7 February 2018

Platform for NGO-ECHA discussions
Meeting note

Time: Wednesday 7 February, 16:30 – 18:10 Helsinki Time (EET, GMT+2)

Place: Meeting room K325, European Chemicals Agency

Participants:

NGO Representatives: BERNARD Alice (ClientEarth); BAINES Julia (Peta International Science Consortium)*; FASSBENDER Christopher (Peta International Science Consortium – PISC)*; HÖK Frida (International Chemical Secretariat – ChemSec); LOONEN Helene (European Environmental Bureau – EEB); REGO Laura (European Coalition to End Animal Experiments – ECEAE)*; Costanza ROVIDA (European Consensus Platform for Alternatives – ECOPA)*.

ECHA: YLÄ-MONONEN Leena (Director for Evaluation – Meeting chair); BÜCHLER Frank (Executive Office); ELWAN Adam (Communications Unit); HANSEN Bjorn (Executive Director); HOLMQVIST Jenny (Regulatory Affairs) VAINIO Matti (Risk Management Implementation Unit).

** Attended remotely*

1. Introducing Bjorn Hansen

Leena YLÄ-MONONEN (LYM) introduced Bjorn HANSEN (BH), ECHA's newly appointed Executive Director.

BH explained ECHA's key priorities for the coming years, after 2018. He highlighted ECHA's objectives set out in the legislation and ways of further improving efficiency and consistency in ECHA's work. He highlighted the upcoming REACH review report that will identify areas and give recommendations where the European Commission sees need for improvement.

BH gave two examples:

1. Authorisation: need to improve the understanding and definition of applied uses between.
2. Evaluation: investigate the possibility of performing tasks for certain evaluations in parallel such as compliance check, testing proposals and substance evaluation to speed up the overall process.

Helene LOONEN (HL) welcomes ECHA's commitment to improve the evaluation process and reminded that the currently 7 to 9 years before suspected concern is clarified is too long for identifying substances of very high concern.

She also mentioned that in some cases, complications were faced due to different interests in the compliance checks and substance evaluation needs. She highlighted the need to look into it, while acknowledging possible legal challenges.

LYM acknowledged that the interface between Member States and ECHA needs to be

improved between the compliance check and substance evaluation processes and that ECHA's new strategy will focusses also in this area.

Julia BAINES (JB) asked when the REACH review will be published. BH explained that it was expected during Q1.

2. Risk management

Update from the authorisation conference[1], ECHA's substitution strategy[2] and its implementation

Frida HÖK (FH) asked what is concretely being done to assess and obtain more information about alternative providers in the authorisation process. She called for ECHA to increase SEAC's capacity to get alternative providers to come forward in different ways to make sure all available information is available. She also expressed concern that in her view, comments received in public consultations were not being adequately considered as authorisations were still being granted where alternatives might exist. Matti VAINIO (MV) explained that ECHA nor the Committees usually have the sector specific expertise needed for assessing alternatives. ECHA is looking into how it could acquire such expertise either directly or indirectly. Furthermore, as one part of the substitution strategy ECHA is aiming to raise the capacity of companies and Member States to carry out analyses of alternatives as part of risk management and to set up a capacity building programme for practitioners, reviewers and decision-makers. FH said that this is very ambitious and can take a long time. FH mentioned that ChemSec and ClientEarth will publish a report proposing concrete actions to improve the analysis of alternatives.

Disclosure of all relevant information to promote compliance and substitution

Alice BERNARD (AB) highlighted a report[3] published in December on dissemination which covers many different areas: registration, evaluation, applications for authorisation and restrictions. She raised that ECHA should disclose the names of companies that have received a statement of non-compliance (SONC).

Concerning authorisation applications, MV explained that ECHA has a similar interest with NGOs to have Article 66 downstream user notifications made public. He said that the situation is similar to what has been previously discussed about disclosing the names of authorisation applicants. Currently, the names are disclosed. Building on this experience, MV suggested further cooperation between NGOs and ECHA to build confidence to disclose the names of the downstream users using substances of very high concern and to avoid unnecessary concern. MV concluded that ECHA will be working on this area in 2018 and look forward to collaboration with the NGOs. Regarding SONCs, LYM explained that after improved information on the dossier evaluation lifecycle (anticipated by the end of 2018), one can, in most cases, establish the link to the companies involved through dissemination. The main reason for not disclosing the names of companies having received a SONC is related to the current approach to only address the decisions to the lead of the joint submission. Frank BÜCHLER (FB) mentioned that the Management Board advisory group on dissemination will discuss the outcomes of the ChemSec/Client Earth report in March 2018.

[1] Stock-taking conference on the implementation of REACH authorisation
[2] ECHA substitution strategy
[3] 10 years in: time for ECHA to disseminate strategic information to empower third parties

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3. European Union Observatory for Nanomaterials (EUON)

Jenny HOLMQVIST (JH) presented the European Union Observatory for Nanomaterials (EUON). She covered the main goal of the observatory, to increase transparency of nanomaterials on the EU market.

She mentioned that transparency is a shared responsibility among all stakeholders and policy makers to ensure all viewpoints are considered and that the success of the observatory is dependent on the buy-in from ECHA's partners and stakeholders.

