ECHA|Newsletter

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REACH Conference

What did we achieve in 2010 - how can we ease the way for 2013?

ECHA
European Chemicals Agency

REACH 2013 – Act now!

If you haven't heard this phrase before, you certainly will from now on. There's one very clear piece of advice that every successful Registrant can agree on – start early! Everything is that much easier when you're not in a rush! You may have been one of the hundreds of companies who met together in Brussels at the end of September for the REACH Conference, where experiences from the last REACH deadline were shared and best practice exchanged. As well as starting work early, the recommendations from companies included the importance of effective communication in the Substance Information Exchange Fora, the need to reach agreement in time on the legal and financial arrangements in SIEFs, the challenges posed by extended safety data sheets, and how to work most effectively with downstream users. I watched the webstream live from Helsinki and I found the experience chastening but uplifting.

REACH is not an easy ride and registering successfully requires effort – but the uplifting part is that thousands of companies have done it already, so it can be done. If you couldn't make the conference, I strongly urge you to look at the recording which is still online on the website of the European Commission (link on page 8).

Also in this edition, we are highlighting some extremely topical issues – the inquiry process as a mechanism for data sharing, the upcoming legislation on biocides and PIC (Prior Informed Consent), our new policy on managing conflicts of interest and the new guidance on safety data sheets.

As usual, I hope that you find the Newsletter useful and please remember that your feedback is always welcome – you don't need to wait for a formal survey to tell us how we can better serve your needs.

Wishing you a pleasant and colourful autumn.

Lindsay Jackson
Head of Communications

"There's one very clear piece of advice that every successful Registrant can agree on - start early."

In this issue:

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New ECHA guidance on Safety Data Sheets

The final version of the ECHA guidance on the compilation of Safety Data Sheets (SDSs) was published on ECHA's website on 7 September 2011.

The number of stakeholder comments received on the four drafts of the document generated during the ECHA consultation (over 2000 in total) is already an indication that this document is relevant to a very wide audience throughout Europe. Unlike many of the other obligations arising from the EU chemicals regulation (REACH), the requirements to supply an SDS applies to hazardous and other specific substances put on the market regardless of the quantities involved. This means that this guidance is of particular interest for Small and Medium Enterprises (SMEs) as well as for larger chemical companies and formulators of mixtures containing chemical substances. As a consequence, although the text of the guidance is currently only available in English, its translation into all of the 22 official languages of the EU is a priority for ECHA. The translations will be available in the first quarter of 2012.

Generation of guidance on the compilation of Safety Data Sheets by ECHA was not specifically foreseen in the REACH Regulation. However, the advent of new EU regulations on classification, labelling and packaging (CLP) in 2008 as well as new amendments to Annex II of REACH (which specifies the contents of SDSs) made such guidance extremely desirable. By agreement with industry, and to ensure maximum consultation of and buy-in by all stakeholders, the starting point for ECHA's guidance was a document that industry had been working on even before publication of the amended Annex II. Again due to the potentially high proportion of SME readership, and for the convenience of all those unaccustomed to reading guidance in parallel to a legal text, the document quotes much of the text of the amended Annex II in its entirety, additionally consolidating it in a form which allows the reader to see which text remains "as is" from 1 December 2010 and which will change again from 1 June 2015. This is particularly important for formulators of mixtures.

The guidance document aims to clarify for its readers a series of points which arise for compilers of SDSs, including:

- what is new in SDSs according to REACH by comparison with the previous legislation;
- issues to consider when compiling an SDS;
- details of the requirements for information to be included in each section of an SDS, in particular detailing the changes arising from the revisions of Annex II of REACH;
- the timetables for implementation of the requirements of the (two) amended versions of Annex II to ensure alignment with the classification and labels used on packages according to the CLP Regulation, and
- who should compile the SDS and what competences the author should have.

A major difference in requirements for SDSs for some substances and mixtures by comparison to the pre-REACH SDSs is the requirement for attachment of exposure scenarios to the SDS. The structure and content of these exposure scenarios is not dealt with in detail in this guidance as this is the subject of other ECHA guidance and related documents. However, the available options for attachment or incorporation of exposure scenario information for components of mixtures are discussed briefly in the document. It is also explicitly clarified that exposure scenarios are subject to the same requirements to translate into recipient Member State official languages as the "main body" of the SDS.

Guidance on the compilation of Safety Data Sheets:
http://guidance.echa.europa.eu/docs/guidance_document/sds_en.htm?time=1319014174

ECHA publishes new example exposure scenarios

To support companies in complying with their obligations under REACH, ECHA has developed practical examples of how to generate exposure scenarios (ESs) together with the cleaning products industry and the construction chemicals industry.

The new example exposure scenarios are featured in two publications that are now available on the ECHA website. These are meant to be useful for both registrants and downstream users receiving extended safety data sheets (SDSs) for registered REACH substances.

Further information:
ECHA News Alert, 31 August 2011
http://echa.europa.eu/news/na/201108/na_11_36_example_scenarios_20110831_en.asp

Invalid pre-registrations removed from the REACH-IT database

ECHA supports the data sharing process between registrants by removing outdated or irrelevant pre-registrations from its database. This will enhance the data sharing process between potential registrants.

After consultation with the concerned pre-registrants, ECHA has removed the following:

1. pre-registrations for which the deletion was requested by the pre-registrant during the pre-registration period;
2. pre-registrations corresponding to Annex IV entries;
3. based on inspection reports issued by the Member State Competent Authorities, pre-registrations that are considered invalid because the pre-registrant is not lawfully established in the EU or the pre-registrant could not be identified, because their postal address is not correct and they did not reply to electronic and postal inquiries, and
4. all pre-registrations made by legal entities whose REACH-IT accounts were blocked and the use of the account was never reclaimed.

ECHA advises importers, potential registrants and downstream users to consult the list of invalid pre-registrations on ECHA's new dedicated website.

The Agency reminds pre-registrants who do not intend to register a given substance to deactivate themselves in the corresponding pre-SIEF page of REACH-IT.

Further information:
ECHA News Alert, 21 September 2011
http://echa.europa.eu/news/na/201109/na_11_42_removal_of_pre-registrations_en.asp

List of invalid pre-registrations
http://echa.europa.eu/chem_data/invalid_pre-registrations_en.asp

List of pre-registered substances
http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx

REACH-IT Industry User Manual on "Pre-SIEF" (deactivation in REACH-IT)
http://echa.europa.eu/reachit/ium_en.asp

ECHA has published the analysis of substances that were not registered by the first deadline despite the reported intentions

Some 1500 substances, identified to be registered according to a survey carried out in April 2010, were not registered by the first registration deadline. The Directors' Contact Group (DCG) agreed to conduct an analysis of the reasons, and ECHA published the results of the analysis in September.

DCG carried out a survey in spring 2010 to focus the estimates of substances intended to be registered by the first registration deadline. The list was assembled from different sources. After the deadline, ECHA reported a gap of about 1500 substances, which represented 30 % of all the intentions.

ECHA has now published the list of those substances that were identified to be registered by the first registration deadline but have not been registered yet. The coordinated efforts of ECHA, industry associations and Member State Competent Authorities have produced information for over 1200 substances and the explanations are given in the list. ECHA was unable to trace the reason for non-registration for the remainder of the substances due to lack of feedback.

The list will not be updated. Therefore, downstream users interested in the status of their substance(s) should first check the list of registered substances, which is updated regularly. Only following this check, should they look for a potential explanation for non-registration in the list.

Further information:
ECHA News Alert, 21 September 2011
http://echa.europa.eu/news/na/201109/na_11_41_substances_not_registered_20110921_en.asp

List of substances intended to be registered but were not by 1 December 2010
http://echa.europa.eu/chem_data/list_registration_2010_en.asp

List of registered substances
http://apps.echa.europa.eu/registered/registered-sub.aspx

A draft list available for substances proposed for evaluation

ECHA has submitted the first draft Community rolling action plan (CoRAP) to the Member States. The draft plan contains 91 substances that are proposed for review by the Member States under the substance evaluation process of the REACH Regulation. These substances are divided for evaluation during the years 2012, 2013 and 2014. ECHA has also published a public version of the draft plan including the non-confidential substance names, CAS- and EC-numbers, and the tentative year of evaluation.

