ECHA
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Newsletter

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REACHing 2013

Greetings from a snowy and cold Helsinki! At the beginning of February we welcomed around 100 participants to our first lead registrant workshop here in Helsinki.

Our guests were a mixture of experienced and new lead registrants from all over Europe, coming together to share experiences and prepare for the 2013 deadline. The event was organised together with a number of our Accredited Stakeholder Organisations who represent industry and their input was invaluable in helping to make the event useful and full of practical case studies from the side of industry. You can read about the workshop on page 3 and interviews with a couple of lead registrants on page 4. There is also a link to the presentations and the video recording of the workshop sessions.

In this edition of the newsletter, we are talking about the registrants' obligation for a joint submission, highlighting the importance of communication in the supply chain and advising registrants to start gathering information on the uses of their chemicals with a top-down approach. We also tell about Chesar, which is a software tool to support you with your safety assessments, and introduce REACH implementation in Slovenia, enforcement in Italy and the Danish EU presidency - from the chemicals policy point of view.

We have also included an interview with Mr Guido Sacconi, former Italian MEP and the Parliament's lead Rapporteur on the REACH proposal, who has recently stepped down from ECHA's Management Board.

I hope that our new website has been a hit with you. It was redesigned according to your feedback and since the launch in mid-December we have had over 420 000 visits to the site. It is our main communication channel, and we aim to keep it relevant and clear, both content and structure wise. As you can imagine, with such a massive project is it impossible to get everything right first time, and I've been grateful for your feedback which is helping us to make small adjustments here and there to improve the site further. Please don't hesitate to get in touch if you have ideas to improve it.

The ECHA Newsletter is here for you. Let us know what topics you would like to see covered in the coming issues, what has been good, and what should be improved. Please contact us at echanewsletter@echa.europa.eu.

Lindsay Jackson
Head of Communications

"The ECHA Newsletter is here for you. Let us know what topics you would like to see covered in the coming issues, what has been good, and what should be improved."

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Editor-in-chief: Lindsay Jackson
Editor: Hanna-Kaisa Torkkeli

European Chemicals Agency
Annankatu 18, P.O. Box 400,
FI-00121 Helsinki Finland
Tel. +358 9 6861 80
Fax +358 9 6861 8210

http://echa.europa.eu
echanewsletter@echa.europa.eu

Lead registrants network and share experiences about successfully leading a SIEF

TEXT BY ADAM ELWAN

The Lead Registrant Workshop, which took place in Helsinki from 2 to 3 February 2012, welcomed around 100 participants representing both experienced and new lead registrants. In addition, around 800 people were following the workshop online. Available tools and lessons learnt from the 2010 registration deadline were among the issues discussed during the workshop.

ECHA invited companies that have notified themselves as lead registrants for the 2013 registration deadline to a specific workshop to learn more about the necessary steps to be taken to lead a successful SIEF and to share experiences with other lead registrants about sharing and assessing data for the preparation of joint submission dossiers. The workshop was part of a series of information sessions directed exclusively to lead registrants as part of the "REACH 2013 – Act Now!" campaign.

The workshop provided participants with an overview of support available for lead registrants including tools, checklists and case studies. A special focus was also given to challenges faced by small and medium enterprise (SME) lead registrants during a presentation given by ECHA, which gave an overview of advantages for SMEs and available guidance and support.

Participants also had the opportunity to discuss one-to-one with ECHA staff about topical issues. The participants appreciated the ample time reserved for networking and one-to-one discussions with the Agency staff as well as with experienced lead registrants. The two-day workshop concluded with training on IT-tools used for preparing and submitting registration dossiers.

Workshop participants.

Sophie Bornstein from Concawe (oil companies' European association) gave a presentation on updating dossiers due to new information, within the SIEF process.

WHAT NEXT?

ECHA has gathered feedback both from lead registrants that participated in the event as well as a smaller scale collection of feedback from those that were not able to attend to evaluate the need to organise a second workshop for lead registrants in the autumn of 2012. The next large-scale external event organised by the Agency will be the seventh Stakeholders' Day, scheduled to take place on 23 May 2012. The conference expects to welcome hundreds of participants and will be organised in conjunction with the Helsinki Chemicals Forum.

