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Cefic response to Commission's request for further details on joint ACC-Cefic proposals for enhanced cooperation on chemicals under TTIP

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1. Introduction

The document has been drafted by Cefic, with the cooperation of ACC, with the aim to meet the Commission's request for further information following the submission in December of the joint ACC-Cefic proposals for enhanced cooperation in chemicals. The document aims to put the joint proposals into the context of processes and procedures under REACH and TSCA. The proposals in this document are all in line with the joint ACC-Cefic proposals of December. However, in some cases the proposals are slightly modified to fit the relevant processes under both REACH and TSCA. The document focuses on processes and actions rather than underlying principles. For principles underpinning the proposals reference is made to the joint ACC-Cefic proposals of December.

2. Co-operation in prioritisation of chemicals for assessment and assessment methodologies

Expected result of TTIP

Common prioritisation principles and burden sharing for assessments of high priority chemicals and, where appropriate, categories of substances (e.g. substance evaluation under REACH and high priority targeted risk assessments under the current TSCA and safety determinations under a modernised TSCA).Recognition of each other's data and studies and harmonized standards and methodologies for hazard and risk assessment are necessary for effective burden sharing.

Benefits

Closer cooperation on prioritisation of substances for further assessment would lead to cost reductions for both authorities and companies by creating opportunities for burden sharing. That would also contribute to narrowing the difference in outcomes of assessments by fostering coherence and building confidence in each other's assessments. In the long run that could also result in greater coherence in regulatory outcomes including down-stream legislation which would further reduce regulatory divergence.

Current Legislation

REACH and TSCA are very different with regard to prioritisation of substances for assessment and further risk management actions. Whilst TSCA applies risk based prioritisation, REACH includes prioritisation based on production volume or hazard and in several procedures risk.

REACH

The REACH Regulation sets rules for prioritisation. In the case of safety assessment and registration the timetable is based on volume manufactured in or imported into the EU (as a proxy for possible exposures). Hazard is the basis for prioritising e.g. CMR substances for registration and assessment and for one of the risk management options (authorisation).

However, the Regulation also provides for some flexibility in the application with regard to prioritisation notably in:

Substance evaluation under REACH

Criteria

Prioritisation for substance evaluation is defined in Article 44 that states that the approach for prioritisation shall be based on risk including hazard e.g. persistence and bio-accumulation, exposure and tonnage. Both ECHA and Member States are involved in that process.

Process

In cooperation with the Member States, ECHA defines risk-based criteria and then selects the substances that are to be evaluated. The selected substances are listed by ECHA in the community rolling action plan (CoRAP) following the opinion of the Member State Committee. An evaluating Member State will be designated for each substance on the final CoRAP. Member States then evaluate the substances based on the registration dossiers submitted by companies. The substance evaluation process assesses all registration dossiers from all registrants specific to the same substance, i.e. in order to take into account the combined exposure. Other available sources of information are also considered. Further information can be requested from companies.

Currently there are 82 substances on the Community Rolling Action Plan (CoRAP list).

If the evaluation concludes risks are not properly controlled, it may lead to the proposal of EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH. The evaluation may also conclude that the risks are sufficiently under control with the measures already in place.

TSCA

Criteria and Process

EPA has recently adopted a screening approach to identify priority chemicals for further evaluation and others for further information gathering. Substances are ranked into "hazard levels" in a two-step process incorporating both human health and environmental toxicity concerns.

Step 1 was used to identify candidate chemicals meeting one or more of the following factors: substances with reproductive effects; persistent, bioaccumulative, and toxic (PBT chemicals); probable or known carcinogens; chemicals used in children's products, in consumer products, and chemicals and detected in biomonitoring programs.

Step 2 utilised a chemical scoring analysis of three categories: Hazard; Exposure; and Potential for persistence and/or bioaccumulation.