The REACH Regulation (EC) No 1907/2006 requests ECHA to submit the first draft CoRAP to the Member States by 1 December 2011. The plan addresses substances that are suspected of posing risk to human health or the environment.

The draft plan has been prepared in close cooperation with the Member States, taking into account the agreed risk based criteria for the selection of substances. The Member States have also proposed substances based on national priorities.

In many cases, the initial concerns are related to potential PBT -properties, suspected endocrine disruption, or carcinogenic, mutagenic and reprotoxic properties in combination with wide dispersive or consumer use(s). In general, the uses of these substances cover various areas and are not focusing on any particular industrial, professional or consumer uses.

ECHA has now submitted the draft CoRAP to the Member State Competent Authorities and the ECHA Member State Committee. The Committee will prepare an opinion on the draft plan in February 2012. ECHA will then adopt the final CoRAP on the basis of the Committee's opinion. The CoRAP process does not include a public consultation but ECHA informs the stakeholders of the progress made by publishing the draft list of substances.

ECHA's aim is to adopt the final CoRAP by end of February 2012 with the final CoRAP published on the ECHA website. The final CoRAP will indicate the Member State responsible for the evaluation of each substance and the initial reasons of concern. From the publication of the final CoRAP, the respective Member States have one year to evaluate substances specified for 2012 and, where regarded as necessary, to prepare a draft decision for requesting further information to clarify the suspected risks. Such draft decisions will be reviewed and agreed by the other Member States, ECHA and the Member State Committee before it becomes effective. Registrants of substances listed on the final CoRAP will be provided an opportunity to comment before any final decision to request further information will be taken.

Further information:
ECHA News Alert, 21 October 2011
http://echa.europa.eu/news/na/201110/na_11_50_corap_en.asp
CoRAP list: http://echa.europa.eu/doc/reach/evaluation/corap_2011.pdf
New CoRAP web pages: http://echa.europa.eu/reach/evaluation/corap_en.asp
Evaluation web pages: http://echa.europa.eu/reach/evaluation_en.asp

Report of the Directors' Contact Group (DCG) available

The European Commission has published a report presenting achievements, lessons learnt and recommendations from the Directors' Contact Group between the European Commission, ECHA and Industry Associations on meeting the first REACH registration deadline.

The report sets out the achievements, lessons learnt and recommendations of the group, demonstrating that obstacles to registration can be reduced. The group continues its work under a new and revised mandate, thus continuing its support in facilitating the registration process through to the next major registration deadline of 31 May 2013. The report is also available on the ECHA website.

Further information:
ECHA News Alert, 23 September 2011
http://echa.europa.eu/news/na/201109/na_11_43_DCG_en.asp

Report of the Directors' Contact Group
http://echa.europa.eu/doc/reach/RRD-57-10_DCG10_ Report_20110923.pdf

IUCLID 5 stand-alone installation video tutorials are now available

IUCLID 5 installation video tutorials are now available for all users wishing to successfully download and install IUCLID 5 in a stand-alone environment.

Further information and links to the tutorials:
ECHA News Alert, 4 October 2011
http://echa.europa.eu/news/na/201110/na_11_47_iuclid5_videos_en.asp

New ECHA policy on handling conflicts of interest

Independent and scientifically-based opinion and decision making is at the core of ECHA's existence. The management of potential conflict of interest situations is therefore a key element of governance and crucial for maintaining the trust of stakeholders and citizens in the Agency's integrity. To increase the visibility of ECHA's efforts in this field and to further improve its approach, the Management Board, in its September 2011 meeting, decided to adopt an overarching policy for managing potential conflicts of interests.

Since the Agency's inception, ECHA has given high priority to avoiding potential conflicts of interest. In fact, the first decision ever taken by the (then interim) Executive Director was to adopt Guidance on declaring conflicts of interest as well as a template for these declarations. Since then, the Agency has put in place a robust framework for preventing and handling any potential conflict of interest situations.

It should be clear however, that expertise is by nature based on prior experience. Having a background in the chemicals sector does therefore not necessarily mean that one should be disqualified from participating in the activities of the Agency, while having an interest is also not equivalent to having a conflict of interest. As a consequence, ECHA needs to carefully evaluate every potentially harmful situation on a case-by-case basis taking into account all the aspects of each specific incident.

Strengthening independent decision making

With the newly adopted policy ECHA wishes to bring together its existing procedures through which independent decision making is guaranteed in one single document. At the same time some new elements are introduced to further improve the Agency's procedures for managing potential conflicting interests.

The policy defines a conflict of interest as a situation where *the impartiality and objectivity of a decision, opinion or recommendation of the Agency, including its bodies, is or might in the public perception be compromised by an interest held by, or entrusted to, an individual working for the Agency.* This definition is inspired by the European Commission and is in line with the OECD recommendations* and holds both the elements of public interest versus private interest, and actual conflict versus perceived conflict.

The scope of the policy is set to include the entire ECHA organisation and all of its activities. It thus applies to the members of the Management Board, the Committees and the Forum, including their advisers, invited experts and observers, as well as to the staff of the Agency and the Board of Appeal. The networks, experts groups and third parties working with the Agency are within the scope of the policy, as no participants in the activities of ECHA should be excluded.


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Declarations of interest made public

An important new element of the policy is the creation of an Ethical Committee within the Agency. It shall have a consultative function and its advice can be requested before a decision is taken on any individual case of potential conflics of interests. Another important aspect is the introduction of a more detailed template to be used for declaring interests. This should increase the quality of the information gathered on the basis of which it is determined whether the individual concerned can take part in the activities of the Agency, and if so, to what extent. The members of the Management Board, the Committees and the Forum, as well as all staff members of the Agency are required to make an annual declaration of their interests. The more detailed template shall be used for this purpose in the future. For reasons of transparency the declarations of the main actors behind ECHA's decision making are also made publicly available on the Agency's website.

Overaching policy

The policy will be integrated in all working processes of the Agency, and it will be complemented with implementing rules and codes of conduct containing the detailed procedures to prevent and handle conflicts of interest. ECHA will keep striving to deliver high quality, scientifically-based opinions and decisions, independent from any undue interests.

Policy for Managing potential Conflicts of Interests:

http://echa.europa.eu/about/organisation/management_board/management_board_approved_documents_en.asp

** Recommendation of the Council on OECD Guidelines for Managing Conflict of Interest in the Public Service (28 May 2003 – C(2003)107).*

Biocides and PIC coming under ECHA's umbrella

In the future, four European regulations for chemicals will be dealt with under the same roof, as ECHA takes over the administrative responsibility for the revised regulations for biocides and Prior Informed Consent (PIC).

There are many synergies between these two regulations and the processes for REACH and CLP. For that reason the Commission has suggested handing over the administration of Biocides and PIC regulations from the European Commission research centre JRC to ECHA", says Jukka Malm, Director of Regulatory Affairs at ECHA.

The change of administrative responsibility is part of the revision process of the EU legislation covering biocides and the PIC process. The proposed regulations are currently in the EU decision making process and the entry into force is expected in 2012. At ECHA, preparations for biocides are already underway and will start for PIC in early 2013.

"We are currently planning the IT tools, preparing guidance documents and developing our regulatory processes. Selection and recruitment planning has also started", says Jukka Malm.

Biocides

The proposed Biocides regulation replaces the Biocidal Products Directive (BPD) from 1998. Both contain two steps: the approval of an active substance followed by granting an authorisation for the biocidal product. A new element in the regulation is the Union Authorisation of biocidal products, which allows companies to get an EU wide authorisation, in contrast to national authorisation. The Biocides regulation has some commonalities with REACH for example in applying the principles of sharing data on animal tests and related costs. The required information package and the evaluation of the risks are normally more detailed.

Prior Informed Consent (PIC)

The Rotterdam Convention on Prior Informed Consent (PIC) is a global treaty that came into force in February 2004, with the intention to protect developing countries from the import of dangerous chemicals. The PIC Convention is implemented in the EU by means of regulation concerning the export and import of dangerous chemicals. Under the proposed recast of this PIC Regulation, the companies will continue to notify to their national authorities their intention to export banned or severely restricted chemicals. ECHA will take over the task to communicate with the destination country and to keep a register of the notifications.