Follow the ECHA e-News to stay up-to-date with the latest information about upcoming events. The presentations and a video recording of the workshop are available on ECHA's website at: http://echa.europa.eu/view-article/-/journal_content/b5961cb7-ee61-4c40-9a14-9068f23f28f9

Lead registrants share their views

INTERVIEWS BY HANNA-KAISA TORKKELI

During the Lead Registrant Workshop, ECHA Newsletter interviewed two representatives of companies that act as lead registrants for the 2013 deadline. These companies have different experience with the REACH Regulation as well as a different operational environment to run their business. What are their thoughts on REACH, expectations for ECHA and how are they going about their preparations for 2013?

Jan Schüller, Director of REACH and Regulatory Affairs at Eastman, is a regular visitor to ECHA events. He represents a big chemical manufacturing company, which already has a lot of experience with REACH and of acting as lead registrant. Eastman is a manufacturer of chemicals, fibres and plastics that are used in consumer products.

In 2010, Eastman submitted around 50 registrations, covering some 45 substances. The company was appointed lead registrant for 18 registrations, which were managed either through consortia or by the company itself through Substance Information Exchange Fora (SIEFs). The same pace will continue for the 2013 deadline. "In 2013 we will submit just below 40 registrations, and will be lead registrant for half of the cases. This reflects the character of our speciality chemicals portfolio: we have a leadership, second or third market position for most of our products", says Mr Schüller. The last deadline went smoothly for Eastman, and the company prefers to take the role of lead registrant. "When we were co-registrants and dependent on others, we sometimes had to go knocking on the door and ask for information. We would prefer not to be dependent on others preparing the dossier for us whilst keeping us in the dark about the progress of the submission", Mr Schüller explains.

SMALLER SIEFS, LESS DATA

As for the next deadline, Mr Schüller expects to see much smaller SIEFs. "I don't see a big role for consortia or a growth for SIEF leadership teams. What I do anticipate is that the substances will be less data rich. This poses a challenge because for most substances there is not such a big difference in data requirements for Annex 9 (concerns quantities of 100 tonnes or more) and Annex 10 (concerns quantities of 1000 tonnes or more). In my opinion, this means that we will have more data gaps and fewer experienced people to justify waiving statements or the use of read-across and other non-test methods."

Mr Schüller thinks that the main message to old and new lead registrants is the same as in 2010: start early and make sure you have a solid plan on how to move forward. "Active communication to the members is crucial. At Eastman, we do that via REACH platforms, but also through our website.

Jan Schüller.

We give a lot of information to our co-registrants as well as our customers on the status of the different dossiers that we are working on. It's really all about diligent project management," he says.

DEALING WITH BACKLOG

REACH has now been operational for almost four years and there is more and more information available about the impacts of the regulation. Mr Schüller sees REACH fundamentally as a good approach, but also as an obligation of the industry, which should have been fulfilled a long time ago. "It is right that companies are responsible for managing the safe use of their products. I'd rather let the companies do that than the governmental organisations.

But basically, what we have in our hands is an enormous backlog. We are trying to catch up on what we should have done in the past", he explains. Mr Schüller sees some opportunities for innovation in replacing substances on the authorisation list. "But I think those same substances would have been under suspicion also without REACH. I struggle to see how REACH really helps innovation and the competitiveness of European industry", he adds.

Mr Schüller appreciates ECHA's initiatives for organising meetings such as the Lead Registrant workshop. "These events are perfect opportunities for companies to interact and develop more informal contacts with ECHA staff." From ECHA, he would like to see clarity on how to make best use of non-test methods: "A lot of companies have used read-across or the category approach to fill in their data requirements. It would be helpful to know how to bring the reality of industry in line with the expectations that ECHA has for information produced with non-test methods. Using these methods is one of the aims of REACH but in reality, I feel that ECHA often takes a more conservative approach", he concludes.

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The presentations and a video recording of the workshop are available on ECHA's website at: http://echa.europa.eu/view-article/-/journal_content/b5961cb7-ee61-4c40-9a14-9068f23f28f9

Benjamin Noel.

Benjamin Noel, REACH coordinator at Stéarinerie Dubois – a French fatty ester manufacturing company – has been working with REACH for many years. His company is registering for the first time in 2013 and is a lead registrant for several substances. Stéarinerie Dubois falls under the SME status and benefits from the advantages for SMEs under REACH.

To manage the registration process, Stéarinerie Dubois became a member of a consortium already years ago. "As an SME we cannot do everything by ourselves. The consortium is managed by a consultant; decisions are taken jointly with all the members during our annual meeting", Mr Noel says.

