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DISCUSSION NON-PAPER

How to put ideas for cooperation under TTIP into practice – a few examples

Introductory Note: *This paper provides descriptions of various processes under REACH and CLP, and is destined to examine possibilities for cooperative interactions with the US authorities with a view to identify areas of cooperation of mutual interest, within the EU and US regulatory systems and respecting the procedures and timetables set therein. They focus on intensifying the technical and scientific exchanges among regulators and on the sharing of their expertise, which should facilitate that decisions are based on, and take account of, the best available information, and therefore reinforce the soundness, efficiency and effectiveness of regulatory action. These are highlighted in the respective steps with a grey background. These ideas are destined for discussion and do not constitute any formal commitment at the current stage of the negotiations. The suggested actions are already possible under, and therefore would be consistent with, the relevant EU regulations (in particular the REACH and the CLP Regulations) as they fall within the scope for administrative action under which the Commission and ECHA operate, and therefore would not require any regulatory change. Such actions would be conducted in full integration with the procedures and within the deadlines foreseen under REACH and CLP, and therefore would not lead to any delays. Consultations and exchanges among regulators that could take place as proposed in the paper could facilitate that the decisions adopted take into consideration, in addition to what is available in the EU (and from stakeholders), also all relevant information available to the US authorities – and vice-versa for comparable procedures in the US.*

Although this note focuses on practical steps that could be envisaged under the EU framework, it is understood that comparable steps would need to be envisaged in the US framework to enable a fully reciprocal level of consultation and interaction in the US chemicals regulatory process.

1. Prioritisation of Chemicals for Assessment and subsequent evaluation

1.1. Updates of CoRAP under REACH

1. The current criteria for selecting substances for CoRAP updates are listed below[1]. The current criteria have been used for several years. However, in principle they should be reviewed in 3-5 years intervals and then potentially revised. ECHA considers initiating the revision of the CoRAP selection criteria this year – there is no pre-defined process, but Member States and stakeholders will be consulted. As part of this process, ECHA could also consult with the US EPA to assess whether there may be prospects to share information or coordinate some current or planned criteria.

[1] All details available at :
http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf

Hazard related selection criteria:

- Suspected Persistent, Bioaccumulative and Toxic substances (PBTs), Very Persistent and very Bioaccumulative substances (vPvBs) and PBT-like substances (e.g. close to meet REACH Annex XIII-criteria and/or based on structural similarities)
- Known PBTs/vPvBs
- Suspected endocrine disruptors (e.g. based on reproductive effects and/or on structural similarities)
- Suspected Carcinogenic, Mutagenenic and Reprotoxic substances (CMRs) (e.g. based on structural similarities)
- Known CMRs4 (Category 1A , 1B and 2 according to CLP)
- Suspected sensitizers (e.g. based on structural similarities)
- Known sensitizers (skin and especially respiratory sensitizers)

Exposure related selection criteria:

- Wide dispersive use
    - The number of sites of use
    - Pattern and amount of releases/exposure
    - The number and type of reported uses and exposure scenarios from different registrants
    - The substance is incorporated into mixtures or articles used by the public (e.g. consumers)
    - The potential size of the exposed population
- Number of using sites if emission due to industrial use
- Consumer use and exposure of sensitive subpopulations such as children
- Aggregated tonnage

Risk related selection criteria:

- The risk assessment in the chemical safety report shows that risk characterisation ratio is not well below to 1 (for human and/or environmental exposure)
- Cumulative exposure from structurally related substances with critical hazardous properties (e.g similar endocrine disrupting property like antiandrogenic or estrogen-like effect).

2. Member States in collaboration with ECHA propose substances for CoRAP update in principle by end of May including a justification document with initial concerns. In addition Member States Competent Authorities may, whenever necessary, notify candidates based on Art. 45(5) of REACH.

3. ECHA prepares draft CoRAP list and submits to Member States for expression of interest over the summer months for evaluating the substances.

