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Update of the Work plan on international activities 2012

(Document endorsed by the Management Board)

WORK PLAN FOR INTERNATIONAL ACTIVITIES OF ECHA 2012

1. Introduction

The Agency "aspires to become the world's leading regulatory authority on the safety of chemicals" (see ECHA's vision, as endorsed by the ECHA Management Board at its 21st meeting on 24/25 March 2011). This entails having presence on the international scene, something that ECHA could not escape in any case, given the prominence of REACH and CLP as well as the interest with which international organisations and third countries follow ECHA's activities in implementing these core pieces of the European Union's chemicals legislation.

The REACH Regulation foresees that the European Chemicals Agency (ECHA), in addition to its tasks in managing and implementing REACH processes, plays a role in the international cooperation and activities related to sound management of chemicals.

For certain types of international activity, the legal text already provides a clear basis. Such legal mandate is given for cooperating with the Organisation for Economic Cooperation and Development (OECD) to further develop the IUCLID format (Art 111).

The legal text assigns the ECHA Management Board to decide on the participation of third countries and international organisations in the work of ECHA (Articles 106 and 107), while in some specific other cases the initiative has to come from the European Commission (Article 77(2)(l)).

In its Article 77(2)(l), the REACH Regulation lays down the general frame for the role of ECHA in international cooperation. The Secretariat shall provide, at the Commission's request, technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries. Recitals (95) and (109) further clarify ECHA's role in supporting the implementation of REACH and efforts on international harmonisation of scientific and technical approaches used in REACH.

In June 2008, the Commission formally requested ECHA to provide technical and scientific support to certain international activities, in particular to the cooperation with the OECD, the work concerning Persistent Organic Pollutants, and support to regulatory dialogues with the main trading partners of the EU. The Commission followed up this request by adding some additional items in August 2009 and may further expand its request for support in the future.

The work plan for 2012 also takes into account, as a new element, the foreseen extension of the Agency's mandate to include also scientific and technical tasks related to biocides and to the export and import of dangerous substances (PIC procedure).

To ensure appropriate coordination with the European Commission in these areas, ECHA bases its activities on an annual work plan agreed with the Commission. The first such work plan was established for 2009 and approved by the Management Board at its meeting in December 2008 (MB 82/2008). The corresponding work plans for the two following years were approved by the Management Board in September 2009 (MB 57/2009) and September 2010 (MB 49/2010), respectively. .

Alike other EU agencies, ECHA also acts as an agent for the European Union's external and EU enlargement policies, for which – in line with respective policies established on the participation of candidate countries, potential candidates and ENP partner countries in EU

agencies (see doc. MB/83/2008 final, page 4, adopted by the ECHA Management Board at its 10th meeting on 17/18 December 2008) – the European Commission outlines its expectations and provides financial assistance by means particularly of the Instrument for Pre-Accession Assistance (IPA).

Finally, as an EU regulatory agency, ECHA has a public profile in a globalised world which makes communication with third-country counterparts and audiences an inherent part of its mandate of managing the implementation of REACH and CLP (Article 75 of REACH).To maintain such a profile has also been recognised by the Inter-Institutional Working Group on Agencies as a main element in the functions of any EU agency.

Like the previous work plans this 2012 ECHA work plan on international activities has been developed in consultation with the Commission. For activities within the confines of Article 77(2)(l) of the REACH Regulation, it aims to provide a solid basis for the various international activities for which ECHA will provide its support to the Commission.

The annual work plans provide the basis for ECHA to employ the limited resources it allocates to international activities

2. Priority activities for international cooperation in 2012

ECHA conducts its international activities mainly in five fields:

1. supporting the Commission in its cooperation with multilateral organisations and conventions;
2. participating in OECD activities;
3. establishing peer contacts with selected regulatory counterparts; supporting candidate and potential candidate countries;
4. and disseminating information on the implementation of REACH and CLP;
5. as well as the work of ECHA by attending events in third countries, particularly in non-EU OECD countries and the EU's main trading partners.