According to Mr Noel, SMEs face a lot of challenges with resources and the fact that they have to multi-task. "We can participate in the consortium discussions, follow the SIEF communication and work on our dossiers in IUCLID on the same day. We also have to deal with cost-sharing, data evaluation and with the cost of the studies. We have kept track of the changing guidelines and meet with the national authorities to know what is going on at the national level. We constantly take stock of all the substances in our portfolio and see how things evolve", he says.

Mr Noel says that it is not always easy to understand what ECHA can and cannot do. Coming to the workshop brought clarity on ECHA's role. "Being here at the workshop helps us to see how ECHA works. You can talk with ECHA staff and get answers from the one-to-one sessions. I now better understand the goals of ECHA and how the work is managed", Mr Noel explains.

From ECHA, Mr Noel expects clear and stabilised guidance, which would illustrate a step-by-step approach for preparing a registration. "I personally would appreciate having a full overview of the obligations for different players for 2013 in the form of guidance. Something concise that would explain all the different steps in the process depending on your role, whether you are a lead registrant or a member in a joint submission", he concludes.

REACH 2013, Act Now!

Get organised for joint submission and decide on the chemical safety report

TEXT BY JAVIER SANCHEZ-SAEZ

Joint submission of data is an obligation under REACH, where companies are required to communicate with each other and share available data. Additionally, they need to decide whether the chemical safety report will be submitted jointly or separately to ECHA.

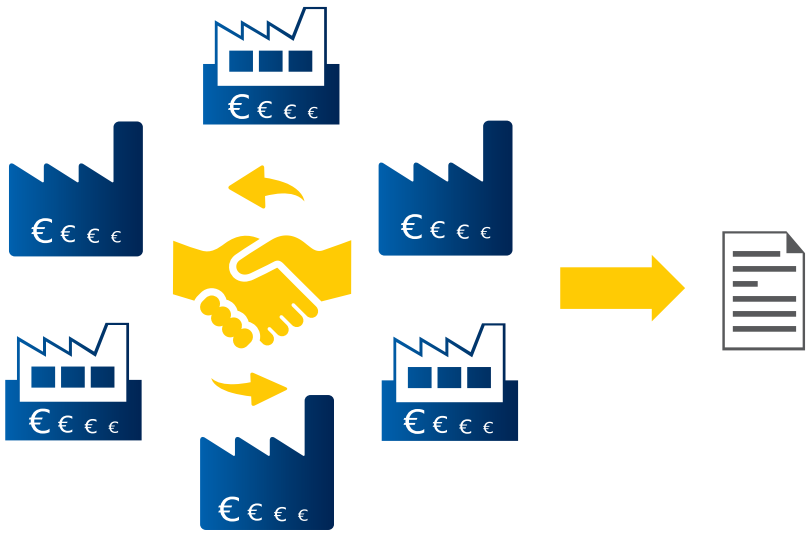
Registration under REACH is based on the principle of "*one substance, one registration*". This means that when a substance is manufactured or imported by other companies, the companies are all required to submit certain information together in a joint submission. As highlighted in the December 2011 newsletter (page 6), companies firstly need to share information about this substance in a Substance Information Exchange Forum (SIEF). All participants in the SIEF then need to agree on who will act as lead registrant and take the responsibility for building the joint registration dossier. Once the lead registrant has successfully submitted the joint dossier to ECHA, the rest of the members of the joint submission will need to submit their member dossiers. These member dossiers contain only company and substance specific information, such as composition, tonnage and uses. Joint submission is not only a legal obligation, but it brings benefits to registrants by facilitating the registration process and reducing overall costs. The registration fee applicable in the case of joint submission is also lower than for individual submissions.

JOINT OR SEPARATE CHEMICAL SAFETY REPORT?

The chemical safety report (CSR) should be a key element of the early discussions between registrants. It is important to understand that REACH allows flexibility in the nature of the submission of CSRs to ECHA, i.e. jointly or separately. This is a decision that has to be carefully considered by each registrant, agreed within the SIEF and appropriately indicated in IUCLID when creating the dossier.

