ECHA
EUROPEAN CHEMICALS AGENCY

Workshop Proceedings (2) and Follow-up Actions

Accredited Stakeholder Workshop
Brussels 23 November 2011

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Reference: ECHA-11-R-009.1-EN
Publ.date: December 2011
Language: EN

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Workshop Proceedings (2) and Follow-up Actions

Accredited Stakeholder Workshop 2011

Summary

The Accredited Stakeholder Workshop 2011 resulted in a number of suggestions related to ECHA's processes, enforcement, support to SMEs, downstream users, awareness raising and cooperation with the ASOs. This input has given ECHA a good overview of the stakeholders' interests, and has been very valuable. We have discussed the suggestions thoroughly at ECHA and looked for pragmatic ways to improve our various activities, including cooperation with our Accredited Stakeholder Organisations (ASOs).

We have grouped our response on the one hand according to the theme and on the other according to the status for each of the suggested actions. Some of the activities are already completed, some are ongoing and some of them are ideas that we are willing to further explore. There were also some suggestions, which we have considered to be inapplicable and we are here explaining the reasons behind this.

Many of your suggestions relate to issues we have identified as areas with room for improvement, and we are already working on them. Your feedback confirms that you also consider these as priorities. In order to make monitoring more tangible, when possible, we have identified target dates for the elements to be improved.

In several cases, we could see a benefit in joining forces with stakeholders, and would therefore like to propose some initiatives for us to work on together. These topics are marked with an asterisk (*). We will be sending concept papers on these ideas during the coming months and ask for your interest to participate. ECHA will be happy to coordinate the projects, but in order to succeed we consider it crucial to have you on onboard.

REACH, CLP, Biocides – General

Completed

1. Introduce a switchboard
   A switchboard and an InfoDesk for public enquiries were introduced in January 2012. The switchboard is open from 9 am to 6 pm (Finnish time) at +358-9-686180.

2. Shift to a more risk based approach
   Most of the decision-making in REACH is risk based, so that is the approach already in use.

Ongoing

3. Support training in academia
   ECHA launched a graduate scheme in 2011 to respond to the high demand for REACH and CLP specialists and to assist young graduates to find employment as regulatory scientists and professionals in the field of chemicals. As a concrete measure, the number of ECHA traineeship posts will be doubled with effect from 2012. ECHA staff also participates in a large number of events and gives presentations on REACH. In relation to online training material, ECHA is also looking into the possibility of drawing together existing online learning modules developed in the Member States.
   Target date: ongoing

4. Address safety of unborn babies
   ECHA's processes, such as evaluation, authorisation and restriction, contribute to ensuring that companies collect data on, and assess and replace dangerous chemicals including those, which may have impact on unborn babies (i.e. "cause harm to the unborn child"). Information on hazardous substances including, where applicable, possible impacts on the unborn child is taken into account in the chemical safety assessment that industry needs to perform as part of their registration.
   Target date: ongoing

5. International cooperation
   The European Commission has an important role in the safe management of chemicals at a global level, including the harmonisation of chemicals legislation globally (SAICM). ECHA contributes to the cooperation through its international activities, as described in ECHA's work programme. This activity could be presented in a more transparent way on the website.
   Target date: Q4/2012 for improving information on the website

6. Facilitate/enable dialogue between notifiers
   A feasibility study has been launched to assess the possibility of setting up a platform for notifiers under CLP.
   Target date: Q4/2012

7. Ensure effective integration of biocides activities in ECHA
   ECHA is currently planning and implementing the regulatory processes related to the new Biocidal Products Regulation. Recruitments have started and will continue throughout 2012. ECHA is presently looking into the synergies with REACH and CLP, in order to ensure effective development of processes.
   Target date: throughout 2012-2013

8. Address endocrine disruptors
   The first case of an SVHC based on endocrine disrupter properties has been identified. ECHA, as well as some Member State authorities, is looking into further cases.
   Target date: ongoing