Of the 83 "Work Plan" chemical substances identified after Step 2, EPA initiated 7 chemical assessments in 2012 and completed peer reviews of five of those 7 assessments. EPA is currently finalizing those assessments and beginning work on another 23 substances. It is estimated that, at EPA's current pace, it may take more than 10 years to complete all 83 chemical risk assessments.

Opportunities for cooperation

To establish common prioritisation principles, burden sharing and alignment in assessment methodologies taking account of

- REACH: CoRAP and the selection of substances for risk management actions
- TSCA: prioritisation criteria for substances for further review and selection of substances for Work Plan chemicals risk assessments

Activities

Establish a formalised process between EPA and ECHA to

- agree on common risk based principles for setting priorities for substance evaluation under REACH and for high priority risk assessments under the current TSCA and safety determinations under a modernised TSCA.
- cooperate in identifying categories or classes of chemical substances that could assure an efficient prioritisation and assessment.
- identify opportunities to share the burden for assessment by

- sharing the results of respective prioritisations (list of chemical substance based on the prioritisation criteria and for which assessments or safety determinations have not been completed).
- endeavour to coordinate work on overlapping priorities to the extent possible

- build confidence in each other's data and assessments and move towards alignment in assessment methodologies
  - a process similar to what is used in the OECD could be used i.e
    start by working in parallel on some test cases, compare results and outcome, identify differences in assessment methodologies and seek alignment

- The long term objective should be mutual acceptance of each other's assessments as a basis for decision making

For further details and options for scientific cooperation see chapter 3.

3. Scientific cooperation to give advice on chemicals assessment including on new and emerging issues of Trans-Atlantic relevance

Expected result of TTIP

Industry aims at a formalized process to discuss and agree on basic standards and definitions for emerging regulatory issues. To achieve this goal, several options are possible.

1) Establishment of a Trans-Atlantic Joint Scientific Advisory Committee (TSAC) to promote common Trans-Atlantic understanding of scientific evidence. It is recommended that the TSAC should be a cross-sectoral (e.g. horizontal) committee, including senior scientists covering all major sectors of TTIP. The Committee will have agreed terms of reference utilizing the experience of established scientific committees on both sides of the Atlantic. The members of the committee would function under an agreed code of conduct.
2) No permanent scientific advisory body. Instead, under predefined conditions, the Trans-Atlantic Regulatory Cooperation Council appoints an ad-hoc Scientific Advisory Committee composed of Trans-Atlantic experts on a specific issue. The work of the ad-hoc Scientific Advisory Committee would be time-limited and restricted to specific questions. Following completion of its work, the Committee would be disbanded again.

Benefits

A common understanding of the scientific evidence would increase prospects for agreement on common regulatory definitions and standards. Formalized scientific cooperation would allow for close cooperation of regulators and scientists and thus would form the basis for Trans-Atlantic regulatory cooperation grounded in common scientific evidence.

Activities to get expected result

General requirements for formalized cooperation:

- Members of an ad-hoc Scientific Advisory Committee (SAC) should be senior scientists from EU and US agencies/scientific committees, nominated and approved by the Trans-Atlantic Regulatory Cooperation Council (TRCC). Requirements for SAC membership would need to be defined, formalized in a terms of reference and code of conduct for members and will operate according to the highest standards of science. This process should include EU and U.S. government experts as well as encouraging broad stakeholder participation (similar to U.S. EPA Scientific Advisory Committees).

- The advice of a SAC (whether permanent or ad-hoc) would be requested (mandatory under defined conditions) by either the TRCC or sector specific committees such as the Chemical Sector Joint Coordinating Committee (CSJCC). Any scientific opinions and conclusions of the SAC would be shared with regulators on both sides of the Atlantic. Any scientific opinion released by the SAC as well as any mandate should be publicly accessible via the internet. The advice of the SAC would not be legally binding. Topics of regulatory concern on both sides of the Atlantic should be addressed or when significant data gaps do not allow for a comprehensive assessment of the situation.
- In addition to new and emerging issues and common standards for hazard and risk assessment other possible tasks for the Scientific Advisory Committee could include scientific advice in the fields of classification and prioritisation (See relevant sections)

- In case of a permanent Trans-Atlantic Scientific Advisory Committee, the TSAC should have the ability to recruit senior scientific specialists as deemed necessary to address specific issues. This process should include EU and U.S. government experts as well as encouraging broad stakeholder participation (similar to U.S. EPA Scientific Advisory Committees).