4. In October-November of year N-1, draft CoRAP is sent to Member State Committee. In parallel, publication of public version of draft CoRAP update with contact details of the proposed evaluating Member State. No public consultation foreseen. However, ECHA could inform EPA and invite comments on proposed update, indicating also a deadline by which comments would have to be submitted.

5. Final discussions in Member State Committee February year N. Comments received from the US EPA could be presented for consideration and ECHA could compile responses to US EPA's comments. If considered necessary, comments and responses could be discussed in a tele-/videoconference, while respecting the timescale for CoRAP updates.

6. Final publication of updated CoRAP for years N to N+2 in March of year N, including justification for each substance and contact details of evaluating Member State.

7. Actual evaluation of substances for year N is conducted by Member State authorities within 12 months from publication of CoRAP. Evaluation can be focused on initial concern or become broader. During that time, contacts between evaluating Member States and registrants (normally via lead registrant) and also certain downstream users.

8. Draft Decision on additional information requirement (if considered necessary) needs to be submitted to ECHA within the formal 12 months period. It could concern all or part of the registrants (or downstream users). ECHA sends the first Draft Decisions (DD1) to concerned Addressees (i.e. registrants and certain downstream users) who have 30 days to submit comments to ECHA. ECHA forwards the comments to the evaluating Member State, who has to address the comments but has no specific timeline at this stage.

9. When the evaluating Member State has considered the comments from registrants/downstream users (if any), it notifies other Member States and ECHA of the (revised) Draft Decision (DD2), initiating a 30-day period for them to propose amendments (PfA). The initial comments from the registrants/downstream users on DD1 are also made available to the other Member States. If there are no PfAs, the Decision will be adopted by ECHA as proposed in DD2. If there are PfAs, the draft Decision (and PfAs) will be discussed in the Member States Committee in ECHA.

10. Discussions in Member States Committee on draft Decision – in the presence of lead registrant/coordinator. Final conclusion (= unanimous agreement or resolution that there is not unanimity) of the Member States Committee in closed session (i.e. only Member States representatives and ECHA).

11. If unanimity in Member States Committee on draft Decision, adoption by ECHA – otherwise, referral to the Commission, who has then to adopt the Decision.

12. When the additional information is submitted, Member State evaluates it and decides on the need for possible follow-up action (see next sections for different possibilities).

To note: *The US to develop a similar scheme for their Chemicals Work Plan updates and assessment of chemicals, as well as for preparing and adopting test orders (or other informal/formal arrangements with companies to provide test data). Maybe also related: process run by NTP to decide on testing needs for a chemical to be conducted by its own institutes?*

2. Classification & Labelling: Process for harmonised C&L

1. Member States include their intention for submitting a proposal in ECHA's public 'Registry of Intent' including the expected date of submission of the dossier with the proposal. As of 6 May 2014 this is also possible for companies wishing to submit proposals (*To be noted: inclusion of intentions in the registry is voluntary*).

2. Member State or company(ies) submits a formal proposal, which ECHA (in co-operation with the Rapporteur from the Risk Assessment Committee (RAC) scrutinises in a conformity check for compliance with legal requirements. If necessary, submitter of the proposal re-submits a new

version (*To be noted: there's no legally binding timeline for re-submission)*. If no new version is submitted, the procedure is terminated.

3. ECHA launches public consultation on proposal for 45 days. ECHA could inform US authorities specifically and invite comments.

4. All comments are forwarded to the dossier submitter who prepares also a response to comments document. Comments received from the US EPA would also be addressed.

5. RAC Rapporteur (in cooperation with Co-Rapporteur) evaluates proposal and comments (and the responses proposed by the dossier submitter) and prepares draft opinion and response to comment document. This would also address comments from the US authorities.

6. RAC discusses draft opinion and response to comment document (in the presence of accredited stakeholders). If necessary due to complicated scientific issues, ECHA can organise 'expert meetings'. Based on the assessment of comments submitted earlier, ECHA could invite technical experts from the US authorities to participate in RAC meetings and/or expert meetings as observers[2].

