



Helsinki, 29 September 2009

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WORK PLAN FOR INTERNATIONAL ACTIVITIES OF ECHA 2010

(Document endorsed by the Management Board)

1. Introduction

In June 2008, the European Commission requested the ECHA Secretariat to provide technical and scientific support to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues related to the safety of chemical substances. This request formed the basis for the first work plan which was endorsed by the Management Board at its meeting in December 2008 (MB 82/2008). The first request from the European Commission was followed up by an additional request in August 2009. This request specifically asks ECHA to provide technical and scientific support to the Commission in relation to the OECD Working group of National Coordinators for the Test Guidelines Programme and its subsidiary bodies. Furthermore ECHA is requested to provide support to the Commission's work at the Strategic Approach to International Chemicals Management (SAICM) and the Commission of Sustainable Development (CSD) through participating in workshops and side-events of SAICM and CSD, on the specific request for the Commission and as far as this is directly related to the tasks ECHA carries out in support of REACH or CLP. As these requests are mainly linked to activities in 2010, no review of the 2009 Work Plan was deemed necessary but the requests are reflected in the work plan for 2010.

The attached draft work plan for ECHA has been developed by the ECHA Secretariat in consultation with the relevant Commission services.

After having been endorsed by the Board, the work plan will be published on ECHA's website.

2. Short description of the Work plan 2010

The draft work plan for 2010 is divided into five main sections: 1) introduction, 2) a general description of priority activities for international cooperation in 2010, 3) work plan itself, 4) short description of resources and finally 5) review of the Work Plan and reporting. The work plan is divided into three items: OECD cooperation, other multilateral activities and activities related to third countries.

The document represents a more detailed work plan within the general frame laid down in chapter of the ECHA Work Programme for 2010 (Activity 11).

Particular attention will have to be paid to ensure that the resources allocated to the international activities laid down in the work plan are not exceeded. The human resources for 2010 will increase by approximately by one person year in comparison to what has been allocated in 2009. There are no significant changes in the financial resources allocated to the international activities.

Attachment:

Work plan for international activities of ECHA 2010

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WORK PLAN FOR INTERNATIONAL ACTIVITIES OF ECHA 2010

1. Introduction

The REACH Regulation foresees that the European Chemicals Agency (ECHA), in addition to its key tasks in managing and implementing REACH processes, plays a role in the international cooperation and activities related to sound management of chemicals. In certain cases the legal text already provides a clear basis for cooperation. This is the case in particular with the cooperation with the Organisation for Economic Cooperation and Development (OECD) to further develop IUCLID format (Art 111). In other cases, the legal text assigns the Management Board to decide on participation of third countries and international organisations in the work of ECHA (Articles 106 and 107), while in 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 the 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. This request has been followed up with some additional items by the Commission in August 2009.

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 laid down for 2009 and approved by the Management Board at its meeting in December 2008 (MB 82/2008).

Like the first work plan this 2010 ECHA work plan on international activities has been developed in consultation with the Commission. It aims to provide a solid basis for the

different international activities to which ECHA should provide support. Taking into account the limited resources ECHA can allocate to international activities, in particular in view of the important regulatory deadlines in 2010, the work plan also provides steering on the relative priority of the different activities. It should be noted that the Commission may at any time request further support from ECHA. Should the Commission request that, this may necessitate ECHA to re-prioritise its activities, and ultimately ECHA may even have to decline such requests, given its resource constraints.

2. Priority activities for international cooperation in 2010

The overall objective of ECHA's work on international activities is to provide the Commission with scientific and technical support in its international activities. Therefore ECHA's international work is based on the obligations assigned to it by legislation, focusing on issues which increase scientific and technical harmonisation, as well as contributing to increased knowledge on REACH worldwide.

In 2010, ECHA will continue to give priority to following **types of activities**:

- Activities that develop international standards which can be directly applied for the implementation of REACH (in particular OECD activities);
- Activities which directly support the understanding of the implementation of REACH in third countries;
- International activities which assess chemicals falling within the scope of REACH;
- Activities which exchange practical experience between the ECHA and similar agencies in third countries bi- or multilaterally.

In general, the **methods of support** ECHA can provide to the Commission 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 ECHA website
- exchanging practical experiences with other regulatory agencies.

3. Work plan for 2010

3.1 OECD

ECHA will in 2010 continue participating in a number of OECD activities which are of relevance for the implementation of REACH.