In the discussions, NGOs thanked ECHA for the efforts in launching the observatory. Tatiana SANTOS (TS) explained that in addition to resource constraints, NGOs were choosing not to contribute to the observatory due to the Commission's lack of willingness to require industry to submit data to proof the safety of nanomaterials, as REACH requires for all other chemicals. JH explained that the vote to amend REACH annexes to include nanomaterials is currently with the REACH committee and the vote is expected by the summer. Once voted on, ECHA expects that the new obligations to report safety information for nanomaterials would take effect in January 2020.

JH concluded that while waiting for new requirements for industry, there may be other means of cooperation, for instance by asking NGOs to propose topics for studies that the EUON could conduct that would be of interest for civil society.

4. Animal-welfare

Developments promoting skin sensitisation testing strategies with companies

Laura REGO (LR) asked whether there is a plan to help companies clarify testing strategies ahead of the REACH 2018 deadline through guidance or workshops. LYM explained that guidance development has been frozen as of June 2017 to avoid last-minute changes for companies preparing to register. She mentioned that test methods are constantly being developed further and ECHA is looking into them and how to best clarify them to registrants.

Costanza ROVIDA (CR) asked whether ECHA could promote a webinar series organised by Peta International Science Consortium (PISC) and ChemicalWatch. LYM explained that due to corporate policy ECHA is not able to promote events organised by others. Adam ELWAN (AE) mentioned that the webinar series was reposted in ECHA's social media channels and would be further highlighted in a news bulletin, sent to ECHA's 113 accredited stakeholder organisations.

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

LYM highlighted that a CARACAL follow-up discussion has been done and at least one of the Member States who received a follow-up on a pilot case had investigated the issue further with the company. The pilot cases as such are now closed but information submitted by companies did not allow ECHA to draw a final conclusion on compliance with Article 13(1). The Enforcement Forum has also been informed of the outcome of the pilots.

JB asked how ECHA is able to find companies breaching Article 13(1) if compliance checks were proving less efficient than direct contacts with Member States. LYM explained that

ECHA has good screening methods that identify potential cases and that these cases were also identified in ECHA's alternatives to animal testing report, published every 3 years. ECHA is investing some resources to manually check these cases once picked up by screening activities. JB asked whether a similar report would be produced that follows-up on what ECHA has informed the Member States and any feedback received, in particular for skin and eye irritation non-compliances. LYM concluded that there are plans for follow-up but an internal priority setting is still needed to determine the timelines and resources invested in this activity.

Update and possible discussion on ECHA's report on the regulatory applicability of non-animal approaches (ANAA)

LYM mentioned that the report[4] was published in November and highlighted concerns received from NGOs during the consultation phase on the purpose of the report. She mentioned that ECHA had listened to feedback and worked on the tone of the report as requested by NGOs. However, she reminded that ECHA's conclusions remained that for higher tier endpoints, no alternative methods were available aside from read-across, categories and weight of evidence.

Christopher FASSBENDER (CF) asked whether the report will be updated regularly. LYM answered that it had not been decided yet but expects a need to review it, if not by ECHA, possibly by another scientific body.

CR highlighted that the applicability of alternative methods should be considered as part of dossier compliance. If read-across is not properly defined, instead of requesting an in-vivo test, further advice should be given with a clear information on how to correct the read-across. LYM explained that ECHA does give a lot of explanations for registrants on where their adaptations fail but has to follow the legal text regarding actual requests for information included in its decisions.

Update on timings for EOGRTS testing proposal batches

LYM explained that ECHA has been receiving dossier updates following-up the Commission's decisions on the over 200 cases related to EOGRTS. Around half rely on adaptations as opposed to testing proposals for which ECHA still has to check the compliance of their adaptations. The other half submit new extended one testing proposals. A large part is in categories so there will be less testing involved. Around 50 independent cases will be prioritised first together with other cases where there may be significant concern for human health or the environment. Third party consultations will be regularly published from spring onwards. LYM concluded by inviting NGOs to provide input and scientifically valid information through the third party consultations.

5. AOB & agenda setting

Participants agreed that the next meeting could take place with the Member State Committee in April. Adam Elwan (AE) to propose possible dates and collect topics.

[4] Report on the regulatory applicability of non-animal approaches reviews their current status under the EU chemicals legislation

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Annex I – Meeting Agenda

16:30 – 16:35 **Opening of the meeting**

16:35 – 16:55 **Introducing our new Executive Director**
- ECHA's key priorities
- How to accelerate compliance check and substance evaluation
- Discussion

16:55 – 17:15 **Risk Management**
- Update from the authorisation conference
- ECHA's substitution strategy and its implementation
- Disclosure of all relevant information to promote compliance and substitution

17:15 – 17:35 **European Union Observatory for Nanomaterials**
- Update: where we are now and next steps for the observatory
- Discussion

17:35 – 18:00 **Animal Testing as a last resort**
- Developments in promoting skin sensitisation testing strategies with companies
- 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
- Update and possible discussion on ECHA's report on the regulatory applicability of non-animal approaches (ANAA)
- Update on timings for EOGRTS testing proposal batches
- Update of REACH Annexes on nanomaterials

18:00 – 18:10 **AOB & Agenda setting**

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Annex II – Presentations