MEETING DOCUMENT

From: Commission

To: Trade Policy Committee

Subject: TTIP chemicals – revised versions on papers on outline of provisions and modalities for cooperation

Delegations will find attached a note by the Commission services on the above-mentioned subject.

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NB: Please note that the document in annex is an individualized copy.

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Brussels, 18 September 2014
TRADE 56/2014

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NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: TTIP: Chemicals - revised versions of papers on outline of provisions and modalities for cooperation

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OBJECTIVE: For information

REMARKS: The enclosed papers contain revisions reflecting the outcome of the technical meeting with Member States held on 16 September. Should there still be any remarks, they should be sent to the contract officials indicated above by Tuesday 23 September close of play.

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EU-US TTIP Negotiations

18 September 2014

Without prejudice

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Outline for provisions on chemicals

Introduction

The outline below suggests provisions that could be appropriate for the chemicals sector. They are based on maximizing the scope for interaction between regulators within each side's regulatory system in a way that preserves the respective levels of protection and is consistent with the mechanisms under which they function. The provisions on regulatory coherence in the Horizontal Regulatory Chapter will be applicable to the chemicals sector, and will equally be based on the respect of the integrity and protection offered by each side's regulatory system. The TTIP specific provisions concerning chemicals would prevail, in case of conflict, over the provisions of the Horizontal Regulatory Chapter. Consistency between the horizontal provisions on regulatory coherence and the specific provisions for chemicals will be kept under review as both sets of provisions start taking shape.

1. **Objectives**

Recalling the principle of high levels of environmental, worker and consumer protection as an objective of chemical regulation including their implementing measures and procedures in accordance with the systems of each Party, and that accordingly nothing in these provisions is to be understood as requiring changes in the legislative framework of either side, which are considered to be consistent with respective WTO obligations.

To promote regulatory cooperation with a view to: (i) facilitate the coordination of regulatory actions, including for new technologies or issues, on the basis of the best available scientific information and knowledge; (ii) avoid unnecessary duplicative requirements; (iii) enhance exchanges on scientific issues including on risk assessment and other methodological issues; (iv) if possible and compatible with the regulatory framework of each side and their desired level of protection, to identify and implement actions that can lead to a reduction of unnecessary costs to transatlantic trade

To promote alignment in classification and labeling of chemicals in accordance with the UN Global Harmonized System (GHS) for classification of substances

To cooperate in the development and implementation of international disciplines and to work on international regulatory fora relevant for chemicals, notably at the UN and OECD levels

2. **Fields of cooperation**

Principles:

- Parties commit to respond to comments/requests for consultation – but no obligation to stop or suspend a process, including where timelines apply.
- Parties are not obliged to participate in the other's procedures if they choose not to do so.

Topics

a) Cooperation on ***prioritization of substances for assessment***, in particular informing the other Party to allow for mutual consultation upon request when:
   - Setting or reviewing criteria for defining priority substances
   - Updating priority lists

   Cooperation during the actual assessment that is being conducted in line with each Parties' rules and procedures, including in particular alerts to the other Party when occasions for commenting arise.

b) Cooperation and exchanges on ***assessment methodologies***, in particular informing the other Party to allow for mutual consultation upon request when assessment methodologies are reviewed and/or technical guidance documents are developed or reviewed, taking into account, where relevant, the work [missing] in international fora

c) ***Alignment in classification and labeling*** of chemical products – Commitment to apply GHS across all chemicals within X years, and to implement the periodic amendments subsequently. Cooperation in GHS matters both towards greater alignment of building blocks actually implemented in the Parties, and for further development of GHS at UN level.

   Agreement on classifications for individual substances through participation in each other's existing processes. Parties to inform each other when processes to classify substances start to allow for submission of comments. Parties to commit to respond to the other's comments before taking decisions. Possibility to participate in expert meetings reviewing data for determining classification.

d) ***Exchange of information on regulatory plans*** (concerning general regulations as well as plans for regulating individual substances). Each side to publish regularly their regulatory plans when available (and if possible periodically for instance every six/other months, or as matters arise (e.g. when substances are selected for risk management option analysis, when the Registry of Intent of ECHA is updated (which contains intentions for classification and labeling, restrictions, etc.). Regulatory activities concerned covered at both EU and Member States, Federal and State level under defined mechanisms.

e) Parties to alert each other to allow for ***consultation on regulatory processes affecting individual substances and on new draft regulations*** upon request, commitment to consider comments expressed to the other Party and to respond to them in accordance with the other applicable TTIP provisions (i.e. Regulatory Coherence and TBT). Where appropriate, Parties to offer each other the possibility to participate in expert meetings reviewing data in view of proposed regulatory action.

f) ***Cooperation on new and emerging issues of common interest*** and in particular to exchange scientific and other information and data on these issues and to promote insofar as possible a common understanding of the science underpinning regulatory decisions.