9. Introduce procedures for nanomaterials
   ECHA has updated the annual work plan to include nanomaterials and intends to be more proactive in the nano field in the future. For example, an update will be provided later this year for the Guidance on Information Requirements and Chemical Safety Assessment based on the output of the two European Commission's REACH Implementation Projects on nanomaterials. The specific advice from the stakeholders provided during these projects will be incorporated in the Guidance.
   Target date: Q2/2012 for the Guidance documents

To be explored

10. Improve standard letters
    ECHA is continuously developing its processes, including its standard letters. Work is ongoing to.further improve the standard letters related to evaluation and registration. ASOs are welcome to provide feedback on specific improvement needs.
    Target date: ongoing

Not applicable

11. Provide information on chemical safety to workers in the waste sector
    ECHA does not have any information on wastes and REACH does not have a mechanism for providing information on waste to the workers on the sector. Safety Data Sheets do not include the waste sector as that sector is not directly regulated by

the chemicals legislation. Therefore, it would be difficult for ECHA to have a role in this activity.

12. Changes in REACH Regulation
In terms of making changes in the REACH Regulation, it should be noted that possible changes are initiated by the Commission, not by ECHA. ECHA has given its feedback on REACH in the Article 117 report, which was published in June 2011.

13. ECHA to be relocated in Brussels
The location of the Agency was decided by the European Union Heads of States, and thus ECHA itself cannot influence the issue. However, the Agency participates in events in Brussels and in different member states. We also arrange many online events and use modern technology to communicate with our stakeholders. Therefore, location of the Agency should not play such a crucial role.

Evaluation

Ongoing

1. Evaluation of substances to ensure high quality dossiers
This has been selected as one of the key priorities in the Multi-Annual Work Programme 2013-2015. ECHA is committed to conclude compliance checks on 5% of the highest volume dossiers by the end of 2013.
Target date: Q4/2013

2. Introduce more non-animal testing methods
It is the legislation that determines which tests are allowed, but ECHA contributes by updating its Guidance to take account of new developments as and when possible. ECHA has contributed 400 000 euros per year to the development of the OECD QSAR toolbox since 2008. This is currently the most promising alternative to animal testing to predict the long-term toxicological and CMR properties. The project is still ongoing. Other possibilities include read-across which could possibly be used more. That would require that the registrants would get more familiar with the correct use of read-across possibilities. The registrants have a key role in avoiding unnecessary animal testing. ECHA cannot take the responsibility of the registrants.
Target date: ongoing

Not applicable

3. Speed up the processing of evaluating testing proposals
The process is becoming more efficient but unfortunately in many cases the poorly described substance identity has forced ECHA to first perform a targeted compliance check. In any case, ECHA works within the legal deadlines and will thus conclude all relevant testing propsals on phase-in substances registered by December 2010 by 1 December 2012. All testing proposals submitted on non-phase in substances are processed in 180 days, as REACH requires.

Registration and dissemination

Ongoing

1. Provide information on substances to be registered in 2013
The first list of substances was published in February 2012. There is also information available on the names of (candidate) Lead Registrants who agree to have their names published. The amount of names is still rather limited but will increase as the next registration deadline approaches.
Target date: throughout 2012-2013

2. Allow companies to contact ECHA
   Some dossiers already include names of a scientific officer and questions can also be submitted via the contact form. As a general rule, ECHA contacts those companies that have questions related to dossiers, rather than the other way round. ECHA will be contacting companies to an increasing extent when the deadline approaches, in line with the available resources, as was done in the period preceding the 2012 registration deadline.
   Target date: ongoing

3. Introduce search functionality of registered substances to ECHA-CHEM
   ECHA is currently building a roadmap for improving access to data. Stakeholders will be consulted at the end of 2012 to collect input, and we welcome any input from ASOs. Meanwhile, substances registered to ECHA can also be searched through the OECD's eChemPortal.
   Target date: Q4/2012 for collecting input

4. Promote best practice for data quality and high-quality registration dossiers
   This strategic objective is included in ECHA's Multi-Annual Work Programme 2013-2015. See also point 1 on Evaluation above. Model Chemical Safety Reports will contribute to providing best practice.
   Target date: Multi-annual activity (2013 – 2015)