ECHA sets up ENES - an Exchange Network on Exposure Scenarios

The new network aims at identifying good industry practices on drafting exposure scenarios and building a dialogue between supply chain actors to improve the protection of human health and the environment. ECHA together with the European Chemical Industry Council (CEFIC), Eurometaux, CONCAWE (the oil companies' European association), the European Association of Chemical Distributors (FECC) and the International Association for Soaps, Detergents and Maintenance Products (AISE) on behalf of the Downstream Users of Chemicals Coordination Group (DUCC) have established a cross-sector collaborative network to share knowledge, techniques and approaches to building and applying (REACH) exposure scenarios. The first meeting will be held in Brussels, on November 24 and 25, 2011. Sectors of industry, NGOs, Member State authorities and other stakeholders will be invited to participate.

ENES will share the approaches and practical experience of industry and other stakeholders from the first REACH registration deadline, the areas that are working well and the areas where improvements are needed.

The Exchange Network of Exposure Scenarios is among the activities that ECHA is rolling out to support companies for the second registration deadline in 2013. Practical solutions for preparing and communicating exposure scenarios identified by the first Network meeting will be published in the beginning of 2012 by the Agency.

Further information:
ECHA News Alert, 26 September 2011
http://echa.europa.eu/news/na/201109/na_11_44_ENES_en.asp


The REACH Conference participants.

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REACH Conference

What did we achieve in 2010 – how can we ease the way for 2013?

ECHA and the European Commission jointly organised a REACH conference in Brussels on 23 September. The aim of the one day conference was to assess the lessons we have learnt during the 2010 registration process and the improvements that are needed for the 2013 registration deadline. ECHA also launched the 'REACH 2013 - Act Now!' campaign at the conference and announced a new campaign webpage.

Most speakers at the Conference were positive about the developments so far and expressed their congratulations to ECHA and other actors including the NGOs and industry. In his opening speech, the Commissioner for Environment, *Janez Potočnik* praised industry for having done an excellent job in submitting 25 000 registrations for 4 500 substances: "I'm well aware of the efforts and the hard work behind these figures. Well done!"

The Executive Director of ECHA, *Geert Dancet*, emphasised the impact of REACH for the protection of human health and the environment: "If higher levels of protection for our citizens and the environment are not worth working for then I don't know what is."

The quality of dossier content was discussed with many speakers identifying this as a challenge for the future. ECHA's Director of Evaluation, *Leena Ylä-Mononen*, highlighted in her presentation ten top tips to improve the content of dossiers during her presentation.

Tony Musu, from the European Trade Union Institute (ETUI), proposed that the possibility to withdraw a registration number from a company after an evaluation should be incorporated in the legislation. "This could lead to an improvement of the data quality", he said.

Douglas Leech from the UK based Chemical Business Association (CBA) appreciated the feedback given from the SIEFs and getting the first hand information from the Commission on the REACH review process. "There was not a great degree of detail regarding the information in the dossiers. It kept being quoted that 50 % of dossiers were unsatisfactory, but only limited details regarding the discrepancies were given", he said.

Media professional *Aminda Leigh*, who moderated the conference, told the ECHA Newsletter that she appreciated the high quality of the presentations and the presenters being well briefed and keeping to the point. She also appreciated the assurances of ECHA to do things better in the coming years.

Jan Wilmer, the Managing Director of Wilmer Tox Consulting, has been working with chemicals industry for the past three decades, mainly in a multinational chemical company. In his opinion, the conference was very good for the less experienced people, the small companies who will submit dossiers for the first time: "I am very impressed by ECHA's IT approach and am happy with the assistance ECHA provides to the stakeholders. But I'm a bit concerned that new IT tools are developed at the same time as the registration period is running. The industry finds it somewhat troublesome that new versions of the tools are expected to arrive in 2012 when the companies are in the middle of preparing their dossiers."

ECHA launched the 'REACH 2013 - Act Now!' campaign at the Conference and announced a campaign webpage, which has information for the 2013 registrants as well as special material for the downstream users, who will need to notify their uses to their suppliers by end of May next year if they wish these uses to be included in the 2013 registration dossiers.

Visit the campaign webpage at:
http://echa.europa.eu/2013_en.asp

Recordings of the conference and the presentations are available online:
http://webcast.ec.europa.eu/eutv/portal/archive.html?viewConference=12888

Feedback from the REACH Conference

Over 400 stakeholders from 30 countries attended the REACH Conference in Brussels on 23 September. 103 of them replied to a follow-up survey by ECHA. Most of the respondents (83 %) gave the conference an overall rating of excellent or good. The presentations given received an average rating of 'good'. The panel discussions were considered excellent or good by 52 % of the respondents.

To make the content of the presentations even better next time, the respondents suggested more practical examples and detailed information, as well as more input from industry.

TEXT BY PIA FALLSTRÖM MUJKIC

From 2010 to 2013

Experiences with REACH

ECHA newsletter interviewed representatives of a stakeholder organisation and a company representing the soaps and detergents industry to get their impressions of the registration process, to learn how they managed the first registration deadline and to examine what they have taken in from their experiences.

TEXT BY PIA FALLSTRÖM MUJKIC

Dr Peter Freunscht is the Regulatory Affairs Manager at Unilever. Unilever is a British-Dutch multinational company that owns many of the world's consumer product brands in foods, beverages, cleaning agents and personal care products.

Dr Freunscht, after the 2010 registration deadline, what are the lessons you have learnt and do you have any advice for other companies that are preparing for the upcoming 2013 deadline?

With regard to the Consortia and SIEFs, we discovered that there is a need for clear legal structures. Also, the members' engagement levels have to be high. We also learnt that the *Letter of Access* management is complicated.

Exposure scenario development also needs enough time and focus. There is a need for scaling tools and rules for aggregation. These tools and rules would be needed both for substance aggregation and exposure scenario aggregation.

We learnt that the key to successful supply chain communication is a good mapping of uses and that the uses are communicated to the suppliers. The downstream users need operational conditions to analyse exposure scenarios. They also need guidance from suppliers on how to implement extended safety data sheets and exposure scenario requirements.

What in your opinion has not worked well or caused your company particular problems during the registration process?

The late arrival of guidance and the lack of clarity in the format and content of exposure scenarios, especially in supply chain communication, caused many problems. This may have lead to lengthy extended safety data sheets, some of which were even hundreds of pages long. These documents are difficult to manage. A lack of transparency from some *Lead Registrants* or consortia on the cost structure of the *Letter of Access* has also been a problem.

What in your opinion has been the most useful aspect of the REACH registration process in general for your company?

The creation of a portfolio of raw materials that have been assessed for our uses was particularly beneficial. We now have a comprehensive data package. It establishes safe use for the benefit of workers and consumers. This achievement should also be communicated widely by authorities. REACH has established a risk based safety assessment because exposure scenarios have been introduced into the legislation. We consider this as a great step forward in creating realistic and useful safety reports.

Dr Hans Razenberg is the Director of Technical affairs in the Dutch association for detergents, maintenance products and disinfectants (NVZ). NVZ represents manufacturers of household, industrial and institutional cleaning products, their ingredients and finished packaging. It has 55 member companies from industry, including producers of disinfectants. Some of the members are big multinationals but many are downstream users who are buying their raw materials from European suppliers. The total market share of the members is around 80% of the Netherlands' soap and detergents market.

Dr Razenberg, what are your members' main interests?

The SMEs are normally not interested in debating with ECHA. They need very practical guidance on how to fulfil their REACH obligations. To help them, we have provided training on REACH and CLP to our members. We also wrote a number of easy to understand guides in Dutch and English on REACH, CLP and the extended safety data sheets. We did this together with specialists from authorities and inspectorates. These guides are available in the Uitgevers webshop.

What in your opinion has been the most useful aspect of your work from your members' point of view with regard to the REACH process?

We have spent a lot of time and effort in making REACH workable. For instance, we advocated the exemption of ionic mixtures from REACH*. We also helped to build various instruments, such as a database for the C&L inventory for CLP.

