



Helsinki, 30 September 2010

Doc: MB/49/2010 final

Work plan international activities 2011

(Document endorsed by the Management Board)

1. Introduction

In May 2008 the European Commission requested the ECHA Secretariat to provide technical and scientific support to improve cooperation between the European Union, its Member States, international organisations and third countries on scientific and technical issues related to the safety of chemical substances¹. 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 is reflected in the current work plan for 2010.

The attached draft work plan for international activities of ECHA for 2011 has been developed by the ECHA Secretariat in agreement 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 2011

As the previous plan, the draft work plan for 2011 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 cooperation with and support to countries outside the EU/EEA.

The document represents a more detailed work plan within the general frame laid down in chapter of the draft ECHA Work Programme for 2011 (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.

Attachment:

Work plan for international activities of ECHA 2011

¹ Letter by Messrs ZOUREK and CARL to the Executive Director of 21 May 2008

Helsinki, 30 September 2010

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Annex

WORK PLAN FOR INTERNATIONAL ACTIVITIES OF ECHA 2011

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 the 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 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 and may be further expanded in the future.

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) and the second one for 2010 (MB 57/2009) was approved by the Management Board in September 2009.

Like the previous work plans this 2011 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, 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 2011

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 2011, ECHA will continue to give priority to following types 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 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;
- International activities which assess chemicals falling within the scope of REACH and CLP;
- Activities which exchange practical experience between 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 2011

3.1 OECD

The Organisation for Economic Co-operation and Development (OECD) has an extensive cooperation programme in the area of chemicals. ECHA is currently actively following and contributing to the ongoing preparation of OECD cooperation on the assessment of chemicals after 2010, taking into account all interim implementation activities in 2009 and 2010. Once approved by the Joint Meeting (expected by

November 2010), ECHA will review its participation in the new activities and refine the work programme, as appropriate, in dialogue with the Commission. 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. The Agency will also continue contributing to the work of the Task Force on Hazard Assessment (formerly called the Task Force on Existing Substances) 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 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, ecotoxicological 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 release of its second version is scheduled for October 2010. The project work in 2011 and 2012 will result in a third version scheduled to be released at the end of the project in 2012.

Another OECD project in which ECHA will remain involved through 2011 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 2011, the Agency is expected to implement additional OECD harmonised templates in IUCLID (e.g. for nanomaterials) and/or new functionalities, depending on the needs collected from the stakeholder community and prioritised by the Expert Panel.

The development of the 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. This integrated system allows users to simultaneously search multiple databases established for governmental chemical review programmes worldwide. 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 has co-managed the development of the second phase of the portal in cooperation with OECD and under the supervision of an OECD Steering Group and has also committed to host the portal. The official launch of the second phase is scheduled for November 2010. To promote worldwide accessibility to data and to achieve synergies with its own dissemination obligations, ECHA will continue to play in 2011 an active role in this project by participating in the steering group, proposing and analysing new functionalities.

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.

Other OECD-related activities in which ECHA is involved, as appropriate, 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. 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 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.

In addition, ECHA will also create contacts with new OECD member countries to facilitate their REACH and CLP understanding

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

3.2 Other multilateral activities

2011 is the International Year of Chemistry. It is an initiative of IUPAC, the International Union of Pure and Applied Chemistry, and of UNESCO, the United Nations Educational, Scientific, and Cultural Organization. ECHA may support events and activities arranged by the European Commission with a focus on international stakeholders, resources allowing.

As requested by the Commission, ECHA will also in 2011 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. In May 2011 the fifth Conference of the Parties (COP- 5) of the Stockholm Convention will meet and ECHA may support the Commission if so requested.

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 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. This task force did not have any meeting in 2010 but activities and meetings are expected to resume in 2011. The Commission will have to increase efforts for co-ordination with the Member States experts and has expressed the wish of being supported by ECHA experts as appropriate. This may involve one to two experts depending on the scope of issues covered in the UN meetings.

During 2010 the two-year CSD² Policy Review session started. One of the main items during this period is devoted to chemicals. In the second year of this process which is the "Policy Year", 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 2011 but there may be a request by the Commission for ECHA to participate in some inter-sessional work such as workshops or other activities arranged in relation to information on chemicals in products (articles) or perfluorinated substances (PFCs).