5. Include a function for providing information of substances in registration dossiers
   Any third party may electronically submit information to the Agency relating to substances that appear on the list of of pre-registered substances. The Agency shall consider this information when checking and selecting dossiers for compliance checking. This was implemented in 2008 already, when the list of pre-registered substances was published. For every substance on the list, there is a link to a submission form where information on the substance can be entered and submitted to ECHA. The new version of IUCLID is currently under preparation and due to be published in summer 2012. IUCLID 5.4 will bring changes on how to compile a dossier and submit certain data to ECHA.
   Target date: Q2/2012 for the launch of IUCLID 5.4

Authorisation

Completed

1. Early contact with with companies in the authorisation process
   ECHA has published information on its website whereby industry can make a request for a pre-submission information session. More information can be found here.

Ongoing

2. Ensure early participation of stakeholders in the authorisation process
   ECHA has regular contact with the industry and NGO stakeholders and will continue to arrange workshops to discuss the issues.
   Target date: ongoing

3. Promote the communication on SVHCs
   ECHA is working on explaining more clearly what information should be provided on the website and at which stage. In the longer term, the plan is to extend the Chemicals in our lives web section with a more detailed explanation on the right of consumers to request information on SVHCs in consumer products.
   Target date: 2013 for publishing information on the website

4. Increase transparency of the authorisation process*
   ECHA's revamped website is a step towards an increased transparency in the

authorisation process. We are also working on increasing the visibility of public consultations, which are also important for transparency. This is one of the areas where joint forces would be useful.
Target date: ongoing

Not applicable

5. Simplify the authorisation process
   The authorisation process is defined in REACH and it is ECHA's task to follow it. We do, however, provide supporting material and explain on the website how the process works.

6. Facilitate consortium formation for authorisation applications
   This is an internal issue for the industry to deal with, ECHA cannot be involved in the formation of consortia.

7. Substitution of SVHCs
   This is an internal issue for the industry to deal with, ECHA has no direct responsibility in the substitution of SVHCs but is in close contact with the national authorities and the Commission on how best to use the regulatory risk management instruments under REACH.

Guidance and tools

Ongoing

1. Simplification of guidance
   ECHA is working on improving the processes related to guidance. Feedback from the stakeholders is much appreciated and should be given via the online feedback form. Additionally, Guidance in a nutshell, Fact Sheets, Navigator, other documents such as Practical Guides and the ECHA-term database are developed to complement the detailed Guidance documents.
   Target date: ongoing

2. Nomination and tasks of PEG observers
   ASOs can participate in the work of the PEGs and are informed about new PEGs as a standard practise. ASOs will be asked to update their areas of interest on an annual basis. For the sake of transparency, the names of ASOs participating in PEGs could be published on ECHA's website. A distinction needs to be made between the technical guidance documents that are consulted with relevant stakeholders following the Guidance Consultation Procedure available on the ECHA website and ECHA's "Quasi-guidance" that follow a restricted internal ECHA consultation. The "Quasi-guidance" are based on the actual Guidance documents. For some of these documents, such as the Guidance in a nutshell documents, an informal consultation of relevant stakeholders may be appropriate and will be considered before issuing such documents in future. This could also be clarified on the website.
   Target date: Q2/2012 for updating areas of interest and website updates

3. Consider impacts of conservative approaches of Chesar for data rich substances
   In assessment situations where the registrant cannot demonstrate control of risk based on conservative Tier 1 exposure estimation tools, but the registrant has data available to use higher Tier approaches including measured data, assessment based on measured data and external exposure estimation tools can be reported in Chesar already now. For the future, ECHA will create compatible data structure and interfaces, in cooperation with the tool owners, so that data exchange between these tools and Chesar becomes possible.
   Target date: 2012-2015, depending on the tool

To be explored

4. Updating of Guidance on Substance in Articles
   ECHA is aware of the specific issue related to checking whether a substance is covered by an existing registration (Article 7(6) "registered/notified" for that use). ECHA is looking into the most appropriate way to clarify the issue.
   Target date: needs to be defined