Why was the exemption of *ionic mixtures* so important?

For our members, who mainly are SMEs, it would have been very difficult to register all the substances that could appear in an ionized mixture. It would in fact not have been possible to identify many of those substances that were a result of a chemical reaction. For our members, the exemption of ionic mixtures was very helpful. It saved them a lot of time and spared them from a lot of administrative burden.

** The definition of an ionic mixture and the exemption from the obligation to register can be found in the Guidance for Annex V - Exemptions from the obligation to register:* **http://guidance.echa.europa.eu/docs/guidance_document/annex_v_en.pdf**

ECHA launches a new procedure for submitting Alternative Chemical Name Requests

A new online form allows manufacturers, importers and downstream users to request the use of alternative chemical names. They may choose to do this, if they believe that the disclosure of a substance name on the label of their mixtures or in the safety data sheets reveals business secrets. This is in accordance with Article 24 of the CLP Regulation.

Producers of mixtures are obliged to inform the users of any relevant hazardous ingredient in the mixture by disclosing its chemical identity. Typical mixtures are for example; paints, cleaning agents or dish washer detergents. Under certain conditions ECHA or EU Member States authorities may grant exemptions from this obligation. Article 24 of the EC Regulation (1272/2008) on Classification, Labelling and Packaging (CLP) allows the submission of requests for the use of an alternative name for the substance not to be revealed. Before such exemptions are granted, ECHA examines whether the safe use of the mixture may be compromised.

Manufacturers, Importers and Downstream Users can submit their application for using an alternative name to ECHA only if the mixture(s), which contains the substance for which the alternative name will be used, is classified and labelled according to the CLP Regulation. If the mixture is classified and labelled according to the Dangerous Preparations Directive (DPD), the alternative name request has to be submitted to a Competent Authority in one of the EU Member States where the substance is placed on the market. According to the CLP Fee Regulation, a fee will be charged for all requests submitted to ECHA.

A Data Submission Manual, now available on ECHA's website, provides step-by-step instructions for how to prepare an Alternative Name Request dossier in IUCLID 5 and submit it via a web form to ECHA. Additionally, to assist companies in the preparation of an alternative name request dossier, the latest version of the TCC plug-in (version 5.3.1) simulates several of the business rules checks performed at ECHA for this dossier type.

Further information:
Request an alternative chemical name for a substance in mixtures
http://echa.europa.eu/clp/request_for_alternative_name_en.asp

Data Submission Manual part 14 – How to Prepare and Submit a Request for Use of an Alternative Chemical Name for a Substance in a Mixture using IUCLID 5
http://echa.europa.eu/doc/reachit/dsm_14.pdf

Alternative name request dossier submission web form
https://comments.echa.europa.eu/comments/clp24.aspx

Guidance published in May-September 2011

June 2011	
Guidance in a nutshell on requirements for substances in articles, revision (29 June 2011)	http://guidance.echa.europa.eu/guidance2_en.htm
Guidance Fact Sheet on requirements for substances in articles, revision (6 June 2011)	http://guidance.echa.europa.eu/guidance3_en.htm
August 2011	
Guidance on information requirements and chemical safety assessment, new Chapter B8 - Scope of exposure assessment (31 August 2011)	http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1318340742
September 2011	
Guidance on the compilation of safety data sheets , new guidance (7 September 2011)	http://guidance.echa.europa.eu/docs/guidance_document/sds_en.htm?time=1318340769

Ongoing consultations:

Harmonised classification and labelling
http://echa.europa.eu/consultations/harmonised_cl_en.asp

Restrictions
http://echa.europa.eu/consultations/restrictions_consultations_en.asp

Testing proposals
http://echa.europa.eu/consultations/test_proposals/test_prop_cons_en.asp

Preparing for EU membership

Since 2010, ECHA has been introducing the cooperation with, roles and responsibilities of Member states to the European Union candidate countries and potential candidates. This has been part of the Instrument for Pre-Accession Assistance (IPA) project funded by the Commission.

The IPA project aims to introduce the candidate countries to the processes of Member States in working together on REACH and CLP in ECHA. The goal is to ensure that the countries and the experts nominated by them are prepared to participate effectively in all the activities and work of ECHA involving Member States, and to increase the understanding on how a Member State works with the Agency.

Since the start of the project, ECHA has arranged workshops and seminars for the three candidate countries Croatia, the Former Yugoslav Republic of Macedonia and Turkey at ECHA as well as in these countries. The aim has been to give the participants more in-depth knowledge, and to help them to effectively participate in ECHA's work.

A workshop for the potential candidate countries was held in ECHA on 3 October. Representatives from Albania, Bosnia and Herzegovina, and Kosovo* attended the one and a half day seminar to learn more about the work of Member states in the REACH and CLP Regulations, and the role of ECHA. Earlier this year a similar seminar was arranged for representatives from the Serbian Chemicals Agency (see ECHA Newsletter issue 4 of 2011).

Taking the first steps

Laureta Dibra from Albania told the ECHA Newsletter that Albania is taking the first steps with regard to the REACH and CLP Regulations. Ms Dibra is the Chief of Air, Climate Change and Chemicals in the Albanian Ministry of Environment, Forestry and Water Administration. Her sector was established in early 2011. "We hope to start the transposition of REACH and CLP in our legislation in 2012 – with the help of the European Commission. We need to amend the existing legislations or even create a completely new one. We also need to look at the structure and the responsibilities of our ministries, and establish new institutions", she says. Ms Dibra continues stating that Albania has already made good progress with plant protection products: "Our Ministry of Agriculture has experience with plant protection products. They have a specific sector dedicated to this and a research institute for analysis." She also says that the Albanian Ministry of Health is in the process of preparing legislation on biocides: "At this seminar we learned more about the future tasks for ECHA in the biocides area. We also realised that we actually might not need to transpose all the articles of the regulations into our national legislation."

The first challenge for the Albanian government is to set up a registration office that will collect information on chemicals that are imported and exported. "We are currently preparing our national profile of chemicals under the Strategic Approach to International Chemicals Management (SAICM) policy. We have strong cooperation with different institutions in this respect. We hope this cooperation will help us in identifying our own needs and establishing our own system on the management of chemicals", remarks Ms Dibra.

Gordana Banjac from the Ministry of Foreign Trade and Economic Relations in Bosnia and Herzegovina says that her country needs to do more at the state level to coordinate the activities related to chemicals management: "In Bosnia and Herzegovina we have a very unique structure. We have a state level government and an entities level government. Chemicals management is at the moment dealt with at an entity level. One of the entities has chemicals legislation, the other does not. We therefore, need to establish a chemicals management function at the state level to be able to cooperate with the European Union", she says.

The IPA workshop participants from the potential candidate countries with coordinator Eva Sandberg (third from right) from ECHA.

** under UNSCR 1244/99*

ECHA Management Board adopts Work Programme for 2012

On 29 and 30 September, ECHA's Management Board held its 23rd plenary meeting and took a number of important strategic decisions. The Management Board adopted the ECHA Work Programme for 2012. It describes ECHA's activities in the year before the 2013 REACH registration deadline. Apart from ensuring the readiness for the 2013 deadline, the priorities for ECHA in 2012 will be to live up to the expectations on evaluation and authorisation applications as well as preparation for the new Biocides and PIC Regulations. Providing information for the public will also be a focus of the Agency's attention in 2012. The Programme is based on the assumption that ECHA will receive approval from the EU Budgetary Authority for ten new posts. If this is not approved, the Programme will be reviewed by the Management Board in December 2011.

The Board also adopted a policy for avoiding and managing potential conflicts of interest. The policy is applicable to all ECHA bodies and networks, the ECHA Secretariat and Board of Appeal as well as to third parties working for the Agency. The new policy demonstrates the importance of transparency and independence of decision-making; two of ECHA's core values. It will be available on the ECHA website. Concerning international relations, the Management Board decided to invite Croatia as an observer to ECHA's Committees and Forum. Additionally, Serbia was invited as a guest to the next HelpNet Steering Group meeting. The Board will decide on the inclusion of Serbia as an observer in the work of the HelpNet at its next meeting, by when the further developments regarding Serbia's candidate status for EU accession are expected to become clearer.