In 2012, ECHA will continue to give priority to following set of activities:

- Activities that develop international standards such as harmonised tools and assessment approaches which can be directly applied in the implementation of the REACH and CLP Regulations (in particular OECD activities and UN GHS related activities);
- Activities supported by the Instrument for Pre-Accession Assistance to Candidate countries and Potential Candidates as far as new funds are made available by the European Commission;
- International activities which assess chemicals falling within the scope of REACH and CLP;
- Continued exchange of practical experience between ECHA and similar agencies in third countries bi- or multilaterally , with a focus on further enhancing the cooperation with regulatory authorities with which ECHA has established cooperative agreements;
- Activities which directly support the understanding of the implementation of REACH and CLP in third countries and reduce the number of questions to the Helpdesk and improve the quality of registration dossiers.

In general, the methods by which ECHA will execute these activities can entail:

- participation in international conferences, workshops and meetings
- participation as a member or as an observer in international working groups
- provision of written comments and briefings to the Commission services
- delivering presentations in international events or events organised in or for third countries
- organising workshops or training events
- providing written information and training material, mainly via the ECHA website
- exchanging practical experiences with other regulatory agencies.

3. Work plan for 2012

3.1 OECD

The Organisation for Economic Co-operation and Development (OECD) has an extensive cooperation programme in the area of chemicals. ECHA is actively following and contributing to the OECD cooperative chemicals assessment programme which was approved by the OECD Joint Meeting in November 2010. ECHA has, in cooperation with the Commission and the Member States, developed relevant procedures ensuring adequate coordination between REACH and CLP implementation and contributions from the EU to the refocused OECD programme. The Agency continues contributing to the work of the Task Force on Hazard Assessment which is overseeing and coordinating the implementation of a significant portion of OECD activities relevant to ECHA.
A major part of OECD Chemicals programme is focused on the development of harmonised formats and tools. As many of these formats and tools are directly applicable and relevant for the implementation of REACH, biocides and CLP, ECHA continues to give priority to close cooperation with the OECD and participation in this work. Some of the most important projects in which ECHA participates are detailed below.
The OECD (Q)SAR Application Toolbox (QSAR Toolbox) is a software application which is developed to facilitate the identification of similar chemicals with the aim to make reliable predictions on toxicological, eco-toxicological and environmental fate properties. The use of such non-testing methods has the objective to avoid unnecessary animal testing and to reduce the costs of tests. The QSAR Toolbox is being developed in line with the REACH and OECD guidance on grouping of chemicals. Thus, it will support the application of a harmonised approach on how registrants derive and document predictions of chemical properties. The first version of the Toolbox was released in 2008. Upon request of the Commission, ECHA is co-managing its further development in cooperation with OECD and under the supervision of an OECD Steering Group. The project is predominantly financed by ECHA, complemented by satellite projects from OECD and is expected to run over four years. The second version was released in November 2010. The ongoing project work in 2011 and 2012 will result in a third version scheduled to be released at the end of the project in 2012. Additionally, projects are planned on the development of controlled toxicology vocabularies and interrelations in order to improve data integration of experimental data from different sources in the QSAR Toolbox and thus facilitate grouping, read-across and data gap filling.

Another OECD project in which ECHA will remain involved through 2012 relates to the IUCLID User Group Expert Panel. Under Article 111 of the REACH Regulation, ECHA has the duty to coordinate with the OECD the further development of IUCLID to ensure maximum harmonisation. Upon request of the Commission, ECHA chairs the OECD IUCLID User Group Expert Panel established in 1999 to provide a catalyst for the development of IUCLID and collect user requirements. ECHA also centralises requests for new Harmonised Templates or updates on behalf of the Commission and communicate them to the OECD Harmonised Templates Group. In 2012, the Agency is expected to implement additional OECD harmonised templates in IUCLID (e.g. for nanomaterials, pesticides and in-vitro studies) and/or new functionalities, depending on the needs collected from the stakeholder community and prioritised by the Expert Panel. In 2011 a dedicated working group was set up under the IUCLID User Group Expert Panel for biocides to prepare for the Biocidal Products Regulation. ECHA has a leading role in this working group together with DG JRC. The working group will continue its activities in 2012.