5. Chesar also to include mixtures
   At present, Chesar is a tool for the safety assessment of substances. ECHA is considering the possibility of adding a functionality that would allow consolidating exposure scenarios for different substances in a mixture and enable risk management advice for the whole mixtures to be created. This is currently in an idea phase and the development is likely to take some time.
   Target date for for analysing the feasibility and usefulness to widen the scope of Chesar to mixture assessment: end of 2013

Downstream users and supply chain communication

Ongoing

1. Support with Safety data sheets and harmonisation of exposure scenarios
   ECHA has taken a proactive role in working with the stakeholders within the Chemical safety assessment (CSA) development programme. The ECHA Stakeholder Exchange Network on Exposure Scenarios (ENES) is one of the initiatives that aims to find standardised ways of dealing with exntended SDSs. The network was established in mid-2011 and will have two annual meetings. Publishing examples of good CSRs is part of the CSA programme and some exposure scenarios are already published on ECHA's website. ECHA is preparing a road-map for improving the quality of information in the CSAs and the exposure scenarios during the next five years.
   Target date: ongoing

Support for SMEs

Ongoing

1. Training and other support
   ECHA arranges 25-30 webinars per year and some are specifically targeted at SMEs. Lead registrant workshops and Stakeholders' days are also targeted at SMEs and they may also get their travel expenses reimbursed. These events are also open for consultants who intend to support SMEs with their dossiers. ECHA has also developed a number of publications for SMEs. All publications intended for SMEs are translated to 22 languages. In order to increase the visibility for these materials, ECHA is preparing a Quick guide for finding information for SMEs.
   Target date: Q2/2012 for the Quick guide

To be explored

2. Publish a website listing SDS tools*
   Most of the tools are commercial products, and it would be difficult for ECHA to select which should be selected without seemingly favouring some service providers. However, if such a service is considered helpful, ECHA could link to pages maintained by the industry associations. This could be discussed as a possible joint initiative.
   Target date: Q4/2012 for discussing the issue further

Not applicable

3. IT tools for SMEs
   ECHA works on developing user-friendly tools for the use of all stakeholders, but we do not believe that developing specific tools for SMEs would be feasible. This could easily create incoherence in the data and risk complicating the process. We believe that putting resources in the development of our tools for the benefit of all users is a better investment. However, supporting tools such as the Navigator and IT manuals are intended to help the SMEs in using the tools.

Enforcement

Ongoing

1. Harmonised enforcement
   ECHA considers harmonised enforcement as an important issue and supports the Member States in efforts for harmonising enforcement, in particular through the Forum for Exchange of Information on Enforcement. However, it is the Member States who are responsible for enforcement. Harmonising practises in 30 countries takes time and all actors need to collaborate to make it happen.
   Target date: ongoing

2. Transparency of Forum
   An annual Forum Enforcement Workshop with Stakeholder Organisations is arranged to discuss enforcement topics with the Accredited Stakeholder Organisations. This has proven to be an efficient way to discuss specific topics and to change views on enforcement related issues. ECHA continues to arrange these stakeholder sessions, and the next one will take place in November 2012 together with Forum-13. Furthermore, the ECHA website contains the Forum's Agendas and key documents, including meeting minutes.
   Target date: Q4/2012 for next Forum Enforcement Workshop with Stakeholder Organisations

3. Enforcers should communicate to SMEs
   Many Member States organise national events, which are also intended for SMEs. Ensuring that enforcement authorities communicate is responsibility of the Member States. ECHA supports these events to the maximum extent possible, for example by providing speakers. In addition, ECHA also provides enforcers with information material they can distribute e.g. when making on-site visits, such as leaflets describing obligations for Downstream users in the supply chain.
   Target date: ongoing

To be explored

4. Contribute to making enforcement questions available
   Making inspectors' manuals available in all countries could be a topic in one of the upcoming Forum meetings. ECHA will keep ASOs updated on the outcome of the discussions on this subject in the Forum.
   Target date: Q3/2012