7. RAC finalises opinion and ECHA transmits it to the Commission. The opinion is also published on ECHA's website. The comments and the responses are made public when the opinion is published.

8. COM prepares draft amendment of Annex VI to the CLP Regulation and notifies under WTO-TBT. COM could specifically inform US authorities and, if so requested, discuss bilaterally before a vote in the REACH Committee and taking a final decision. (***To note***: already today, such prior consultations would have to take place if requested under the TBT Agreement, the suggested procedure would offer an avenue for an alternative and more in depth technical discussions directly among regulators). It would have to be designed in a way that avoids duplication of procedures.

To note: *The US to develop a similar scheme for the NTP activities regarding classification of substances.*

3. Nomination of SVHC for Candidate List

1. ECHA and Member States screen substances in accordance with the SVHC 2020 Roadmap Implementation Plan. List of substances selected for a Risk Management Option Analysis (RMOA) and Member State (or ECHA) conducting the RMOA will be made public. Stakeholders can contact the authority conducting the RMOA for commenting/discussion. US authorities could also do so, if they wished to submit information to a Member State conducting a RMOA.

2. ECHA or Member State prepares draft RMOA that is shared for comments by other Member States. In some cases these are as well discussed in meetings of the Risk Management Meetings

[2] Nota bene: ECHA's Management Board would first have to adopt a Decision to allow for participation of technical experts from US authorities at meetings of the Committees or other expert meetings.

(RIME). These meetings are not open to stakeholders. The conclusions of the final RMOA are made public.

3. Depending on the outcome of RMOA, Member States or ECHA enter intention to identify a substance as SVHC (or to prepare a restriction – see section 5) into Registry of Intent (RoI). The conclusion can also be to take no specific action (under REACH and/or other legislation)/

4. Member State or ECHA submit proposal for identifying a substance as SVHC.

5. ECHA informs all other Member States and launches a public consultation for 45 days on the proposal. All stakeholders can submit comments. ECHA could inform US authorities specifically and invite comments.

6. If no comments are received, ECHA includes the substance into the candidate list.

7. If comments are received (from either Member States or stakeholders) the submitter of the original proposal prepares a response to comments document, which, together with the proposal is discussed in the Member States Committee (MSC). If there is unanimity in MSC, the substance is added to the candidate list – if not, ECHA refers the decision to the Commission [***To note:*** this has not happened so far].

8. In case of referral to the Commission (which has so far not happened), the Commission would have to launch a formal decision-making process (including notification to WTO-TBT). The Commission could specifically inform US authorities and, if so requested, discuss bilaterally before a vote in the REACH Committee and taking a final decision (***NB***: similar comment as under paragraph 8 of section 2 applies).

4. Prioritisation of SVHC from Candidate List for Inclusion into Annex XIV (i.e. making the substance subject to authorisation

1. ECHA screens the substances on the candidate list against agreed prioritisation criteria[3] and submits draft recommendation for prioritisation to Member States Committee (MSC). Draft recommendation also takes ECHA's capacity into account to handle requests for authorisation following the inclusion of the prioritised substances into Annex XIV.

2. Following a first discussion in MSC, ECHA launches a public consultation for 3 months inviting al stakeholders to comment (including in particular on possible exemptions). ECHA could inform US authorities specifically and invite comments.

4. ECHA prepares response to comments document and submits (updated) draft recommendation to MSC. The response to comments document would also address comments from the US authorities, as, in fact, already happens today for comments from US Stakeholders if such comments are submitted in the context of the public consultation.

[3] http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

5. MSC provides opinion on draft recommendation, but this is not binding on ECHA. ECHA finalises recommendation and transmits it to the Commission (including all relevant background documents).

6. The Commission prepares draft Regulation to amend Annex XIV and notifies it to WTO-TBT, before vote in the REACH Committee and formal adoption. The Commission could specifically inform US authorities and, if so requested, discuss bilaterally before a vote in the REACH Committee and taking a final decision (***NB***: similar comment as under paragraph 8 of section 2 applies).