The development of harmonised tools and templates has made it possible to create an internet gateway, the Global Portal to Information on Chemical Substances (eChemPortal), to information on the properties, hazards, and risks of chemicals available to the public. The portal allows users to search simultaneously in more than 23 databases, including the ECHA database (ECHA CHEM), gathering information prepared for government chemical review programmes at national, regional, and international levels. To promote worldwide accessibility to data and to achieve synergies with its own dissemination obligations, ECHA

will continue to play in 2012 an active role in this project by participating in the steering group, proposing, analysing, and funding new functionalities, e.g. such as a "tracking tool" to avoid duplication of work on chemical assessment across regulatory authorities or the ability to search GHS classification. In addition ECHA has committed to continue hosting eChemPortal.

In the context of its contribution to the OECD Task Force on Exposure assessment, ECHA will concentrate on the work related to the harmonisation of use pattern description systems and the exchange of information on (tiered) exposure estimation tools. Both items are closely related to the further development of the exposure assessment functionalities of Chesar.

Finally, ECHA will also lead the correspondence group aimed at better characterising the identity of substances of unknown, variable chemical or of biological origin (UVCBs), formed at the last meeting of Task Force.

Other OECD-related activities in which ECHA is involved, as appropriate, include contributing to the work on the health and environmental aspects of nano-materials, the Test Guidelines Programme and to the work of the Task Force on Harmonisation of Classification and Labelling and its subgroups. ECHA may also hold, if necessary, joint conferences with the OECD on specific topics. When necessary, ECHA will participate also in other relevant OECD meetings, including the Joint Meetings.

ECHA also acts as a "commenting party", reviewing eight to ten dossiers per year for the OECD Cooperative Chemicals Assessment Programme (formerly HPV programme), a programme that was initiated in 1990 in order to assess HPV chemicals in a cooperative way. Substances relevant to REACH (i.e. pre-registered, high tonnage in the EU, high risk or exposure) are selected for review by ECHA as these OECD HPV dossiers will be used in REACH registrations and vice versa.

Under the Biocidal Products Regulation ECHA will in the future take over the role of DG JRC. One of the activities to be taken over is the participation of DG JRC in the OECD Biocides Task Force. ECHA will liaise with DG JRC to prepare for this take-over in the second half of 2012.

Following up on the respective interests shown by "old" (such as Korea or Mexico) as well as "new" OECD Member States (such as Israel), ECHA will continue contacts with OECD member countries to facilitate their REACH and CLP understanding

A detailed plan of OECD activities is provided in the Annex, part 1.

3.2 Other multilateral activities

During 2012 the third International Conference on Chemicals Management (ICCM) will take place. This is the high-level conference that regularly reviews the Strategic Approach to International Chemicals Management (SAICM) adopted at the first ICCM in 2006. . As an agency that aspires to become the world's leading regulatory authority on the safety of chemicals ECHA is ready to support events and activities that may be arranged by the European Commission in connection with ICCM 3 with a focus on international stakeholders.

As requested by the Commission, ECHA will continue to support in 2012 the Commission's work on the Stockholm Convention on Persistent Organic Pollutants (POPs), in particular the work carried out under the POP Review Committee (POP RC), by providing technical expertise for the annual POP Review Committee meeting.

Following the new tasks for ECHA under the PIC Regulation (import and export of dangerous substances) ECHA will also start following and contributing to the relevant developments under the Rotterdam Convention, and in particular the work of the Chemicals Review Committee.

Considering the role and the different tasks given to ECHA in the Regulation on Classification, Labelling and Packaging of substances and mixtures, it is foreseen that ECHA takes part in the work of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals and its correspondence groups in case the work is of scientific and technical nature. The Commission should express its wishes of being supported by ECHA experts as appropriate. This may involve several experts depending on the scope of issues covered and participation to UN meetings if appropriate.

A table of these activities is provided in the Annex, part 2.

3.3 Cooperation with and support to countries outside the EU/EEA

Countries outside the EU express a significant interest in the REACH and CLP Regulations and their implementation. ECHA frequently receives requests for visits to ECHA both from government institutions and industry as well as requests for making presentations at seminars, workshops and conferences of different kinds and sizes. The majority of these requests emanate from the EU's main trade partners within the OECD, such as the Canada, Japan, and the USA or from non-OECD members such as China, India and the Russian Federation.