5. Produce "Top 10 tips on enforcement" for companies
   We do think this could be a useful project and could explore whether such a document could be produced in cooperation between the Forum and the stakeholders.
   Target date: Q4/2012 for discussing in the Forum

ASO engagement

Ongoing

1. Flexible and organised participation of ASOs in Committees
   Stakeholder observers are involved in the work of the ECHA Committees and participate to Committee meetings. ECHA is working to streamline the efficiency of the Committee working procedures and structure the contributions made by stakeholder observers in the Committees' work.
   Target date: ongoing

2. Experts' involvement in Committees' work
   Stakeholder observers and experts are encouraged to provide information through Public Consultations, rather than during the opinion-development process. Stakeholder observers and experts, nominated by the stakeholder organisation may participate in Committees' work or working groups depending on the issue under discussion. The main rules of participation of nominated stakeholder experts are laid down in the Rules of Procedure of the Committees. We realise that there is room for improvement in clarifying the guidelines for the participation of the stakeholder observers and the experts, and are currently working on stakeholder involvement in CLH and authorisation processes for RAC & SEAC.
   Target date: ongoing

3. Increase transparency of Committees
   Committees' discussions, draft agendas and outputs or decissions taken are published on ECHA's website. Main conclusions and action points are normally published immediately after each meeting in CIRCABC and are accessible for all participants. Full minutes are published within 21 days after the meeting. Draft decisions on dossier/substance evaluation cannot be made available as such because they contain confidential information based on the registration dossiers. Confidentiality declarations prevent distribution of the Committee documents. However, it has been said that the observers can discuss the issues with their "constituences".
   Target date: ongoing

4. Stop relying on umbrella organisations
   ECHA is following the established practice following the rules of procedure for MSC, RAC and SEAC: 1) recognising eligible stakeholder organisations 2) letting the Committees to decide which eligible organisations should be selected as observers of the Committee. Please note that the main input from stakeholders should take place via the registration dossiers and public consultations. For some processes (e.g. CLH) ECHA is actively identifying all parties concerned to ensure that all relevant experts can participate in the further discussions.
   Target date: ongoing

5. Open dialogue with stakeholders
   ECHA considers it very important to have an open dialogue with its Accredited Stakeholder Organisations and has committed to arranging a strategic workshop on an annual basis. We are also looking into the possibility of arranging specific workshops to discuss scientific issues with the stakeholders and will update the ASOs on the progress of the plans.
   Target date: Q4/2012 for the next strategic workshop

6. Involve all ASOs in consultations
   ECHA continues to improve its processes to ensure that all stakeholder sectors are involved in it activities. All ASOs are consulted on issues related to REACH implementation. However, for technical questions related to e.g. the submission of dossiers, we consider it reasonable to target the consultation at the future users.
   Target date: ongoing

7. Flexible practise for updating contact information
   An online form will be introduced to facilitate contact information updates in a user-friendly way.
   Target date: Q2/2012

8. Make ECHA staff's contact information available
   Names and phone numbers of key ECHA staff are published on ECHA's revised website. There are many ways to contact ECHA, and using functional mailboxes ensures that the issue is processed by the available staff members.
   Target date: ongoing

9. Include links to ASOs websites
   ECHA is currently working on the stakeholder webpage and links to ASO's websites will be added. This is also to encourage smaller organisations to discuss with the representative of their field regarding issues related to REACH and CLP.
   Target date: Q2/2012

10. Continue testing IT tools with ASOs
    ASOs are an important reference group for testing the Agency's IT tools. For the sake of transparency, the upcoming testing opportunities could in the future be announced in the newly established Stakeholder Update, which will be sent to the ASOs four times a year.
    Target date: Q1/2012 onwards for promoting testing opportunities

11. Produce tailored information
    ECHA is developing its website to include a possibility for refining areas of interest and filtering information of interest. However, in relation to ASOs, ECHA's approach is to provide the same information for all in order not to exclude any organisations. In addition to e-News, we send updates and information on important developments to ASOs. An annual workshop is arranged to facilitate strategic discussions.
    Target date: ongoing

