26 - 27 April 2016

Platform for NGO-ECHA discussions
Meeting note – Animal welfare

Time: Tuesday 26 April, 14:00 – 15:30 Helsinki Time (EET, GMT+2)

Place: Meeting room K325, European Chemicals Agency

Participants:

NGO Representatives: BUSQUET Francois (European Consensus Platform for 3R Alternatives to Animal Experimentation – ECOPA*); HYNES Jarlath (Humane Society International – HSI*); REGO Laura (European Coalition to End Animal Experiments – ECEAE); REID Kirsty (Eurogroup for Animals*); STODDART Gilly (Peta International Science Consortium – PISC); WILKS Susie (Humane Society International - HSI*).

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); HOFFSTADT Laurence (Evaluation Unit); SOBANSKI Tomasz (Computational Assessment and Dissemination Unit); ELWAN Adam (Communications Unit).

* *Attended remotely*

1. Alternatives to animal testing

Follow-up of new approach methods workshop - 19 to 20 April 2016

SOBANSKI Tomasz (TS) gave an update on ECHA's scientific workshop on new approach methods[1]. The main topic of the workshop was the use of new approach methodologies (NAM) in the regulatory context.

The general outcome was that in the case studies developed by SEURAT-1 and Cosmetics Europe, NAM provided additional evidence for toxicodynamics but there is still more work to be done to cover information gaps related to toxicokinetics before such methods can be widely used to support read-across cases. The metabolomics case (3rd case study) is trying to incorporate both toxicokinetics and toxicodynamics parameters within extended in-vivo experiment which many participants received as very usefull approach. Current limitation is that this approach require advanced pattern recognition combined with reference DB to identify relevant MoA and these tools are not yet publically/commercially available.

The workshop also tried to identify barriers for using new approach methods for regulatory science in the coming years. The main outcome was that common performance standards and a common understanding of the new methods were needed so that both industrial users and risk assessors could use them in a harmonised way.

NGO participants concurred that the technical difficulties and high costs for the methods described in the case studies currently rules them out for REACH purposes but that they should be developed and in the near future could bring more benefits also in the REACH context. The workshop recordings and presentations are available on the ECHA website. The workshop proceedings are planned for publication in September.

[1] Scientific workshop on new approach methods

Action point

- ECHA to send workshop proceedings to the Endocrine Disruptor Expert Group (TS)

Follow-up of Ombudsman and Board of Appeal cases

ECHA gave a short update on the two EU Ombudsman cases, the first on compliance check from 2014[2] and the second on testing proposals from September 2015[3].

Two of the first compliance check cases are being discussed in the Member State Committee in its ongoing April meeting. Some registrants have had shortcomings in explaining why they have opted for in vivo testing when viable alternatives exist or where a reasonable justification to opt for in vivo testing would have been required by REACH.

Regarding the second case on testing proposals, LYM explained that the new version of IUCLID (6) will incorporate mandatory fields where registrants submitting testing proposals must provide an explanation of their considerations for alternative methods. This information will then be checked for completeness as part of their registration dossier and used for public consultations. Currently around 20 dossiers with TPs have been submitted to ECHA where these considerations should be provided and each case has responded positively although their considerations vary in quality.

There are nearly 200 testing proposals for extended one-generation re-productivity study (EOGRTS) currently pending with the Commission. The Commission expects to submit them to the voting committee in the coming months. The outcome will most likely require a revised testing proposal or an adaptation to be justified by the registrant. ECHA expects a wave of testing proposals involving animal testing in 2017/2018 which will all be subject to third party consultations.

Participants went on to discuss a case [4] of the Board of Appeal (BoA) on carbon tetrachloride. The NGO representatives felt that the BoA case set a useful paradigm by introducing a 3-step "necessity test" which lays out the basis for conducting a test and whether it provides a realistic opportunity to improve risk management. These considerations are a part of the substance evaluation process but the NGO participants felt they could also be more generally applicable. LYM explained that using the same principles in dossier evaluation would not be applicable as the standard information requirements are laid down by the legislator as minimum requirement for demonstrating safe use. On the other hand, the risk management considerations are already embedded in the current compliance check process where the most relevant substances are prioritised.