The benefits of one CSR per substance are clear: users would receive harmonised and consistent exposure scenarios from all manufacturers and importers of the substance. The CSR could address environmental exposure and potential risks in a scientifically sound way, based on the total manufacture and market volume. Authorities and registrants could also rationalise their efforts when it comes to the evaluation of the dossier. On the other hand, it may be challenging to organise communication among registrants to ensure that all the information is exchanged with the lead registrant. Registrants may also find it difficult to maintain the mechanisms needed to update the joint CSR after the first submission of the registration dossier.

Therefore, whilst having strong benefits, it is also important to be aware of the commitment required for producing a CSR.
(*Continues on the next page...*)



Joint submission of data is an obligation under REACH. The aim is to facilitate the registration process and to reduce overall costs for industry.

The submission system has been designed to be flexible enough to allow different approaches. Even in cases where the lead registrant provides a joint CSR, the other registrants can decide whether they wish to rely on it or whether they would prefer to provide their own. Furthermore, members can decide to rely only on certain parts of the joint CSR and provide the rest in their own dossiers.

Further information on joint submission and how to submit the CSR can be found on the ECHA website. In particular, we recommend the REACH 2013 dedicated web page:
http://echa.europa.eu/reach-2013

Support page on joint submission:
http://echa.europa.eu/support/dossier-submission-tools/reach-it/joint-submission

Data Submission Manual 19: How to submit a CSR as part of a joint submission:
http://echa.europa.eu/documents/10162/17248/dsm_19_how_joint_csr_en.pdf

ECHA Newsletter December 2011
http://echa.europa.eu/documents/10162/17911/echa_newsletter_2011_06_en.pdf

Communication in the supply chain

Making uses known to registrants well in advance of the registration deadline

TEXT BY LAURA WALIN

Efficient communication on uses and conditions of (safe) use in the supply chain needs complementary actions by both manufacturers/importers and downstream users. Some lessons have been learnt during the previous registration deadline, and a top-down approach is recommended by both manufacturers' and downstream users' associations.

"Manufacturers and importers are now gathering information on uses they intend to cover in their registrations and should be able fairly soon to inform their customers", explains *Mercedes Viñas Viñas* from the European Chemical Industry Council (Cefic). "In principle, if a use has been covered in a previous SDS that the downstream user has received or is covered in the use-mapping done by their trade association, it will most likely be taken into account by the registrant."

Top-down communication has proven to be the best approach for gathering information on uses of chemicals and conditions of safe use in the supply chain.

Laura Portugal from the Downstream Users of Chemicals Coordination Group (DUCC) agrees that starting with a top-down communication is the best approach. She reminds, however, that if downstream users have not heard anything from their supplier or they cannot find their use in other sources of information provided by their supplier, they can make use of their right to make their use known according to Article 37(2) and (3) of REACH. "Also in this case a structured approach should be remembered and trade associations' mapping used as reference", she emphasises. "The communication should be supplier and substance specific and standard forms developed by industry associations should be used."

The use should be explained in terms of the use descriptors system, and a brief description of the operational conditions and risk management measures for the use should be included. The registrant can then make the subsequent chemical safety assessment in a realistic way. This, in turn, enables the registrant to record the results of the chemical safety assessment into meaningful exposure scenarios that are practically relevant for the downstream users.

Further information on ECHA's website:
http://echa.europa.eu/regulations/reach/downstream-users
REACH 2013 campaign page:
http://echa.europa.eu/reach-2013

Chesar tool - in support of your safety assessments

TEXT BY LIVIA BRIESE

The Chesar software tool helps registrants to carry out the exposure and risk related parts of their Chemical Safety Assessments (CSA) to generate their Chemical Safety Report (CSRs) and to extract the exposure scenarios for communication in the supply chain.

Chesar has been developed by the European Chemical Agency (ECHA) and is available as a free plug in to IUCLID 5 on the Agency's website.

WHAT DOES THE TOOL OFFER?

Chesar supports the harmonisation of formats among industry and enables registrants to generate consistent and transparent CSRs and exposure scenarios (ESs). The tool also facilitates the re-use of all or part of assessments already carried out by the registrant or prepared by industry associations, thanks to data exchange functionalities.

In order to fully benefit from Chesar's capacity to re-use assessment elements (for various substances), downstream user sector organisations can provide information on uses within their sectors and the associated conditions of use. With Chesar, such information can be generated in XML exchange format(s) and made available to all registrants in support of their CSR preparations.