12. Continue ASO workshops
    ECHA has committed to organising the workshop as a recurrent event and will continue as long as it is considered useful.
    Target date: Q4/2012 for the next workshop

To be explored

13. Set up an ASO communicators' network*
    We are very interested in exploring the possibility of forming a communicators' network for developing communications cooperation. The network could contribute to developing joint communications initiatives, and in giving advance notice of upcoming key issues.
    Target date: Q3/2012 for presenting a concrete suggestion to ASOs

14. Give ASOs advance notice of key issues*
    ECHA has so far informed the ASOs of upcoming issues with separate emails. In order to improve efficiency and userfriendliness, we are starting to collect the issues and to send regular Stakeholder Updates once every three months. The intention is to highlight upcoming issues and activities, not to duplicate information sent through ECHA's e-News. The Stakeholder Updates can also be developed into a joint communication channel for the ASOs to share information between each other. ECHA could be the moderator for this exercise.
    Target date: Q2/2012 for launching the pilot, assessment late 2012

Awareness-raising

Ongoing

1. Ensure sufficient communication
   ECHA has already made much information available and is continuously working to ensure transparency in its processes. The revamp of the website with 22 language versions was a major step in this direction. We communicate through several channels, e-News with 15 000 subscribers being one of the primary channels. We also have an interactive approach to the preparation of our events and identify the needs of our audiences in advance. Survey results on our communications efforts have been very positive, but we always appreciate being given ideas for improvement. This feedback could also be channelled through the potential Communicators' network.
   Target date: ongoing

2. Provide more information to the general public/consumers*
   ECHA introduced an Info Desk at the beginning of 2012 to answer questions from the general public. A new section "Chemicals in our life" intended for the general public was introduced as a part of the new website. The section could be updated with information about Substances in articles from a consumers' perspective and by introducing links to relevant external websites, for example on ASOs' or national authorities' websites.
   Target date: 2013 for publishing information on the website

3. Be more actively present in the media*
   As an expert organisation we do not strive for a constant media presence, but consider media as one of our communications channels. Specialised press serving key stakeholders is ECHA's main focus in media communications and there we have a good coverage. We also work proactively towards the general media, but it is a challenge to get them interested. One potential area of interest for the general media could be the list of Substances in Articles, which was published for the first time on 5 March 2012 and will from now on be updated twice a year. For overall political issues, it is the role of the European Commission to communicate to the media. We would, however, be pleased to discuss and support any ASO willing to take a stronger role in media communications. This could be considered a joint initiative*
   Target date: 2013 for exploring the cooperation possibilities

4. Involvement of ECHA staff in ASO events
   ECHA staff participates annually in 60-100 events. Speaking requests are dealt with based on Agency-wide criteria, the availability of staff and the mission budget. According to the criteria, priority is given for European-wide or multinational events that involve multi-sectoral industry associations or support REACH implementation. National authorities may also be relevant contact points for ASO events.
   Target date: ongoing

6. Communications projects for specific audiences*
   Some projects are already ongoing this year and we welcome initiatives from the ASOs. ECHA's resources would allow 2-3 such projects per year. The order of priority could be decided in the annual Accredited Stakeholder Workshop.
   Target date: Q4/2012 for discussing projects for 2013

To be explored

5. Gather positive messages on the impact of REACH*
   This could be a joint initiative with interested ASOs. ECHA would be happy to coordinate, but input would need to come from ASOs. Quotes gathered from the field could be used in publications and events.
   Target date: Q3/2012 for launching the project

Not recommended

6. Arrange Stakeholders' Days in the Member States
   ECHA does not have the resources to arrange events in several countries, and does not consider it efficient. Instead, we arrange a lot of virtual events that can be accessed from all Member States. We are currently looking into the possibility of translating presentations to support audiences from different Member States. Additionally, ECHA's speakers participate annually in 60-100 events organised by the industry or the Member States.