A specific target group among third countries are the candidate countries (Croatia, the Former Yugoslav Republic of Macedonia, Turkey, Iceland1 and since late 2010 Montenegro) and the potential Western Balkan candidates to the EU. The Commission has allocated earmarked funds to ECHA from a transitional programme funded through the Union's external assistance IPA (Instrument for Pre-Accession Assistance)2 programme which supported these countries in preparing them for working with ECHA during 2009-2011. In 2011, ECHA carried out a number of activities in the three candidate countries Croatia, the Former Yugoslav Republic of Macedonia and Turkey, providing them an overview and further in-depth knowledge of how ECHA engages the Member States in the work of its different bodies. The European Commission prolonged the (transitional) IPA-programme through its adoption on 18 July 2011 of the Multi-beneficiary Programme under the IPA Transition Assistance and Institution Building Component for the year 20113. On the basis of a specific agreement with the European Commission, ECHA will hence continue to receive financial resources for activities within this programme. As the accession date of Croatia is tentatively set to 1 July 2013, this country may need a specific focus during 2012 in order to build up its capacities in working with ECHA. As from the date of the signature of its Accession Treaty, Croatia will have the right to participate as an "active observer" in EU institutions and organs, including the bodies of ECHA.

ECHA also regularly receives requests to attend topical TAIEX (Technical Assistance and Information Exchange Instrument) events addressing REACH and CLP related chemicals management issues, in many cases in countries that are European Neighbourhood Policy partners. ECHA will continue to support these activities as resources allow and experts are available.

In relation to the regulatory environmental and trade dialogues between the EU and its main trading partners such as the USA, Canada, the Russian Federation or China, ECHA may – on request of the Commission - provide technical and scientific support to the Commission on an ad hoc basis, provided that there are sufficient resources available at the time of the request.

In May 2010 ECHA concluded a Memorandum of Understanding with Environment and Health Canada. In late 2010, a Statement of Intent was concluded with two parts of the US EPA, namely the Office of Pollution Prevention and Toxics (OPPT) and the National Centre

1 Iceland may participate in the IPA programme but cannot be reimbursed from it

2 COMMISSION REGULATION (EC) No 718/2007 of 12 June 2007 implementing Council Regulation (EC) No 1085/2006 establishing an Instrument for pre-accession Assistance (IPA);

3 COMMISSION IMPLEMENTING DECISION of 18 July 2011 adopting the Multi-beneficiary Programme under the IPA Transition Assistance and Institution Building Component for the year 2011;

for Computational Toxicology (NCCT). In 2011, ECHA also established a Memorandum of Understanding with NICNAS of Australia as well as a Statement of Intent with the ministries and an institute in Japan that exercise regulatory powers in the chemicals safety area4. In 2012 work will focus on implementing the Rolling Work Plans that these agreements have established or foresee. These Rolling Work Plans are similar in content and focusing on areas that support the regulatory tasks of ECHA and their counterparts including scientific and technical collaboration and information exchange, exchange of experience and knowledge on specific assessment tools and information systems as well as approaches for non-testing methods and when relevant cooperation on training5.
During 2012, the ECHA Secretariat will explore the potential benefits that agreements on the exchange of confidential business information (CBI) with counterpart regulatory authorities could bring to its regulatory work and inform the Commission accordingly, with a view supporting to the possible initiation of negotiations to establish such agreements with selected partner countries whose chemical legislation permit that type of exchange.

ECHA will also continue to respond to requests for the exchange of information on REACH and CLP at practical level from other important trading partners outside the OECD, such as China and India. Their interest, due either to the introduction of national chemicals safety legislation somewhat analogous to that of the EU as well as to their interaction with the Internal Market, is also reflected through Chinese and Indian participation in ECHA's Stakeholder Days. If the negotiations between the European Commission and Switzerland result in an agreement for Switzerland to participate in REACH, the Commission will likely ask ECHA to participate in the discussions on its practical implementation.