The Global Portal to Information on Chemical Substances (eChemPortal) is an internet gateway to information on the properties, hazards, and risks of chemicals found in the environment, homes and workplaces, and in products used daily. This integrated system allows users to simultaneously search multiple databases established for governmental chemical review programmes worldwide. Its aim is to improve the availability of hazard-

related data on chemicals. A first release of the Portal was launched in June 2007. It is currently hosted on the OECD website. 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. To promote worldwide accessibility to data and to achieve synergies with ECHA's own dissemination obligations, the Agency will in 2010 play an active role in this project expected to be completed in the second half of the year. ECHA also has an important role in hosting the portal which will most probably start in 2011, after the first REACH registration deadline of December 2010.

The OECD (Q)SAR Application Toolbox is a software application intended to be used to identify categories of discrete organic chemicals and to fill data gaps on toxicological, eco-toxicological and physical-chemical endpoints. (Quantitative) Structure-Activity Relationships [(Q)SARs]. are methods for estimating properties of a chemical from its molecular structure. They have the potential to provide information on hazards of chemicals, while reducing time, monetary cost and animal testing currently needed. A first version of the Toolbox was released in March 2008 and updated in December 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 expected to run over four years. The release of its second version is scheduled for end of 2010.

The third OECD project in which ECHA will remain involved through 2010 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. In 2010, the Agency is expected to show progress on enhancing the software further to meet user needs collected from the stakeholder community and prioritised by an Expert Panel.

The Agency will also continue contributing to the work of the Task Force on Hazard Assessment (formerly called the Task Force on Existing Substances). This will cover, among other things, participation in the further planning on OECD cooperation on the assessment of chemicals after 2010, including the implementation of the related OECD work plan in the interim phase. ECHA will, in cooperation with the Commission and the Member States, develop procedures ensuring adequate coordination between REACH implementation and contributions from the EU to the refocused OECD programme.

Other OECD related activities in which ECHA will be involved include contributing to the work of the Task Force on Exposure Assessment, the Harmonised Templates Project, the work on the health and environmental aspects of nanomaterials, the Test Guidelines Programme and to the work of the Task Force on Harmonisation of Classification and Labelling and its subgroups, if appropriate. ECHA may also hold, if necessary, joint conferences with the OECD on specific topics. When necessary, ECHA may 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 High Production Volume (HPV) Chemicals 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 EU, risk, exposure, are selected for review by ECHA as these OECD HPV dossiers will be used in REACH registrations and vice versa.

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

3.2 Other multilateral activities

As requested by the European Commission, ECHA will also in 2010 support 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.

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 it would be useful that ECHA takes part in the work of the UN ECE 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 even though the most relevant work for ECHA is carried out in the OECD Task Force on Harmonisation of Classification and Labelling.

During 2010 the two-year CSD¹ Policy Review session starts. ECHA may participate in this process on the specific request by the Commission, especially for side events on chemicals, which may be arranged by the Commission.

No major meeting within the framework of the Strategic Approach for International Chemicals Management (SAICM) will take place during 2010 but there may be a request by the Commission for ECHA to participate in some inter-sessional work such as workshops arranged in relation to information on chemicals in products (articles) or perfluorinated substances (PFCs).

A table of these activities is provided in Annex 1, part 2.

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

There is also significant and growing interest in the REACH legislation from countries outside the EU. ECHA frequently receives requests for visits to ECHA both from government institutions and industry as well as request for making presentations at seminar, workshops and conferences of different kind and size. A majority of these requests emanate from the EC's main trade partners within the OECD, such as the USA, Canada and Japan, or from China and India, but also from countries that are European Neighbourhood Policy partners.

A specific target group among third countries consists of the candidate countries (Croatia, the Former Yugoslav Republic of Macedonia, and Turkey) and the potential Western Balkan candidates to the EU. Additional funds will be allocated to ECHA from a transitional programme funded through the Community's external assistance IPA (Instrument for Pre-Accession)² to support these countries in preparing them for working with ECHA. Moreover, ECHA may also provide support to specific TAIX (Technical Assistance and Information Exchange Instrument) projects addressing REACH and CLP related chemicals management issues.

One of the main objectives in the cooperation with third countries is to increase the understanding of the implications of the REACH Regulation for neighbouring countries such as the Russian Federation and European Neighbourhood Policy partner countries

¹ United Nations Commission for Sustainable Development

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)

(in particular Belarus, Moldova and Ukraine as well as Mediterranean partner countries) and important other trade partners of the EU. Particular emphasis is given to raising awareness and understanding of REACH in the chemicals management authorities of the trade partners and, where resources allow, also in companies exporting chemicals or articles to the EU. To this end ECHA will send, to the extent possible, speakers to relevant events and provide information packages to third countries as well as admit visitors from such countries.

