

## Statement of Intent

between

**the European Chemicals Agency (ECHA)**

and

**the United States Environmental Protection Agency,  
Office of Chemical Safety and Pollution Prevention's (OCSP) Office  
of Pollution Prevention and Toxics (OPPT) and  
Office of Research and Development's (ORD)  
National Center for Computational Toxicology (NCCT),**

### **Related to Chemical Management Activities**

The European Chemicals Agency (ECHA) and the United States Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention's (OCSP) Office of Pollution Prevention and Toxics (OPPT) and Office of Research and Development's (ORD) National Center for Computational Toxicology (NCCT), hereinafter referred to as the Participants,

Having regard, within their respective mandates as set out in the Founding Regulation 1907/2006 ("REACH Regulation") for ECHA<sup>1</sup> and in relevant provisions of United States law, respectively, to the potential of cooperating, as regulatory authorities in the field of chemicals safety, on technical issues of mutual interest and concern;

Whereas:

1. It is within the Participants' common interest as well as in the public interest to enhance their technical cooperation in contributing to a high level of protection of human health and of the environment;
2. The Participants take note with satisfaction of their initial contacts dedicated to identifying possible areas of mutual interest and cooperation;
3. The Participants remain conscious that issues reaching beyond technical cooperation and the exchange of views on regulatory tasks within their respective mandates and instead touching upon the implementation and further development of EU policies in this sector are to be covered by a separate tripartite accord to be established between the European Commission and the Participants;

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<sup>1</sup> As well as in the Regulation 1272/2008 ("CLP Regulation") and other Regulations that may in future entrust ECHA with further tasks which correspond with the tasks of U.S. EPA OPPT.



4. The Participants confirm their understanding that any exchange of information as described in Article 120 of the said Regulation (EC) No 1907/2006 will furthermore require an international agreement to be established between the European Union and the United States;
5. The Participants, within these boundaries, agree that professional peer contacts between them should be strengthened.

Have reached the following understanding:

**I. Purpose of the Statement of Intent**

The purpose of this Statement of Intent is to enhance technical cooperation between the Participants to share knowledge and exchange experience and best practice on matters of mutual interest through the various means described below.

**II. GVDY**

In accordance with their respective mandates, co-operation between the Participants may relate to the following areas:

- scientific collaboration and information exchange, in particular with regard to the registration (i.e., inventory) as well as hazard and risk assessment of chemical substances;
- exchange of operational experience as well as experience in strengthening regulatory capacities, for instance through training programmes;
- communication activities;
- active dissemination of public information and publications related to each other's activities;
- information exchange on matters of common interest, including emerging risks from chemical substances or guidance development; and
- sharing information and experience on risk identification, risk assessment and risk management tools and other similar products and related expertise.

This Statement of Intent is to be implemented by putting a rolling bilateral Work Plan (see Annex) into effect.

**III. Means of cooperation**

The Participants undertake, where possible and appropriate, to pursue the objectives of this Statement of Intent through the following means:

- (a) General knowledge exchange: The Participants expect to share and communicate materials or technical guidance on programmes and approaches established within their institutional mandates, as appropriate. They expect to provide each other with contact lists indicating staff members employed on matters of mutual interest to promote informal discussions on issues relevant to their execution of regulatory or institutional tasks, and update these lists at reasonable intervals;
- (b) Missions and exchange of staff: The Participants expect to, subject to available resources, promote the exchange of experience by continuing to enable personal

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contact of their staff members through missions to each other's institutions, focusing on priority areas of interest and on an "as needed" basis. Such missions, may also be complemented or replaced by video and tele-conferences. They expect to also investigate the legal and practical possibilities for a potential exchange of staff (i.e., the secondment of staff – unilaterally or in the format of an exchange programme – to each other's institutions for a longer period of time);

- (c) Cooperation on training: The Participants expect to exchange mutually suitable training and self-study material as well as explore possibilities to organise joint training events on matters of common interest and relevance. The Participants expect to share training modules (e.g. webinar material, training manuals established by either of the Participants) and identify specific training needs that may be satisfied through their cooperation. The Participants expect to share – occasionally very informal – "in-house guidance" on topics of interest to the strengthening of capacities of staff. They expect to also exchange experience on training and coaching methods and tools as well as provide contact details of staff members in charge of organising training events;
- d) Cooperation on communication: The Participants expect to exchange information and best practices related to their activities to address the general public and more specific audiences / target groups with information related to chemical safety (i.e., the protection of human health and of the environment) and expect to establish contacts between staff members handling such communications activities;
- e) Any other feasible means: The Participants may furthermore identify any other appropriate means within the parameters of their mandates to further their cooperation on the rolling Work Plan.

#### **IV. Formalisation of cooperation**

On the basis of this Statement of Intent, the Participants expect to at appropriate intervals draw up revised versions of the rolling Work Plan that is – in its initial version – annexed to this Statement.

#### **V. Exchange of information**

All exchange of information between the Participants is expected to take place for the purpose of and in accordance with the provisions of this Statement of Intent. The Participants intend to designate one staff member, each, as a co-ordinator for the maintenance of close, direct and continuing contacts with a view to ensuring the application of the provisions of the present Statement of Intent. These main contact persons expect to keep, and update as necessary, the contact lists of staff members mentioned under heading III a), above.

#### **VI. Use of information**

Information exchange under this Statement of Intent is to be treated in accordance with applicable law. Sharing information is to be consistent with applicable law, including that which is intended to safeguard the rights of third parties (in particular, their intellectual property rights). This Statement of Intent is not to be construed as authorising the disclosure, use and processing of information for other purposes than provided under respective law.