The Board also endorsed ECHA's work plan for international activities for 2012, subject to the outcome of the 2012 budget procedure.

Procedure initiated to prolong the ECHA Executive Director's mandate

As an appointing authority of the Executive Director, the Management Board also agreed at the meeting to initiate a procedure to prolong the Executive Director's mandate for 2013-2017. The Commission was informed that a new selection procedure is thus not required.

The Chairman of the Management Board, *Dr. Thomas Jakl* commented: "After the first REACH registration deadline was impressively managed by ECHA in 2010, there is no time to rest on our laurels. Challenging further steps of the REACH and CLP implementation lie ahead and the legislator is in the process of entrusting important new regulatory tasks to the Agency. The continuation decision with regard to a selection process for the Executive Director reflects the high satisfaction of the Board with his achievements since 2007."

The meeting was hosted by the Maltese Government. The Management Board Members were welcomed by Dr Chris Said, the Parliamentary Secretary for Consumers, Fair Competition and Public Dialogue and held an exchange of views with representatives of the national competent authority for REACH and CLP.

New Head of Evaluation II

▸ As of 1 September, *Claudio Carlon* has taken up his position as the new Head of Unit for Evaluation II (E2). He is Italian and holds a Ph.D. in Chemistry. He has over 15 years experience in the field of risk assessment of chemicals. He started his career at university and in a research and consultancy organisation where he coordinated the risk assessment team. Then he moved to the European Commission JRC in Ispra to work on the EU harmonisation of risk assessment of soil contaminants, and later on REACH implementation. Mr Carlon joined ECHA from the very beginning in September 2007 and before the new appointment was team leader in the Directorate for Evaluation.


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Vacancies in ECHA

ECHA is currently opening a selection for a business analyst.

Read more:
http://echa.europa.eu/opportunities_en.asp

Executive Director appeals to MEPs for EU and national support

"REACH should continue to be seen as a priority"

Executive Director Geert Dancet visited the Committee on the Environment, Public Health and Food Safety of the European Parliament for an exchange of views on 3 October 2011. He reflected on the achievements of 2010, on the experience gained on the operation of REACH and CLP, and the use of alternatives to testing on animals, and on the challenges that lay ahead for the Agency. Mr Dancet appealed to the members for their continued support in the operation of REACH and the functioning of the Agency.


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The Executive Director's main message to the Committee members was that the experiences from the 2010 registration deadline have shown that REACH is working. However, to ensure the success of the legislation in the future, support at EU and national levels is needed. Mr Dancet urged the MEPs with influence on national and EU funding to ensure that REACH remains a priority. He stated that by 2014 ECHA's resources from fees paid by industry will be exhausted and, in order to continue the work, the Agency will need public support during each year of the next financial cycle. He underlined that this was not an unexpected development, but corresponds to the financial planning for REACH agreed by the Parliament and Council when adopting the Regulation in 2006. He appealed to the Committee members to keep this issue in mind when considering the 2014-2020 financial envelope.

Mr Dancet highlighted five challenges that lie ahead for ECHA. These include evaluating as many dossiers as possible; identifying Substances of Very High Concern (SVHC); pursuing new scientific developments; providing information on chemicals for everyone; and taking responsibilities for the biocides and the Prior Informed Consent (PIC) Regulations. He acknowledged the frustration of some MEPs at the slow progress of identifying Substances of Very High Concern, but asked to "keep the big picture in mind." He said that formally identifying SVHCs is only one way among many of managing well-identified risks, and reminded the Committee members that we now have for the first time all known carcinogens, mutagens and reprotoxic substances (CMRs) being registered and their dossiers made publicly available.

The Members of the Committee who have been following ECHA's activities closely since the Agency's inception used the opportunity to ask questions and exchange opinions on various issues. These issues included the quality of dossiers, natural substances and the position of distillers and producers of perfumes with regard to REACH, supply chain communication, nanomaterials in the dossiers, the Candidate List, competitiveness of the European chemicals industry, REACH fees and their financial transparency, and translations.

Watch the recording of the meeting online at:
http://www.europarl.europa.eu/en/multimedia-library/

ECHA welcomes the decisions of the Board of Appeal

The Board of Appeal of the European Chemicals Agency published its first two final decisions on appeals against decisions adopted by ECHA under the REACH Regulation on 10 October. In one of the cases the Board of Appeal decided in favour of the appellant, because it found that the Agency had not provided clear enough information to the registrant on the deadline for payment of their fee. In the other case, the BoA decided in favour of ECHA and confirmed that the Agency had acted correctly in rejecting the registration.

In both cases, the appellants had paid the fee required for the registration of a substance, after the expiry of the deadlines set by the Agency. According to the REACH Regulation and the associated Fee Regulation, non-payment of the registration fee by the set deadline will result in the registration being rejected with any late fee not being refunded.

In the light of the Board of Appeal's decisions, ECHA will be carefully reviewing its communications. Even before these decisions were issued, modifications had been made to the way ECHA issues invoices in REACH-IT. Now further changes are being made to the letters sent to registrants to make the deadline for payment absolutely clear as well as the consequences of late payment.

Further Information

Board of Appeal's decisions:
http://echa.europa.eu/appeals/app_decisions_en.asp

ECHA response:
News alert, 13 October 2011
http://echa.europa.eu/news/na/201110/na_11_49_boa_20111013_en.asp

Inquiry process - enabling data sharing between potential and previous registrants

Data sharing is a cornerstone of REACH and therefore mechanisms have been introduced to help companies share existing data before registration.

For pre-registered phase-in substances, data sharing occurs in Substance Information Exchange Fora (SIEFs) without ECHA's involvement. For non-phase-in substances and substances that have not been pre-registered, a duty to inquire applies and an inquiry process takes place. In this process, ECHA has an active role in placing the registrants and potential registrants of same substances in contact with each other.

Inquiry process at ECHA

To ensure that potential registrants are put in contact with registrants of the same substance and their contact information is handled securely, ECHA needs to be certain of the identity of the inquired substance. Therefore, each inquiry dossier goes through substance identification assessment where it is ensured that the information provided is sufficient and consistent so that the substance can be unambiguously identified.

After the substance identity verification, it is checked whether there are previous registrants for the same substance. If the potential registrant specifies their information requirements in the inquiry, also the availability of the studies is checked. The potential registrant will receive the results of their inquiry via REACH-IT. If ECHA is unable to identify the substance, due to missing or inconsistent information, the potential registrant is informed of the deficiencies via REACH-IT and encouraged to submit a new inquiry dossier.

Statistics

Since REACH entered into force ECHA has received 4788 inquiries. The number of inquiries submitted remained quite stable from June 2008 to August 2010, after which the number of inquiries received per month almost doubled.

Of the submitted inquiries to date, 45 % have been successful but 55 % could not be processed due to missing or inconsistent information. The quality of the inquiry dossiers had improved steadily after the REACH's entry into force, but started to deteriorate with the increase in the quantity of submitted inquiries at the end of 2010. During 2011, the quality of the dossiers has started to improve again and has now reached the level that it had been before September 2010.

Current state of play

Even though the legal text does not specify a deadline for ECHA to process an inquiry, the Agency has set itself an internal target of 20 working days for processing an inquiry (in line with its Code for Good Administrative Behaviour), which was respected with only a few exceptions up to October 2010. Due to the high number of inquiries received and their poor quality on average, processing times started to lengthen towards the end of 2010. In order to improve the situation, ECHA started several projects in 2011 to improve the efficiency of the inquiry process and reduce processing times.

As the efficiency of the inquiry process depends on the quality of the dossiers received and on the productivity of the process, initiatives were launched that targeted both aspects. Firstly, in order to improve the productivity in house, ECHA streamlined its working procedure on inquiries and reinforced the staffing of the Substance Identification and Data Sharing unit. Secondly, in order to improve the quality of the inquiry dossiers an Inquiry plug-in tool for IUCLID 5 was launched as part of the TCC plug-ins. This tool will allow companies to check the dossier's substance identity section before they submit it to ECHA. By using this tool, companies can check that the relevant fields of their inquiry dossier are complete. Even though the tool will be unable to verify whether the data is correct, it can help to improve dossier quality. In addition, to provide further advice, ECHA published an updated version of the Q&A on Inquiry in June 2011, containing a new section on substance identification. The revised document covers several topics that, from ECHA's findings, have proven to be difficult for inquirers.