Action point

- HSI to send their interpretation of using the 3-step necessity test to ECHA's legal unit. To be followed up in the next NGO platform meeting

Reporting

ECHA will publish its 5-yearly report on 26 May 2016 on the performance of the different operations of REACH. The report covers topics related to animal testing including a

[2] 1568/2012/(FOR)AN – Compliance check, animal testing
[3] 1606/2013/AN – Animal testing, alternative methods
[4] Board of Appeal case A-005-2014

recommendation to speed up the adaptation of the REACH Annexes for scientific development.

LYM explained that ECHA had also published a laboratory capacity report for EOGRT study which found that in principle laboratories claim that new, challenging test designs could be carried out. This will however depend on how many requests for testing are submitted at the same time and what other studies i.e. for the REACH 2018 deadline are commissioned. Participants explained that although some new capacity had been identified in the report, some issues were also highlighted, for example the significant price differences between laboratories and insufficient quality and expertise to perform the tests.

Interface between different legislations and REACH

BUSQUET Francois (FB) referred to an ongoing court case in the European Court of Justice on the interpretation of the ban on animal testing for cosmetics and its impact on REACH. LYM explained that ECHA was aware of the case and that if a change in the interpretation would take place following the court ruling, ECHA would further assess its impact on REACH and reflect any potential changes in its guidance and other material. ECHA's factsheet[5] provides further clarification on the interface between the REACH and Cosmetic regulations.

LYM pointed out that a further discussion was ongoing with the Commission about REACH and the general laboratory animal directive (2010/63/EU) to determine how implementation and enforcement should be coordinated and carried out. Work is ongoing to clarify which requirements are applicable for which regulations and to improve cooperation between the different actors involved.

Promoting alternative methods to animal testing for REACH 2018

LH gave an update on what are ECHA's plans to promote alternative methods ahead of the next REACH 2018 deadline. The activities include more support for registrants that have less expertise and capacity. She explained that a practical guide for non-expert SME managers was also under preparation to help them make informed decisions on how to fulfil their information requirements. ECHA is also updating practical guides on *in vitro* and read across and how to use data waiving, and combining them in one practical guide on how to use alternatives to animal testing. Some web pages relevant to supporting less experienced registrants will be updated with higher level information followed by more detailed information for experts. A webinar on assessing hazard and risk[6] will also take place on 20 July.

ZFET for acute fish toxicity and REACH guidance on skin sensitisation

LYM explained that ECHA has requested for an analysis on the applicability of the OECD fish toxicity test guideline (ZFET) for use in REACH framework. A report on this analysis is due within the coming weeks.

The publication of the final revised REACH guidance on skin sensitisation is influenced by the amendment of the REACH Annexes which is due in autumn. The guidance is expected for the same time. The draft is already published on the ECHA website.

[5] Factsheet: Interface between REACH and Cosmetic regulations
[6] ECHA webinar: Assess hazard and risk

Action point

- ECHA to check with the guidance team if a new PEG will be formed for the skin sensitisation guidance

26 - 27 April 2016

Platform for NGO-ECHA discussions
Meeting note – Risk management

Time: Wednesday 27 April, 15:00 – 16:30 Helsinki Time (EET, GMT+2)

Place: Meeting room K323, European Chemicals Agency

Participants:

NGO Representatives: HÖK Frida (International Chemical Secretariat – ChemSec)

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); DE BRUIJN Jack (Director of Risk Management); HERDINA Andreas (Director of Cooperation); VAINIO Matti (Risk Management Implementation Unit); ELWAN Adam (Communications Unit).

1. Risk management

Substitution

ECHA is preparing a second webinar on substitution for the end of the year. The topic is still under discussion but plans include a substance specific approach or presenting the work currently being done by Joel Tickner on the alternative assessment framework within the EU.