In relation to the main EU trade partners and the regulatory, environmental and trade, dialogues between the EU and certain third countries such as the USA, Canada, the Russian Federation and 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. A higher priority is given to strengthen bilateral cooperation between ECHA and the relevant regulatory agencies of the OECD countries outside the EEA, such as, the USA, Canada and Japan. To that end, more formalised arrangements, such as Memoranda of Understanding, may be concluded in consultation with the Commission. Exchange of best practice and cooperation at practical level with other importing trading partners outside the OECD, such as China and India is also of great importance for ECHA. ECHA will also continue to follow the discussions between the European Commission and Switzerland on the Swiss development to gradually align with the REACH regime. These discussions will determine the future bilateral relationship with this third country, and ECHA will design its contacts accordingly.

When assessing speaking or visit requests from third countries, priority will be given to events and visits that directly or through multiplying effect can reach a large key target audience (e.g. events organised via national Helpdesks in countries outside the EU). This would also contribute to the alleviation of the high number of questions to the ECHA Helpdesk from some countries. When travelling outside the EU is required, ECHA will contact the relevant Commission Delegation with the aim that they could, on future occasions, deliver similar presentations and responses to questions. Possibly engaging collaborating partners, ECHA also plans to organise webinars on key topics, targeted especially at third countries. Such events can together with video-conferences provide a feasible alternative to physical participation in an event.

Finally it is worth mentioning that other 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, as well as from information given at ECHA's Stakeholders' days.

4. Resources

In 2010, approximately five person-years are foreseen to be allocated to the international activities. They include the resources needed for the general coordination of the international activities as well as the expert resources to actually participate in the activities.

Concerning the financial resources, the ECHA budget for 2010 foresees € 880,000 for international projects, excluding mission costs related to international cooperation. The biggest part of these funds is allocated to the joint OECD projects: QSAR Toolbox: € 400,000 and eChemPortal: € 280,000. In addition, funds are being foreseen for IUCLID related activities, such as development and update of OECD harmonised templates: €

200,000. In addition mission costs for all international activities are estimated to amount to around € 130,000.

The resources necessary for hosting the eChemPortal will be included in the 2011 budget.

As explained above, additional financial resources will be made available through the Community's IPA (Instrument for Pre-Accession) to support candidate countries and potential candidates in preparing them for working with ECHA. These are expected to amount to around € 200,000 for the period until 2011, inclusively.

In the light of the expected peak in the registrations-related workload towards the end of 2010 and in 2011 it will be necessary to monitor the international activities continuously and timely decisions have to be made on priorities in order not to impede on ECHA's primary tasks in the implementation of REACH.

5. Review of the Work Plan and Reporting

If necessary, the 2010 work plan can be reviewed in summer 2010. 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 can 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 annual activity report.

Multilateral Activities to be covered by ECHA during 2010

Part 1 – OECD Cooperation

Activity	Priority in 2010	Comments
Joint Meeting	low	Participation only if relevant and requested. Briefings may be needed on specific topics
Task Force on Hazard Assessment ³	Very High	
SIDS (Screening Information Data Set) Initial Assessment Meeting (SIAM)	Very High	
IUCLID user group Expert panel and work on Harmonised templates including work in relation on pesticides	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		No meeting yet foreseen for 2010
TF on Environmental Exposure Assessment	High	
<u>OECD QSAR Activities</u> Development of the 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 Nanomaterials	High	Participation in the WP as well as in several of the subgroups
Test guidelines Programme - Working Group of National coordinators -Expert groups	Medium /High	
IT tools	High	
eChemPortal, The Global Portal to Information on Chemical Substances	High	Development of the 2 nd phase of the portal (project management and participation to OECD meetings)
Advisory group on Toxicogenomics	Medium	When relevant and resources allow
Good Laboratory Practice and Compliance Monitoring	Medium	ECHA contact person to be added only on mailing list

³ Previously Task Force on Existing Chemicals Programme

Part 2 – Other multilateral activities

Activity	Priority in 2010	Comments
Stockholm Convention: 6 th meeting of the POP Review Committee, October-November 2010	High	Participation of 1 (or possibly 2) POP expert requested by COM
WHO/IPCS Project on Strengthening Global Collaboration in Chemical Risk Assessment (a start-up meeting will take place by the end of 2009)	TBD	The potential advantage to REACH implementation of this activity (and hence it's priority) can first be determined after the start-up meeting.
UNECE - Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (2 meetings)	Medium	Participation requested by COM
UN CSD Policy review session on chemicals	TBD	Participation to be determined in light of development, probable for side event/learning centre
SAICM workshop(s)	TBD	Participation to be determined in light of development