Substance identification

Unambiguous substance identity is a prerequisite to enable efficient data sharing. It is however, not always simple to ensure the adequacy, correctness and coherence of the substance identity information. ECHA has identified the following main deficiencies in the inquiry dossiers:

- Absence of spectral data or chromatographic data without justification;
- Absence of a description of the methods used to identify the substance;
- More than one substance is inquired about;
- Submitted spectral data is for a different substance than the one manufactured or imported;
- Counter-ion in salt substance is not identified or quantified;
- Description of the process/origin for the manufacturing of UVCB substances is not included;
- Known constituents of UVCB substances are not identified.

The required analytical data has to be generated for the manufactured substance and a clear and concise description of the quantitative and qualitative analyses should be provided. It is important for the information presented to be readable without a need for industry specific knowledge. Industry specific abbreviations, trade names and jargon should be avoided.

ECHA has also noticed that some companies may be reluctant to provide certain information for confidentiality reasons. However, the required information is needed for unambiguous identification of the substance and must be submitted. ECHA will only provide previous registrants and other inquirers with the name of the substance being inquired about, the name and address of the inquirer and a list of information requirements specified by the inquirer. No other substance identification information will be disclosed.

Further information on substance identification and inquiry can be found on the ECHA website:
http://echa.europa.eu/reachit/inquiry_en.asp

- Guidance for identification and naming of substances under REACH
- Data Submission Manual 18: How to report the substance identi ty in IUCLID 5 for registration under REACH
- Questions and Answers on In quiry and Substance Identification

Inquiry process at ECHA, webinar in May 2011:
http://echa.europa.eu/news/webinars_en.asp

REACH Regulation Articles 12(2), 26 and 28
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT

Figure 1. Trend in the number of inquiries received since June 2008. Data as of 30 September 2011.

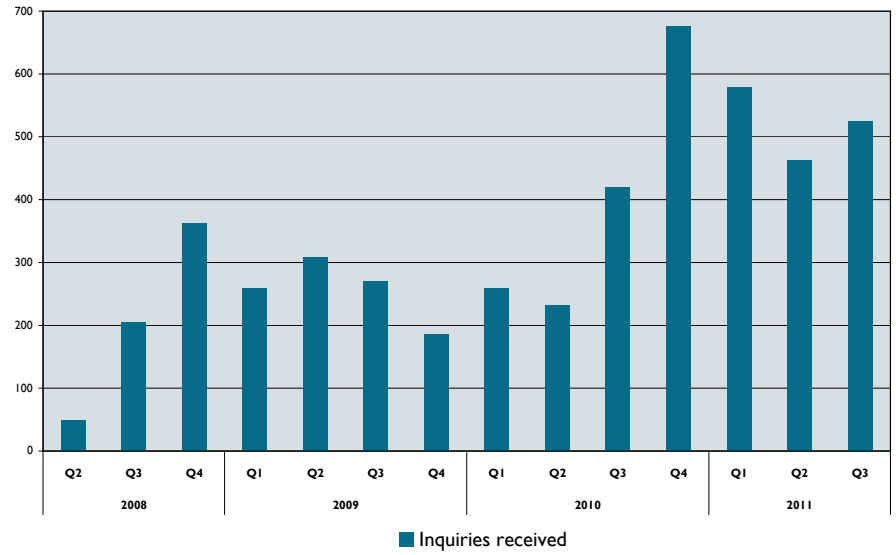


Figure 2. Ratio of successful inquiries and those which could not be assessed due to missing or inconsistent information since June 2008. Data as of 30 September 2011.

Late pre-registration

Manufacturers or importers of phase-in substances in quantities of one tonne or more per year or who use a phase-in substance in production of articles or import articles containing phase-in substances for the first time after 1 December 2008, may use the late pre-registration option (Article 28(6) of the REACH Regulation) instead of inquiring about their substance. To benefit from the late pre-registration option the pre-registration needs to be submitted:

- Within six months of first manufacturing, importing or using the substance in quantities of one tonne or more per year, and
- No later than twelve months before the relevant deadline for the registration.

First-time manufacturers or importers will therefore have to submit their pre-registrations before 31 May 2012 or 31 May 2017, whichever is relevant in view of their tonnage thresholds. Companies that are entitled to submit late pre-registrations, should do so instead of inquiring about their substances.

ECHA refers a draft decision for one testing proposal to the Commission for the first time

The Member State Committee (MSC) could not find unanimous agreement based on scientific and technical arguments on a draft decision for a testing proposal. For the first time, the procedure foreseen in Article 51(7) of the REACH Regulation will therefore be used, requiring the referral of the case to the Commission for decision making involving the Commission REACH Committee.

ECHA's Member State Committee (MSC) held its 19th meeting from 20-23 September 2011. The MSC's agenda had four draft decisions on testing proposal examinations and five draft decisions on compliance checks, with which to find unanimous agreement on their content. The MSC agreed unanimously on the draft decisions for all five compliance checks and on two draft decisions for the testing proposal examinations. A draft decision on one testing proposal was refined at the meeting but agreement seeking will take place by written procedure, following the meeting.

The draft decision, which will be sent to the Commission for decision making, concerns a testing proposal examination where the registrant has proposed to perform a two-generation reproductive toxicity test in accordance with the EU test method B.35. This information would be necessary to fill the data gap regarding reproductive toxicity for any substance that is produced in quantities of over 1000 tonnes per annum.

Some MSC members preferred to ask the registrant to use the recently adopted OECD test guideline 443, the extended one-generation reproductive toxicity study (EOGRTS). Others wanted to maintain the present requirement of performing a two-generation study.

The OECD adopted the new test guideline 443 in June 2011. Discussion is ongoing, lead by the European Commission, with regard to how to use this test guideline for regulatory purposes, and in particular what role it will play under the REACH information requirements concerning reproductive toxicity.

Further information:
ECHA News Alert, 26 September 2011
http://echa.europa.eu/news/na/201109/na_11_45_MSC_en.asp

The Member State Committee webpage
http://echa.europa.eu/about/organisation/committees/memberstate_en.asp

RAC adopts seven scientific opinions on harmonised classification and labelling

The Committee for Risk Assessment (RAC) adopted opinions on seven proposals for harmonised classification and labelling across Europe during its 17th meeting, held from 13-16 September 2011 in Helsinki. Opinions were adopted on:

- Polyhexamethylene biguanide hydrochloride (PHMB)
- Di-n-hexyl phthalate (DnHP)
- Fenamiphos
- Trichloromethylstannane (MMTC)
- 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MMT (EHMA))
- Benzenamine, 2-chloro-6-nitro-3-phenoxy- (Aclonifen)
- Perestane

Further information:
ECHA News Alert, 20 September 2011
http://echa.europa.eu/news/na/201109/na_11_40_rac_seven_opinions_20110920_en.asp

Opinions on the ECHA website
http://echa.europa.eu/about/organisation/committees/rac/committee_opinions_en.asp

SEAC adopts three scientific opinions on lead, mercury and phenylmercuries

The Committee for Socio-economic Analysis (SEAC) adopted opinions on three restriction proposals during its 12th meeting, held from 13-15 September 2011 in Helsinki. The opinions are now available on the ECHA website.