4. Co-operation on new and emerging issues

Expected result of TTIP
A mechanism for early and close cooperation on emerging scientific issues with regulatory relevance

Benefits

Emerging scientific issues present the EU and U.S. with opportunities to align regulatory decisions and prevent divergence of regulations prior to their enactment. This does not only apply for emerging issue currently under discussion (e.g. Endocrine Disruptors and Nanotechnology) but most important, it applies for any emerging regulatory issues in future.

Activities to get expected result

Establish the modalities for mandatory early consultation and review of current scientific knowledge related to emerging issues including scientific advice. Regulatory bodies should have the possibility to request a scientific assessment from the Scientific Advisory Committee (see chapter above) on any emerging issues in order to receive the most up-to-date information possible and provide for a state-of-the art chemicals regulation which is based on risk and sound science.

5. Promoting alignment in Classification and Labelling

Expected result of TTIP

A mechanism in place for further aligning classification and labelling based on GHS, reducing or eliminating the need for dual classifications; promoting reciprocity for classification and labelling across the Atlantic and promoting the UN Global List of Classified Chemicals as a common classification inventory.

Benefits

Promoting greater coherence on classification and labelling issues would help facilitate trade and provide a level playing field for companies. It would also help to promote the cost effective implementation of the Globally Harmonized System for Classification and Labelling (GHS). Any system which would support only a negligible change in labelling would be beneficial to companies trading between the US and Europe. The savings are not only defined by label printing but also packaging type and logistics consideration. Furthermore, a greater alignment between the EU and US would serve as a model for other countries adopting the GHS requirements.

Current legislation

UN Globally Harmonized System (GHS)

GHS provides a common basis for classification and hazard communication. It includes a "building block" approach to facilitate implementation. While the full range is available to everyone, the full range does not have to be adopted. This different take up of building blocks and the variation in interpretation does not currently allow complete harmonisation. However, it is not possible to change the criteria of a building block ensuring consistency among given GHS elements. Additional building blocks may be added to "preserve the already existing level of protection".

EU:

The Classification, Labelling and Packaging (CLP) Regulation, Regulation (EC) No 1272/2008, entered into force in January 2009, and the method of classifying and labelling chemicals it introduced is based on the United Nations' Globally Harmonised System (GHS). The Regulation replaces over time two previous pieces of legislation, the Dangerous Substances Directive and the Dangerous Preparations Directive. There is a transition period until mid-2015. The criteria for classification in the CLP Regulation are regularly amended to follow the updates of the UN GHS (currently, the 4th revision is in force and preparations to include the 5th revision are ongoing).

A set of harmonized, legally binding classifications has been established and is filled in a well-defined process via dossier preparation, public consultation and discussion in the Risk

Assessment Committee at ECHA and adoption by the Commission. Harmonised classifications are generally established for a few defined hazard classes.

- Carcinogenicity, Category 1A, 1B or 2;
- Germ cell mutagenicity, Category 1A, 1B or 2;
- Reproductive toxicity, Category 1A, 1B or 2;
- Respiratory sensitization, Category 1

Harmonized classification and labelling for other hazard classes and/or differentiations is generally done for active substances in plant protection products and biocides (pesticides) and may be proposed on a case-by-case basis, if action is justified at European Union level (Article 36(3) of the CLP Regulation)

To date a harmonized classification has been established for 4200 substances (compared to 125.000 self-classified substances). For many substances the classifications were determined prior to the introduction of the CLP requirements and therefore include classification other than CMR and respiratory sensitizers as defined above. These were then converted to CLP criteria and included into Annex VI of the CLP requirements.