**VII. Divergences of interpretation or implementation and Legal effect**

The Participants undertake to make their best efforts with a view to resolving any divergence of opinion that may arise in the implementation of this Statement of Intent.

This Statement of Intent does not create any legal obligation, or legal right or benefit, substantive or procedural, enforceable against any of the Participants. It will be carried out subject to the availability of appropriated funds and other resources, and nothing in this Statement of Intent legally obligates the Participants to expend funds or provide other resources.

**VIII. Amendments**

The Participants may modify this Statement of Intent by mutual written consent at any time.

**IX. Termination**

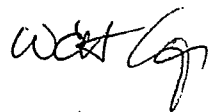
Either Participant may discontinue its participation under this Statement of Intent giving at least three months written notice to the other Participant, or by mutual written consent.

**X. Rolling Work Plan**


The rolling Work Plan attached to this Statement of Intent forms an integral part of the Statement, but can be amended separately by mutual written consent. The Participants intend that it shall be updated at reasonable intervals, in particular when the tasks outlined in the work plan are completed or should be complemented by new or additional actions.

**XI. Entry Into force**

This Statement of Intent is to commence upon signature by the Participants.

A handwritten signature in black ink, appearing to read "W. K. G.", is located in the bottom right corner of the page.

Signed at the U.S. Mission to the Organization for Economic Cooperation and Development (OECD) in duplicate on 15 November, 2010.

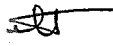
signed 


17. 12. 2010

  
Geert Dancet, Executive Director  
European Chemicals Agency

signed

  
Robert Kavlock, Director  
National Center for Computational Toxicology  
Office of Research and Development  
U.S. Environmental Protection Agency

signed 

  
Wendy Cleland-Hamnett, Director,  
Office of Pollution Prevention and Toxics,  
U.S. Environmental Protection Agency

## 2016-17 Rolling Work Plan

for the Statement of Intent between the European Chemicals Agency (ECHA)  
and

the United States Environmental Protection Agency (U.S. EPA),

Office of Chemical Safety and Pollution Prevention's (OCSP) Office of Pollution Prevention and Toxics (OPPT)  
and Office of Research and Development's (ORD) National Center for Computational Toxicology (NCCT),  
Related to Chemical Management Activities

This document describes the 2016 activities planned by ECHA and U.S. EPA to implement the above mentioned Statement of Intent.

### Topics identified for exchange of information in 2016-17:

#### **ECHA:**

- Updates on REACH implementation.
- Status of on-going evaluations under the Community Rolling Action Plan (CoRAP).
- Substances of Very High Concern (SVHC) roadmap implementation and updates on recommendations for inclusion in the Authorisation list.
- Opinions on Restriction proposals, including the socio-economic analysis, in particular the cost and impact analysis.
- Non-animal & alternative approaches, including new-approach methods, and the Principle of Replacement, Reduction, and Refinement (3Rs).

#### **U.S. EPA:**

- Overall status of TSCA Work Plan Chemicals, including results from TSCA Work Plan Chemical Assessments.
- Updates on risk management actions.
- Exchange of information on Work Plan Chemicals, including the chlorinated solvents, such as: *1,2-dichloroethane; 1,1,2 trichloroethane; carbon tetrachloride; and tetrachloroethylene.*
- Updates on tools to share information, including ChemView.
- Updates on chemical research activities including new predictive toxicology, sustainable chemistry, exposure science, and stakeholder outreach efforts.
- TSCA reform status.

### Means of cooperation envisioned in 2016:

- Scheduled information exchange:
  - o April: U.S. EPA participation in ECHA's Topical Scientific Workshop on New Approach Methodologies in Regulatory Science.
  - o Second quarter: call regarding ECHA CoRAP process; ECHA Executive Director's visit to U.S. EPA.
  - o July: U.S. EPA participation in the OECD Workshop on Socioeconomic Impact Assessment of Chemicals Management, hosted by ECHA
  - o Summer 2016: call regarding U.S. EPA and TSCA Work Plan Chemicals and results from assessments.
  - o Fall 2016: call regarding ECHA's decisions regarding SVHC, recommendations for Authorisation list and Restriction proposals.
  - o Webinars to provide demonstrations of ECHA and U.S. EPA online chemical regulation and research tools.
- Additional activities of interest, such as:
  - o Possible U.S. EPA participation in/contributions to ECHA workshops and sharing of their outcomes.
  - o Possible U.S. EPA -ECHA work on enhanced read-across focussing on examining the usefulness of toxicokinetic prediction tools.
- Regular communications to share regulatory agendas, research plans, and organisational practices.
- Missions to each other's institutions or meetings scheduled around other events, such as Global Chem, Helsinki Chemicals Forum, Society of Toxicology, or OECD meetings.

### Designated staff to coordinate the implementation of the Rolling Work Plan in 2016:

**ECHA:** Petteri Mäkelä, International Relations Officer, Directorate of Cooperation (+358 9 6861 8236) / ECHA International ([international@echa.europa.eu](mailto:international@echa.europa.eu))

**U.S. EPA OPPT:** Dr. Ana Corado, OPPT International Team ([Corado.ana@epa.gov](mailto:Corado.ana@epa.gov); +1-202-564-0140) and Laura Nazef, OPPT International Team ([Nazef.laura@epa.gov](mailto:Nazef.laura@epa.gov); +1-202-564-7523)

**U.S. EPA ORD:** Monica Linnenbrink, Strategic Communications and Outreach Lead for Chemical Safety for Sustainability Research Program ([Linnenbrink.monica@epa.gov](mailto:Linnenbrink.monica@epa.gov); +1-919-541-1522)