Further information:
ECHA News Alert, 20 September 2011
http://echa.europa.eu/news/na/201109/na_11_39_seac_three_opinions_20110920_en.asp

Opinions on the ECHA website
http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp

Reaching the "Unreachable" at the European SME week summit

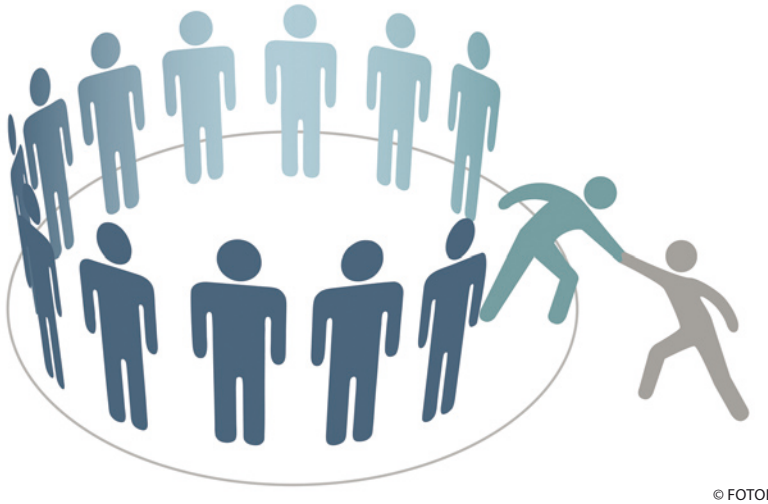
The European Chemicals Agency reached out to small and medium sized enterprises at the 2011 European SME Week Summit in Brussels at the beginning of October.

The SME week summit is organised by the European Commission in cooperation with 37 participating countries to promote local and European-level programmes designed to support small and medium sized enterprises (SMEs) and to reduce the amount of unnecessary financial and administrative burdens these companies are facing in many countries. At the event, ECHA hosted an information stand which promoted the REACH obligations relevant to SMEs, and the best sources of information and assistance such as the ECHA website and National REACH and CLP Helpdesks, which are supporting companies in local languages.

The majority of the SMEs affected by REACH that ECHA staff met during the day were either entirely unaware of the legislation or struggling to interpret it for their particular situation. Some of the visitors to the stand had already experienced the effects of REACH through their suppliers and were eager to learn more. Many also inquired about registration fees for SMEs and sounded relieved when they heard that registration fees for SMEs could be as low as 150 euros per substance. Visitors were also interested to hear about the self-declaration of a company's SME status and the importance of carrying it out accurately or potentially facing significant charges for submitting a dossier with their SME status declared incorrectly.

The event provided an excellent platform for networking and gave fresh ideas for collaboration between ECHA and the SME stakeholders. ECHA will continue supporting SMEs to help them comply with the chemicals legislations and to help create a friendlier business environment for small businesses.

TEXT BY ADAM ELWAN



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Event Calendar

Here you will find the next dates for REACH and CLP related meetings and conferences organised by ECHA and the Commission in 2011.

The next Stakeholders' Day will take place on 23 May 2012 in conjunction with the annual Helsinki Chemicals Forum (HCF). You can request further information about specific events by email at: echa-events@echa.europa.eu.

EVENTS
October-December 2011

- Meeting of the Competent Authorities for REACH and CLP (CARACAL): 26-28 October
- ECHA Accredited Stakeholders' Workshop, Brussels: 23 November
- QSAR Toolbox Workshop, Helsinki: 24 November
- ECHA-Stakeholder Exchange Network on Exposure Scenarios, Brussels: 24-25 November
- ECHA Management Board: 15-16 December

Tentative dates:

- ECHA Risk Communication Network: 25-26 October
- ECHA Committee for Risk Assessment (RAC): 25-28 October / 28 November – 2 December
- ECHA Member State Committee (MSC): 2-4 November / 7-9 December
- ECHA Committee for Socio-economic Analysis (SEAC): 13-15 December

WEBINARS - preliminary plan

- Substance identification and data-sharing: Winter 2011 - 2012
- Information requirements and chemical safety assessment: Spring 2012
- Dossier preparation, tools and submission: Autumn 2012 - Spring 2013

More information available soon on the ECHA website:
http://echa.europa.eu/news/webinars_en.asp

Paving the way for easier and more effective enforcement

In June, ECHA launched a new REACH Information Portal for Enforcement (RIPE). The web-based application provides inspectors with access to key information submitted by companies to ECHA. ECHA Newsletter sat down with Maciej Baranski, who is the product manager for RIPE and asked what RIPE is all about.

Could you tell our readers how the RIPE project got started?

The idea for RIPE came about in 2007, as a consequence of the development of REACH-IT. The Commission discussed with the Member States about how the Member State Competent Authorities will be able to access the data that the registration milestones create. As a result, they came up with REACH-IT. However, the access to REACH-IT was only given to the Competent Authorities; the enforcement authorities were therefore not included. In the first Forum meeting in December 2007, we started to examine what kind of information the enforcement authorities would need to do their job effectively, what kind of a tool they would need and what ECHA could do to support them.

We set up a Forum Working Group that collected the information needs of the enforcers and discussed the requirements and functionalities for an application. In parallel we have discussed these needs with our IT and data security specialists who gave ideas about the solution. On the basis of these discussions, the Forum secretariat prepared a general description of RIPE, which was approved by the ECHA Management Board in June 2009. The project started officially after the scope, plan and resources were approved by the Director's Programme Board in September 2009.

What were your objectives of the project?

We wanted to have something simple and easy to use, something that would fit the inspectors' needs. For information security reasons we could not use REACH-IT. We found out that there were 2 500 inspectors in 1 500 different locations, so we needed something lighter. With RIPE we could reduce the amount of data to help control the security risks.

What kind of challenges have you faced?

Firstly, there was a tight deadline from the start. We started in late 2009 and launched the application in June 2011. The idea in the beginning was that the tool would be ready soon after the first registration deadline of December 2010. This has soon proved to be too optimistic and early on in the project we moved the go live date to June 2011. Another challenge was the deployment of new technology. RIPE makes wide-scale use of the RSA security tokens. In the beginning we had limited in-house knowledge of that technology. It was challenging to learn about its intricacies and implement it at the same time.

What kind of feedback have you received so far, in the short lifespan of the tool?

So far the feedback has been positive. We've received feedback from the tool administrators and Member State representatives but have not yet had much feedback from the end users. The reason for that is that the release only took place three months ago and Member States need more time to make arrangements to appoint and organise trainings for the users. We plan to make a user survey in the early months of next year after the inspectors will already have had some time to use the application.

What are the next steps in the project?

We are now working on having the project wrapped up and completing the originally foreseen scope of the application and adding some new features that the users requested in the meantime. There are some reports and features to be added that we could not complete by June, such as a including the notifications of substances in articles, which ECHA started receiving only in June.

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We have already made good progress and are releasing intermediate versions as soon as a new feature is done and tested. For the next eight to nine months we will be working on finishing the scope of the application and refining what ever needs to be refined.

Why is RIPE important?

Without RIPE there is no effective enforcement. The inspectors would not be very effective in their work if they had to go to their Competent Authority each time they needed information on a substance. With the help of RIPE, the inspector who goes on inspection in a company can easily check whether the situation onsite corresponds to that which has been described in the submitted dossier. To put it plainly, they can see what has been registered, for what tonnage, and whether it is used in line with uses that were identified in the dossier.

RIPE is a big milestone for enforcement of REACH and CLP. The enforcement authorities now have their own tool to help them verify compliance. Enforcement will become more effective and easier, and therefore more thorough.

Highlights of the tenth plenary meeting of the Forum

During its meeting from 3 to 5 October, the Forum members agreed that the third enforcement project will once more be focused on registration obligations. Its scope will cover the verification of the registrations by Only Representatives and cooperation with customs authorities controlling the import of substances. The members also reviewed the results of the prolongation of the first Forum coordinated enforcement project on registration obligations for phase-in substances and on Safety Data Sheets from substance suppliers.

Further information:
ECHA Press release, 10 October 2011
http://echa.europa.eu/news/pr/201110/pr_11_23_forum_plenary_meeting_20111010_en.asp

Evaluation statistics

- Report on dossier evaluation according to Articles 40 and 41 REACH

Dossier evaluation covers compliance checks of registration dossiers and examinations of testing proposals. In examination of testing proposals, all dossiers containing proposals for higher-tier testing, including testing on animals, are evaluated. The aim is to check that tests are justified and adequate, and thereby avoid unnecessary animal testing. Testing proposals that involve tests on vertebrate animals are published on ECHA's website and third parties are invited to provide scientifically valid information.

The compliance check determines whether or not the information submitted is in compliance with the REACH information requirements. At least 5 % of the dossiers received by ECHA per tonnage band are checked for compliance. Details of the REACH dossier evaluation processes can be found at:

http://echa.europa.eu/doc/ECHADocuments/procedure_dossier_evaluation_20110329.pdf).