USA:

New changes to the US Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard are bringing the United States into alignment with GHS, further improving safety and health protections for workers. 'The new hazard communication standard still requires chemical manufacturers and importers to evaluate the chemicals they produce or import but provides a single set of harmonised criteria for classifying chemicals.

The Hazard Communication Standard which will be mandatory from 1 June 2015 is based on the 3rd version of UN GHS. This standard addresses occupational exposure to hazardous chemicals. OSHA also uses different interpretations in classification of carcinogens: instead of applying “GHS weight of evidence criteria” a chemical may be regarded as a carcinogen based on the Report on Carcinogens of the US National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC) monographs and OSHA carcinogen standards. Harmonized classifications in the US only exist for a very limited number of substances and are not legally binding.

Opportunities for cooperation

To align classification and labelling based on GHS.

Both systems, OSHA-GHS and EU-CLP, present differences in the following areas

a) adopted endpoints;

b) adopted categories within the endpoints;

c) some classification criteria and

d) substance concentration limits triggering mixture classification,

Activities to get expected result

- Identify the differences in the structure regarding classification and labelling for chemical substances and mixtures in the U.S. and EU by establishing the differences in the use of UN GHS building blocks in both jurisdictions;

- Seek alignment on the use of the same UN GHS building block approach in both jurisdictions.

- Establish modalities for mutual consultation regarding classification

- Consult manufacturers and importers on proposed classifications

- Where consensus lies, the use in a common classification inventory could be possible

- Promote the UN Global List of Classified Chemicals as a common classification inventory

- Develop mechanisms to promote mutual recognition/acceptance for labels

- Work on enhancing/simplifying import requirements for those substances classified according to this requirement and establish workshops and dialogue with those not yet engaged in the process whether they be international or domestic players.

6. Enhanced information sharing and protection of confidential business information (CBI)

Expected results of TTIP
Development of a mechanism for data/information sharing between governments including adequate safeguards to ensure the protection of commercial and proprietary interests

Benefits
Enhanced data and information sharing would enhance transparency and create significant efficiencies for governments and industry. This includes the elimination of duplication in the generation, testing and submission of data and would also save animal lives.

Current Legislation

1) Definition of CBI

REACH

In line with the jurisprudence of the European Court of Justice regarding the definition of what may constitute confidential material and the definition of undisclosed information in Article 39(2) of the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, a number of common principles have been derived in the implementation of REACH.
Thus ECHA's understanding of what constitutes confidential information is based on the following elements:

- the information must be known only to a limited number of persons, i.e. it must not be in the public domain or general knowledge in the industry. Typically the registrant or third party would have undertaken specific measures to keep the information secret.
- claims must be properly reasoned rather than simple statements
- the existence of a commercial interest must be demonstrated (the information must have some commercial value or legitimate commercial interests need to be at stake).
- disclosure of the information must potentially harm a registrant's or a third party's commercial interests and there must be a causal link between publication of the information and the potential harm.

TSCA

The rules for protection of trade secrets and commercial and financial confidential business information (CBI) disclosure of data are specified in TSCA §14. Everything protected from mandatory disclosure under the. Whether information can be claimed confidential for TSCA purposes steams from the Freedom of Information Act (FOIA) is prohibited from disclosure under TSCA with some exceptions. Generally speaking, the regulations protect any trade secret, commercial or financial information for which a company has taken reasonable steps to maintain confidentiality, and the release of which would substantially harm the businesses competitive position.

2) Data Sharing / Compensation

ECHA

Pursuant to Article 10 of the REACH Regulation, robust study summaries and study summaries may only be used for the purpose of registration where the potential registrant is in legitimate possession of the full study report or has permission from the data owner to refer to the full study report. REACH registrants shall guarantee that they have adequate rights to submit this information to ECHA.

