot cases, ECHA will assess how to deal with future cases. No additional section has been planned in the report on this issue.

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<sup>4</sup> [FET test guidelines](#)

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### Skin sensitisation new requirements

JH presented (Annex II) their view on how to ensure practical alignment of REACH submissions with ECHA's expectations regarding new requirements for skin sensitisation. Based on discussions with different sector groups on their awareness and preparedness of starting to implement the new skin sensitisation requirements, JH found that although companies are aware of the new requirements, they still have a lot of practical questions on how to implement them in practice and how ECHA expects to receive the new data.

JH also asked whether the chemical safety assessment (CSA) would now require a quantitative risk assessment of sensitisers. LR explained that according to ECHA guidance, if data is available, a quantitative assessment can be done but ECHA still recommends a qualitative risk assessment.

LR explained that ECHA guidance is in the process of being updated to include all of the practical advice that can be given at this point of time for companies to implement the new requirements. Participants expressed a need to issue simplified "layman" guidance of skin sensitisation IATA without detailed science. LR concluded that ECHA's web pages on alternative methods and OECD test guidelines will also be updated as soon as new information on alternative methods becomes available.

#### **Action point**

- ECHA to consider how and when to organise a QSAR/alternative methods training either as a physical event or a webinar in 2017

CR asked whether the way in which the user interface of IUCLID 6 could be changed to make a clearer distinction between the different test methods accepted for REACH. Currently, IUCLID displays the different test types in the same window which may cause confusion for registrants. LR explained that IUCLID is used for many other legislations and uses harmonised templates, making it very difficult to change.

#### **Action point**

- ECHA to check internally what options are available for changing the IUCLID 6 interface

### How ECHA can use its experience to practically improve/promote international data sharing

JH explained that their contacts in Korea are preparing for data sharing under K-REACH. According to their contacts, their government plans to test the more costly substances in order to reduce the burden for SMEs. The list of substances proposed for testing includes many that have already been tested or waived under REACH. Their justification is that only 5% of REACH data has been validated. LYM explained that this may be due to the 5% compliance check minimum target set by ECHA and it would need to be clarified together with ECHA's Korean counterparts.

Using K-REACH as an example, participants felt that ECHA could do more with the 10 years of experience from REACH and other European chemicals legislation to avoid unnecessary duplication of data and sharing of best practice on an international level.

BUCHLER Frank (FB) explained that there is already some interaction between ECHA and

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international partners but often on the use of IUCLID and administrative issues rather than more scientific aspects.

LYM explained that REACH data sharing internationally is a priority for ECHA and its stakeholders and was also identified as a part of ECHA's World Summit on Sustainable Development 2020 goal for chemicals<sup>5</sup>.

**Action point**

- ECHA to raise the issue with the colleagues working with international cooperation and the Director of Registration

**2. AOB and agenda setting**

ELWAN Adam (AE) gave a brief overview of ECHA's on-going consumer research asking people what topics related to chemicals they are most interested in. The results will be used to build ECHA's new website on chemicals for consumers at the end of 2017.

According to the results received so far, testing chemicals on animals was not ranked very high when comparing with other topics. AE asked participants to further promote the online questionnaire in their networks.

**Action point**

- ECHA to send online questionnaire link to participants for further promotion

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<sup>5</sup> [Workshop proceedings: 2020 World Summit on Sustainable Development goal on chemicals](#)

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## **Annex I – Meeting Agenda**

**Date & Time:**

Wednesday 26 October

16:00 - 17:25 Helsinki Time

**Location:** Meeting Room 184

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

**16:05 – 17:15      Animal Welfare**

- Discussion points:
  - FET status
  - Feedback on 2018 alternatives guidance and 2016 webinar
  - Status of expected testing proposals for EOGRTS
  - Update on ECHA's preparation of the alternatives to animal testing report (Article 117(3))
  - Skin sensitisation new requirements - how to ensure practical alignment of REACH registrants with ECHA's expectations
  - How ECHA can use its experience to practically improve / promote international data sharing

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

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## Annex II – Presentations



*25 Years of  
Celebrating Animals*

**HUMANE SOCIETY  
INTERNATIONAL**

# Skin sensitisation new requirements - how to ensure practical alignment of REACH submissions with ECHA's expectations?

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