In August 2009 the Commission requested ECHA to take part in the first meeting on the WHO/IPCS Project on Strengthening Global Collaboration in Chemical Risk Assessment to assess the potential advantage to REACH implementation of this activity and hence the future participation by ECHA. This meeting was postponed until March 2010. However, the outcome of the meeting was not concrete enough to enable ECHA to draw clear conclusion of its future contributions to WHO/IPCS activities. Therefore, the conclusions for the further involvement of ECHA is, in the absence of such a clear outcome, that ECHA should continue to select on case-by-case basis what activities of WHO/IPCS it will follow and where it decides to make specific contributions. In the past, the biggest added value has been coming from the harmonisation project. It remains to be seen in which form the WHO/IPCS Secretariat will propose to continue this activity. Furthermore, a potentially interesting new area of work may be the idea of a risk assessment network, but this also needs further specification to allow an informed decision about possible participation.

A table of these activities is provided in Annex 1, 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 kind and size. A majority of these requests emanate from the EU's main trade partners within the OECD, such as the USA, Canada and Japan, or from the Russian Federation, 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. Earmarked funds have been allocated by the Commission to ECHA from a transitional programme funded through the Union's external assistance IPA (Instrument for Pre-Accession Assistance)³ to support these countries in preparing them for working with ECHA. The first activities were carried out during 2010 but as the project period is also covering most of 2011, further activities will be carried out during this year. It is expected that ECHA will get further financial support from this programme starting in the later part of 2011 but the decision for the additional funding is not expected to be taken before March 2011. The accession date of Croatia is tentatively set to 1 January 2012 and hence this country may need a specific focus during 2011 in order to build up its capacities in working with ECHA.

² United Nations Commission for Sustainable Development

³ 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)

ECHA also regularly receives requests to attend specific TAIEX (Technical Assistance and Information Exchange Instrument) events addressing REACH and CLP related chemicals management issues. ECHA will continue to support these activities as resources allow and experts are available.

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 (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 and CLP 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 may 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 the further strengthening of the bilateral cooperation between ECHA and the relevant regulatory agencies of the OECD countries outside the EEA, such as the USA, Canada and Japan.

In May 2010 ECHA concluded a Memorandum of Understanding with Environment and Health Canada. In 2011 work will focus on implementing the Rolling Work Plan contained in the agreement. This Rolling Work Plan is focusing on scientific 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 training.

With the view to possibly concluding a similar Memorandum of Understanding with the US EPA in 2011, discussions have started during 2010. Additionally, ECHA has taken up discussions with the responsible authority⁴ in Australia to open technical cooperation and possibly eventually also conclude a Memorandum of Understanding.

Exchange of best practice and cooperation at practical level with other important trading partners outside the OECD, such as China and India is also of great importance for ECHA. ECHA will continue to follow the discussions between the European Commission and Switzerland on their expressed intention to participate in REACH.

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 may also 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 events organised in third countries.

⁴ Department of Health and Ageing, National Industrial Chemicals Notification and Assessment Scheme (NicNas)

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, the extensive information given through the numerous webinars as well as from information given at ECHA's Stakeholders' days.

4 Resources

In 2011, approximately six 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 2011 foresees € 1 million 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: € 150 000. 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.

As explained above, the Commission is not providing any subsidies for these activities except some 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. The amount remaining for 2011 from the current project resources is around €130 000.

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 and CLP.

5 Review of the Work Plan and Reporting

If necessary, the 2011 work plan may be reviewed in summer 2011. 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 annual General report.

Multilateral Activities to be covered by ECHA during 2011

Part 1 – OECD Cooperation

Activity	Priority in 2011	Comments
Joint Meeting	Low	Participation only if relevant and requested. Briefings may be needed on specific topics
Task Force (TF) on Hazard Assessment ⁵	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, biocides and nanomaterials	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		Possible meetings during 2011 will be clarified after the UNSCE GHS meeting in December 2010
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).
<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	e.g. Tracking system of chemical assessments
eChemPortal, The Global	High	Hosting of the portal - Analysis of new

⁵ Previously Task Force on Existing Chemicals Programme

Activity	Priority in 2011	Comments
Portal to Information on Chemical Substances		functionalities to be added to 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 on mailing list

Part 2 – Other multilateral activities

Activity	Priority in 2011	Comments
Stockholm Convention: 5 th COP of the Stockholm convention 7 th meeting of the POP Review Committee, October-November 2011	High	Participation of 1 expert in the relevant field. Participation of 1 (or possibly 2) POP expert requested by COM
WHO/IPCS Project on Strengthening Global Collaboration in Chemical Risk Assessment	Case-by-case based	. 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)	Medium	Participation to be requested by COM. 1 to 2 experts may be needed.
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