The fact that the data from the robust summaries are subsequently published by the authority does not alter the status of ownership. When the data are obtained via the dissemination portal of the authority, the use of the information without obtaining the permission from the owner(s) of the respective information can still be considered as a violation of the rights of the owner.

Such permission from the data owner is usually granted upon payment of a financial compensation. This means that when data is subject to ownership rights, REACH registrants are either data (co-)owner or have usually paid some compensation to the data owner.
Therefore, in case data are exchanged between EU and US authorities and vice-versa pursuant to TTIP, it should be agreed that a company relying on data or information owned or controlled by a third party under a relevant regulatory process is required to have the rightful and legitimate access to the data via permission of the data owner.
This means that when an authority is provided data by another authority, when the data is published by the receptor authority, such publication should not permit the users to get free right to such data in the context of a regulatory process.

TSCA

TSCA and its implementation by EPA does not require proof of ownership of data (e.g. by a letter of access) nor a formalized compensation mechanism.. EPA only accepts full study reports – robust study summaries, in turn, are generally not considered as sufficient with some exceptions.

Opportunities for cooperation

Considerations on CBI and Data-sharing between EU/US authorities and CBI:

In short:

- the definition of CBI is quite similar in EU/US
- the mechanisms in place in the EU and the way the criteria to define CBI are interpreted and implemented by EU authorities (e.g ECHA) is much more restrictive in EU. While CBI claims under REACH are restricted to well defined areas, there is more flexibility to submit CBI claims under TSCA

Therefore, to translate such reality into the TTIP, there are different options in terms of scope of information to be exchanged between EU/US authorities. Cefic proposes that non-CBI data are to be exchanged, CBI can be exchanged on request and under certain conditions.

In all cases:

- the data that is exchanged (non-CBI or CBI) should never be further disseminated and published by the receiving authority
- the receiving authority should have in place technical and safety IT measures to preserve the security of CBI data (like the ones agreed between ECHA and the REACH Member State Competent authorities to get access to data in REACH-IT data base)

Data ownership

The data held by government and potentially exchangeable with another government includes the common case where the data is in possession of the government but is owned by companies (individually or jointly as in a REACH SIEF or REACH consortium). In other words, the government that possesses the data is the owner of database in the sense that it has the exclusive right to control the use and the making available to the public of information from the database but the content of the databases though might be subject to exclusive rights of third parties (companies). These rights include the right of ownership (proprietary interests) and the right for the protection of Confidential Business information (commercial interests).

Activities to get expected results

Critical for data sharing are mutually agreed CBI principles.

Data, that have been presumed CBI by the legislator or that have been assessed and acknowledged as CBI by an authority should not be shared per se between authorities pursuant to TTIP (e.g. Chemical Safety Reports submitted for REACH registrations). CBI data should be shared between authorities upon the following conditions:

- a request and justification has to be submitted by the requesting authority
- the requested authority shall consult the owner of the data regarding possible objections to the disclosure
- the data to be disclosed, if disclosed, should not be further disseminated and published by the receiving authority
- the receiving authority should have in place technical and safety IT measures to preserve the security of CBI data (like the ones agreed between ECHA and the REACH Member State Competent authorities to get access to data in REACH-IT data base)

In turn, regulatory agencies should share automatically all relevant and non-confidential data. Respective web-based mechanisms should be established.

In case of data exchange between EU and U.S. authorities and vice-versa under TTIP, a company relying on data or information owned or controlled by a third party under a relevant regulatory process would be required to have the rightful and legitimate access to the data via permission of the data owner (this in particular implies the request of original study reports by US EPA). The fact that the data may be subsequently published by the authority does not alter the status of ownership.

7. Mutual acceptance of notification/registration of new chemicals

Mutual acceptance of notification/registration of new substances would benefit innovation as it could provide a possibility for companies to test the market both in EU or the US without delay.

However, it is recognised that further detailed considerations will be necessary to ensure that such a common approach maintains the required high level of protection of human health and the environment on both sides of the Atlantic. As a next step we therefore propose to engage with the regulators to explore a way forward.