Dr. Tickner will present the first findings of his report at the European Commission workshop 'Strategy for a non-toxic environment' from 8 to 9 June in Brussels. The report will include information on both company and Member State level substitution. Follow-up work will take place during the summer to develop the ideas and advice highlighted within the report.

Action point

- ECHA will inform participants once the topic of the webinar is confirmed

Authorisation

DE BRUIJN Jack (JDB) explained that ECHA's Management Board was presented with the work plan and report of the Task Force on the Workability of Applications for Authorisation, tasked to assess how the process has worked so far and propose recommendations for potential improvements. Their work plan and report[7] is published on the ECHA website. The main part of their work will be a practical guide with the aim of improving the quality of applications already at an early stage with clearer advice and guidance.

JDB highlighted a workshop on socio-economic analysis[8] in applications for authorisation and restrictions under REACH taking place on 29 June in Brussels. The workshop will look at how socio-economic analysis (SEA) works, how it is used in decision-making and how

[7] Report of the Task Force on the Workability of Applications for Authorisation
[8] Workshop on socio-economic analysis in applications for authorisation and restrictions under REACH

to best communicate SEA related issues and conclusions to stakeholders. A further workshop on SEA is also taking place on an international level with the OECD in July.

ECHA is working together with the Commission to improve the wording of opinions from the Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) to see what standard texts could be clarified and whether any changes to the current procedures are needed.

HÖK Frida (FH) mentioned ChemSec's report looking into the benefits of restrictions for companies. VAINIO Matti (MV) also highlighted ECHA's report on the cost and benefit assessments in REACH restriction dossiers[9] looking at the costs and benefits of restrictions carried out so far.

FH raised an issue with alternative providers not providing comments during the public consultations for applications for authorisation. The "trialogues" undertaken by ECHA, where the rapporteurs of RAC and SEAC and the applicant discuss issues raised by their application often do not cover all the required information due to confidentiality and business reasons. She explained that more targeted meetings with the providers of alternatives would help them to understand the market benefits they might gain from their contributions.

JDB explained that accurate information is needed to be able to challenge the applicants and the only ones that can provide it are the producers of alternatives. ECHA is exploring other ways of finding the required information for example through Article 66 notifications which will give a better picture of the market and who is actually using the substance and for what purpose. FH went on to explain that use descriptions are also causing issues as it is difficult to match the producer of an alternative to a specific use. JDB pointed out that the task force will look into this issue and take it into consideration in the practical guide.

FH asked whether the alternatives listed in the applications for authorisation would be made available in a searchable database by ECHA. MV explained that ECHA is looking into making the applications searchable in the longer term but for the time being the large number of applications for authorisation to be processed by ECHA has to be prioritised. FH explained that ChemSec is also in the planning stages of an alternatives platform that would pair companies looking for alternatives with those that provide them.

2. AOB & agenda setting

Action point:

- ECHA to approach participants for topics and timing of the next meeting, tentatively agreed for September.

[9] ECHA report: Cost and benefit assessments in REACH restriction dossiers

Annex I – Meeting Agenda
Animal welfare

Date & Time:
Tuesday 26 April
14:00 - 15:30 Helsinki Time
Location: Meeting Room K325

14:00 – 14:05 **Opening of the meeting**

14:05 – 15:00 **Animal Welfare**

- Update from ECHA
- Promoting alternatives to animal testing for REACH 2018
- Discussion

15:00 – 15:05 **AOB & Agenda setting**

Annex II – Meeting Agenda
Risk management

Date & Time:
Wednesday 27 April
15:00 - 16:30 Helsinki Time
Location: Meeting Room K323

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

15:05 – 16:00 **Risk management**

- Update from ECHA
  - How ECHA is working to improve the authorisation procedure
  - Improving the format of public consultations
  - Joel Tickner's alternative assessment project
  - Upcoming activities on substitution
- Discussion

16:00 – 16:05 **AOB & Agenda setting**