5. Restriction Process

1. Member States or ECHA enter intention to submit a restriction proposal for a substance into Registry of Intent (RoI).

2. Within 12 months, Member States or ECHA submit actual proposal (in the format of an Annex XV Dossier). Within 30 days, ECHA Secretariat and Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) verify conformity with requirements. If found not in conformity, reasons are sent to Member State or ECHA within 45 days for addressing deficiencies (to be made within 60 days – otherwise the procedure is terminated).

3. ECHA launches a public consultation for 6 months inviting all stakeholders to comment. ECHA could inform US authorities specifically and invite comments – including on potential alternatives, e.g. based on US EPA's Design for Environment programme.

4. Within 9 months from the day of publication of the proposal, the Risk Assessment Committee (RAC) prepares its opinion on the proposal, taking into account the original proposal and all comments. In fact, the submitter of the original restriction proposal prepares a 'Response to Comments' document, which is then 'validated' by RAC. Stakeholders can participate in RAC discussions. Based on the assessment of comments submitted earlier, ECHA could invite technical experts from US authorities to participate in RAC meetings as observers.

5. Within 12 months from the day of publication of the proposal, the Socio-Economic Analysis Committee (SEAC) prepares its opinion based on original proposal and comments from first public consultation. The process includes publication of a draft opinion and a further public consultation of 60 days. ECHA could inform US authorities specifically and invite comments – including on potential alternatives, e.g. based on US EPA's Design for Environment programme – in case not already done during the first commenting round described under Step 3. Stakeholders can participate in SEAC discussions. Based on the assessment of comments submitted earlier, ECHA could invite technical experts from US authorities to participate in SEAC meetings as observers.

6 ECHA transmits opinions of RAC and SEAC to the Commission, who prepares within 3 months a draft Regulation to amend Annex XVII to REACH and notifies it to WTO-TBT, before vote in the REACH Committee and formal adoption. COM could specifically inform US authorities and, if so requested, discuss bilaterally before a vote in the REACH Committee and taking a final decision (***NB***: similar comment as under paragraph 8 of section 2 apply).

6. Authorisation Process

1. Companies (individual or in consortia) submit applications for authorisation for continued use of a substance in Annex XIV. ECHA Secretariat and RAC and SEAC verify and confirm conformity with requirements – if found not in conformity, applicants have to address additional requests from RAC and SEAC.

2. ECHA launches a public consultation for 8 weeks based on 'broad information on uses' inviting all stakeholders to comment in particular on alternative substances or technologies. SEAC may, if it deems necessary, require the applicant or request third parties to submit additional information on possible alternative substances or technologies. ECHA could inform US authorities specifically and invite comments – including on potential alternatives, e.g. based on US EPA's Design for Environment programme.

3. RAC and SEAC prepare their opinions within 10 months of acceptance of application, taking into account all comments submitted. Applicants may (but are not obliged to) submit reactions to comments received during public consultation. Applicants and stakeholders can participate in the discussions (except when these involve CBI – which are limited to the applicant concerned). Based on the assessment of comments submitted earlier, and except for discussions involving CBI, ECHA could invite technical experts from US authorities to participate in RAC / SEAC meetings as observers.

4. RAC and SEAC opinions are sent to applicants for commenting. Within 30 days applicants shall give notice of whether they intend to comment. If so, comments have to be provided within two months of receipt of opinions. The Committees shall consider the argumentation provided and finalise their opinions within 2 months of receipt of the comments.

5. ECHA transmits opinions of RAC and SEAC to the Commission (where applicable with comments from applicants), who prepares within 3 months a draft Decision to grant (or refuse) authorisation, for submission to the REACH Committee for a vote and formal adoption. As this concerns individual cases, there will be no notification to WTO-TBT.

To note: *The US to develop similar schemes for interaction with regard to any risk management activities related to chemicals – primarily at Federal level, but in absence thereof (e.g. for restrictions/bans) at State level.*