3. Exchange of information

Cooperate in the publication of chemicals related data which are made available to the public. Provisions to facilitate the exchange of non-confidential information among regulators; this includes cooperation on electronic formats and tools used to store data. If considered necessary, establish agreement to exchange and protect CBI: Principles and practical modalities, as necessary to be developed at a later stage [NB: this issue could also be addressed horizontally in TTIP].

4. Chemicals working group

- In charge of overseeing the application of the provisions of this annex and of reporting [yearly] on it to the Regulatory Cooperation Board or similar Body to be established in the Horizontal Chapter; report to be made public. To this effect it will establish periodically a work plan with priorities for cooperation in each of the areas covered by the sector-specific provisions on chemicals.
- In charge of organizing the cooperation among regulators and of facilitating the exchanges of scientific information relevant for regulatory purposes while avoiding duplication of case-specific cooperation activities.
- To exchange information on regulatory issues raised by either side.
- To examine and make recommendations concerning areas for future cooperation and for new actions concerning the chemical sector under TTIP.
- WG to be composed of the relevant regulators and officials from each side. Possibility to invite stakeholder organizations as observers on an ad-hoc basis.
- To meet at least once a year unless otherwise decided, at alternating locations of the Parties.
- Can establish ad hoc expert or scientific groups to discuss particular issues
- In charge of liaising with relevant stakeholders in a way that their input on chemical regulatory issues can be provided and taken into account in regulatory cooperation as appropriate.

- Work to be conducted in a transparent way – Will publish in advance agendas of meetings and summary reports of its conclusions. Questions addressed by stakeholders that require the launch of internal procedures to be replied by each side in accordance with their own procedures.

5. Revision of sectoral provisions

- These provisions can be amended in accordance with the provisions established in [the Horizontal Regulatory Chapter and the institutional chapter].

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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 co-operative 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 state 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 [missing] 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 stakeholder), also all relevant information available to the US authorities – and vice-versa for comparable procedures in the US. Although this note focuses on [missing] steps that could be envisaged under the EU framework, it is understood that similar steps would need to be envisaged in the US framework to enable a comparable level of consultation and interaction in the US chemicals regulatory process.

1. Prioritization 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 similarites)
- 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 (for instance 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 characterization 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.

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.
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 forward 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 (this is only Member States representatives and ECHA).
11. If unanimity in Member States Committee on draft Decision, adopted 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 would usefully devleop 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. <u>Classification & Labelling: Process for harmonized C&L</u>

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 (*<u>To be noted</u>: 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) scrutinizes in a [missing] check for compliance with legal requirements. If necessary, submitter of the proposal re-submits a new version (*To be noted: there is 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.

4. 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.

5. RAC discusses draft opinion and response to comment document (in the presence of accredited stakeholders). If necessary due to complicated scientific issues, ECHA can organize 'expert meetings'. ECHA could invite technical experts from the US authorities to participate in RAC meetings and/or expert meetings as observers.[2]
6. RAC finalizes [missing] 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.
7. 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 not need to duplicate with TBT consultations but offer an avenue for an alternative and more in depth technical discussions directly among regulators).

To note: The US would usefully 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] 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.

2. ECHA or Member State prepares draft RMOA that is shared for comment by other Member States. In some cases these are as well discussed in meetings of the Risk Management 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***: [missing] 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 7 of section 2 applies).

4. <u>Prioritization of SVHC from Candidate List for Inclusion into Annex XIV (i.e. making the substance subject to authorization)</u>

1. ECHA screens the substances on the candidate list against agreed prioritization criteria[3] and submits draft recommendation for prioritization to Member States Committee (MSC). Draft recommendation also takes ECHA's capacity into account to handle requests for authorization following the inclusion of the prioritized substances into Annex XIV.
2. Following a first discussion in MSC, FCHA launches a public consultation for three months inviting all stakeholders to comment (including in particular on possible exemptions). ECHA could inform US authorities specifically and invite comments.
3.
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.
5. MSC provides opinion on draft recommendation, but this is not binding on ECHA. ECHA finalizes recommendation and transmits it to the Commission (including all relevant background documents).
6. The Commission prepares draft Regulation [missing] amend Annex XIV and notifies it to WTO-TBT, before vote in the REACH Committee and formal adoption. The Commission could specifically inform

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

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 7 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 [missing] months, Member States or ECHA submit actual proposal (in the format of an Annex [missing] Dossier). Within 30 days, ECHA Secretariat and Risk Assessment Committee (RAC) and Socio-Economic Analysis 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, for instance 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. 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 [missing] 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. 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 comments as under paragraph 7 of section 2 apply).

6. Authorization Process

1. Companies (individual or in consortia) submit applications for authorization for continued use of a substance in Annex XIV. ECHA Secretariat and RAC and SEAC verity 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 eight 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). 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 finalize 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) authorization, 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 would usefully 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.