When assessing speaking or visit requests from third countries, priority will be given to events and visits that directly or through their multiplying effect can reach a large key target audience. This can also contribute to alleviate the high number of questions to the ECHA Helpdesk emanating from some third countries. When travelling outside the EU is required, ECHA regularly contacts the relevant EU Delegation with the aim that they could, on future occasions, deliver similar presentations and responses to questions. Possibly engaging collaborating partners, ECHA may also organise webinars on key topics, targeted especially towards third countries. Such events can together with video-conferences provide a feasible alternative to physical participation in events organised in third countries.
Finally, it is worth mentioning that most activities of ECHA also have international relevance. Third countries, in particular developing countries, will benefit from the extensive information available on the ECHA website, especially from the dissemination of data on properties of chemicals, the extensive information given through the numerous webinars as well as from information given at ECHA's Stakeholders' days.

4. Resources

In 2012, ECHA will allocate approximately four person-years to its international activities. This includes the resources needed for the general coordination of the international activities as well as the expert resources to actually participate in them (see Annex to the ECHA Work Programme 2012, agenda item 9). .

Concerning the financial resources, the ECHA budget for 2012 foresees € 684,840 for international projects, excluding mission costs related to international cooperation (see doc. MB/40/2011, agenda item 6.1) .

The Commission is not providing subsidies for these activities, apart from the financial resources made available through the Community's IPA (Instrument for Pre-Accession Assistance) to support candidate countries and potential candidates in preparing them for working with ECHA.

[4] These agreements are published on the ECHA website (About ECHA/reports/strategy papers/international cooperation);
[5] As these work plans are revolving documents of a practical and subordinate nature, their changeable content for 2012 cannot be described in this document;

5. Review of the Work Plan and Reporting

If necessary, the 2012 work plan may be reviewed in summer 2012. The purpose of the review would in particular be to ensure that the priorities laid down in the plan are still valid and up to date and that the overall workload is in line with the resources available to these activities. The review may be initiated either by ECHA or by the Commission services. In addition to the case by case reporting from different meetings and missions, reporting on the international activities will be included in the ECHA's General report.

Multilateral Activities to be covered by ECHA during 2012

Part 1 – OECD Cooperation

Activity	Priority in 2012	Comments
Joint Meeting	Medium	Participation where relevant. Briefings may be needed on specific topics
Task Force (TF) on Hazard Assessment	High	
Cooperative Chemicals Assessment Programme and its meetings (CoCAM) (former SIDS/SIAM)	High	
IUCLID user group Expert panel and work on Harmonised templates including work in relation on pesticides, biocides and nano-materials	Very High (Essential to REACH implementation)	Preparation of the meetings, follow-up of the work of the Groups, introduction of the requirements into IUCLID5
TF on Classification and Labelling	Low	Possible meetings during 2012 will be clarified after the UNSCE GHS meeting in December 2011
TF on Exposure Assessment	High	Participation in the work on i) use pattern description and ii) tiered tools for (environment and human health) exposure assessment (both in context of Chesar-based CSA/CSR).
TF on Biocides	Low	Liaise with DG JRC on take over under Biocidal Products Regulation
OECD QSAR Activities Development of the QSAR Toolbox (project management and participation to the OECD meetings):	Very High (Essential to REACH implementation)	Main work is carried out at ECHA
Working Party on Nano-materials	High	Participation in the WP as well as in several of the subgroups
Test guidelines Programme - Working Group of National coordinators -Expert groups	Low	
IT tools	High	e.g. Tracking system of chemical assessments
eChemPortal, The Global Portal to Information on Chemical Substances	Very High	Hosting of the portal - Analysis of new functionalities to be added to the portal (project management and participation to OECD meetings)
Advisory group on Toxicogenomics	Low	When relevant and resources allow
Good Laboratory Practice and Compliance Monitoring	Low	ECHA contact person on mailing list

Part 2 – Other multilateral activities

Activity	**Priority in 2011**	**Comments**
Stockholm Convention: 8th meeting of the POP Review Committee, October-November 2012	Medium	Participation as requested by COM
WHO/IPCS Project on Strengthening Global Collaboration in Chemical Risk Assessment	Low	. Need to be assessed on a case-by-case basis.
UNECOSOC - Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (2 meetings)	Low	Participation as requested by COM.
ICCM 3	Low	Participation to be determined in light of development