The results obtained so far can be found in the annual progress report on evaluation:

http://echa.europa.eu/doc/evaluation_under_reach_progress_report_2010.pdf.

Tables A to C report on the statistics of the dossier evaluation processes from 1 June 2008 to 30 September 2011. The phase-in status is reported as indicated by the registrant in the dossier and this may have changed when the dossier has been updated. The dossier updates may also have testing proposals withdrawn or new ones submitted.

Table A. Testing proposals: dossiers received and output processed between 1 June 2008 and 30 September 2011.

		Phase-in*	Non phase-in	Total
No of registered dossiers [1]	containing testing proposals	525	42	567
	containing testing proposals for vertebrate animals	397	28	425
No of endpoints	covered by registered testing proposals	1 073	98	1 171
	covered by registered testing proposals for vertebrate animals	660	49	709
No of third party consultations	closed	271	26	297
	ongoing on 30 September 2011	71	1	72
	planned	55	1	56
Dossiers with testing proposals opened for examination[2]		382	44**	426
Draft Decision sent to the registrant [3]		29	12	41
Final Decision sent to the registrant		5	16	21
Terminated testing proposal examinations [4]		15	10	25

* Phase-in:
substances subject to transitional arangements in the REACH registration

** Same registration dossier was opened for examination more than once, hence the difference with regard to the number of registered dossiers.

[1] Successfully registered (accepted and fee paid).
[2] Dossiers ever opened for examination notwithstanding their current status.
[3] Draft decisions which did not become final by 30 September 2011 nor withdrawn due to termination of TPE.
[4] Terminated either at the decision-making stage and/or upon further information provided by the registrant (e.g. cease of manufacture, tonnage downgrade or withdrawal of a testing proposal).

Table B. Compliance check: dossiers and output processed between 1 June 2008 and 30 September 2011.

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check[1]	152	139	291
Draft Decision sent to the registrant[2]	52	21	73
Final Decision sent to the registrant	48	29	77
Only Quality Observation Letter sent to the registrant [3]	13	46	59
Terminated compliance checks[4]	7	37	44

[1] Dossiers ever opened for compliance check notwithstanding their current status.
[2] Draft decisions which did not become final by 30 September 2011.
[3] Some additional quality observation letters have been sent together with draft decisions, but are not counted here.
[4] Terminated upon further information being provided by the registrant or terminated without administrative action.

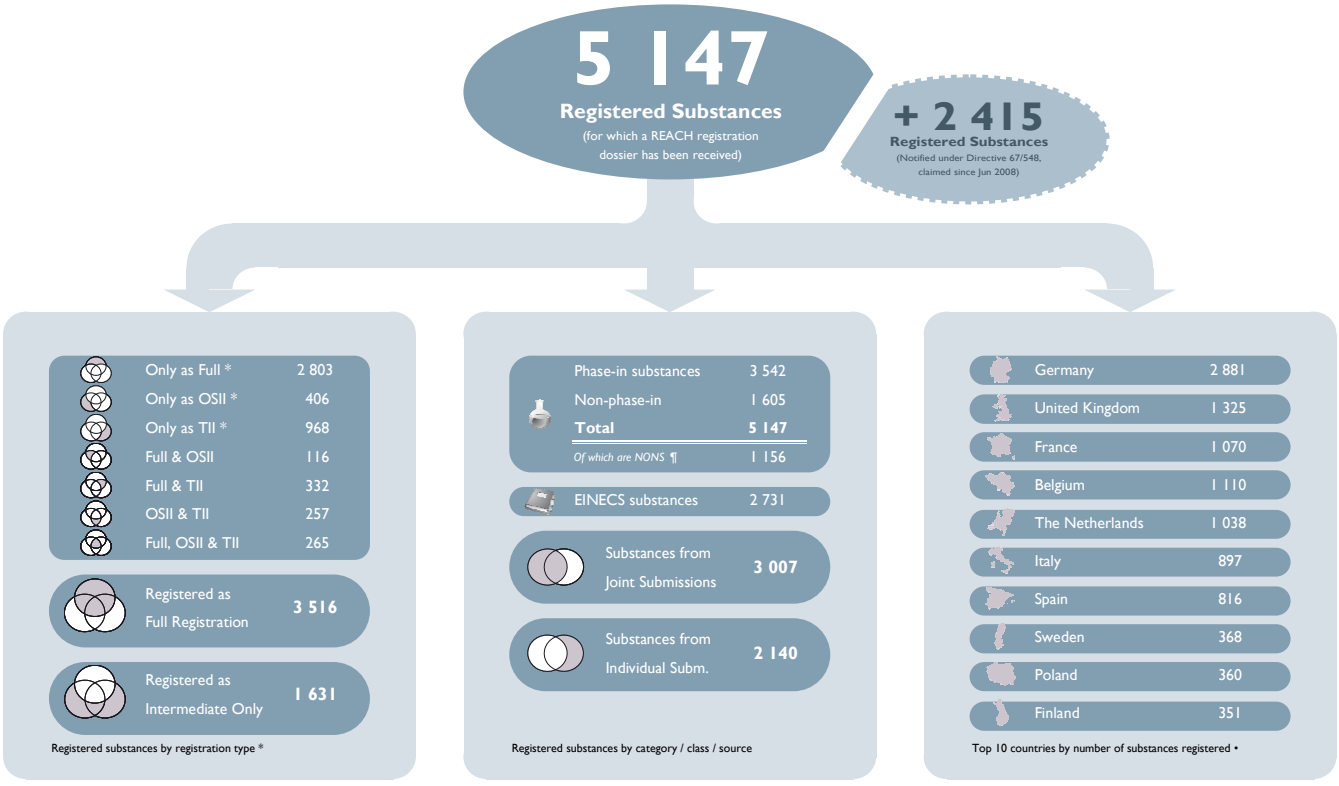
Table C. Status of compliance checks on registration dossiers motivated by the 2010 deadline [1]

	Phase-in
No of registration dossiers [2]	18 403
5% target for the compliance checks on registration dossiers motivated by the 2010 deadline [3]	920
No of dossiers opened for compliance check [4]	124
Draft Decision sent to the registrant [5]	44
Final Decision sent to the registrant	45
Only Quality Observation Letter sent to the registrant [6]	6
Terminated compliance checks [7]	3

[1] Dossiers for normal registrations and transported isolated intermediates which comply with the criteria for the first REACH dossier submission deadline for phase-in substances (1 December 2010). Submissions containing more then one type of registration in one submission (combined submissions containing e.g. both a normal registration and a registration as transported intermediate) are accounted for only once and only if one of the registration types within such a submission satisfies the criteria of the 2010 registration deadline.
[2] All submissions registered by 1 December 2010 including those which were handled with a delay.
[3] This is the target for the 18 403 registration dossiers motivated by the 2010 deadline. According to Article 41(5) of the REACH Regulation ECHA shall select for compliance check at least 5 % of the registration dossiers received by the Agency for each tonnage band.
[4] Dossiers which meet the 2010 registration deadline criteria and that have been ever opened for compliance check notwithstanding their current status.
[5] Draft decisions which did not become final by 30 September 2011.
[6] Some additional quality observation letters have been sent together with draft decisions, but are not counted here.
[7] Terminated upon further information being provided by the registrant or terminated without administrative action.

Registered Substances[§] - Overview

ECHA Website > ECHA CHEM > Registered Substances



§ All numbers for 'Substances' are determined automatically using unique substance identifiers (EC Number / List Number). As substance identities are verified the numbers reported for substances may change.
* 'Full' indicates a registration under REACH Article 10 as a full dossier; 'OSII' under REACH Article 17 as an on-site isolated intermediate; 'TII' under REACH Article 18 as a transported isolated intermediate.
¶ Substances previously notified under Directive 67/548/EEC ('NONS' substances) which have been claimed and updated with a REACH registration dossier; these are counted with the 5147 REACH registrations
• Numbers indicated in this table are the number of substances registered in a country (by at least one legal entity) from the total figure of 5147 substances for which REACH registrations have been received.

Data as of 12 Oct 2011