CHESAR 2 IN SUPPORT OF 2013 REGISTRATIONS

ECHA has collected feedback on Chesar 1 and has considered the past experience of registrants in the further development of the tool. Chesar 2 is planned to become available by summer 2012.
The tool will be much easier to install as it will be a stand-alone software and no longer a IUCLID plug-in. It will better support the workflow for the refinement of initial assessments (iterations).

An improved user interface will make overall navigation easier. Increased efficiency of the assessment process will be achieved through the improved re-use of assessment elements across substances, for example better support of Specific Environmental Release Categories (SpERCs) or Generic Exposure Scenarios (GES) and more extensive copy and paste functions. In addition, a reduction of manual assessment work by the stepwise inclusion of more links to existing exposure estimation tools is foreseen.
Another area of improvement is the transparent scoping of the required exposure assessment and risk characterisation based on the information imported from the IUCLID dossier of the substance to be assessed.

It is planned that the relevant output information from Chesar 2 will be exported in an XML format that can be converted in the ESComXML, which is a standard format under development by industry. This allows downstream users to further process their exposure scenarios e.g. for comparison with their own practice (including scaling), for the processing of exposure scenarios into exposure scenario information for mixtures and finally, for translation purposes. Chesar 2 better supports the use of standard phrases for communication of exposure scenarios and the link to ESCom, industries' phrase catalogue for exposure scenario communication.
(Continues on the next page...)

WHAT IS CHEMICAL SAFETY ASSESSMENT?

The Chemical Safety Assessment (CSA) is an a methodology to

- assess the intrinsic hazards of substances;
- build exposure scenarios (ES) describing the conditions of manufacture and use, which are needed for controlling the risks to human health and the environment. This includes the operational conditions (OC) and risk management measures (RMM);
- estimate the exposure for humans, the emission to the environment and the corresponding environmental exposure resulting from the conditions described in the exposure scenarios;
- characterise the risks by comparing the expected exposure levels with the results of the hazard assessment .

The outcome of the CSA, including relevant data, justifications and judgments has to be documented in a Chemical Safety Report (CSR). In addition, the exposure scenarios are to be communicated to the downstream users as an attachment to the safety data sheet of the substance.

ECHA is engaged to provide support to downstream users. The Agency will therefore continue to develop a common approach with industry to improve the overall process and the quality of exposure scenarios. Further developing and maintaining Chesar and IUCLID as IT tools are an essential aspect of this strategy.

More information on the Chesar website: http://chesar.echa.europa.eu

ADVANTAGES OF USING CHESAR

- Efficient assessment and communication
- Workflow support to focus on the important information needs
- Re-use CSA elements
- Use of information on substance property already reported in IUCLID (ensuring consistency)
- Transparency and harmonised structure
- Systematic and consistent reporting following the CSR format
- Missing or inconsistent information can be spotted more easily
- Exposure scenario for communication is generated in a standard structure
- Information stored in a database facilitates the update of CSR and ES for SDS

Chemical Safety Assessment for REACH 2013 registration deadline

On 17 June, during the EUROTOX 2012 Congress in Stockholm, ECHA is organising a training course for regulators and industrial toxicologists who deal with the REACH Regulation, as well as providing a background on REACH for academia and scientists.

The focus is on distilling ECHA's experience obtained from dealing with registration dossiers submitted in 2010, and how to apply that to the 2013 registration deadline. Registration is subject to a fee for participation in the EUROTOX 2012 congress.

More information:
http://eurotox2012.org/?id=40

Helsinki Chemicals Forum offers an international platform for debate on chemical safety and global chemicals policy

The fourth global chemical industry congress, Helsinki Chemicals Forum, engages international authorities, politicians, industry leaders, NGOs, academics and the media in an open dialogue on key issues of global relevance regarding chemicals policy and the control of chemical safety. The Forum will be organized in Helsinki from 24-25 May.

The congress is well on its way to developing into the industry's key international forum. "The forum aims to make Helsinki known as the 'European chemicals capital' and to strengthen the chemicals cluster in Finland", explains *Hannu Vornamo*, Secretary General of the Helsinki Chemicals Forum.

The Helsinki Chemicals Forum is organised by the Chemicals Forum Association, in cooperation with the European Chemicals Agency (ECHA), the European Commission, the Finnish Ministry of the Environment and the Ministry for Foreign Affairs, CEFIC, the City of Helsinki, the University of Helsinki, and the Chemical Industry Federation of Finland.

More information and programme:
www.helsinkicf.eu

REACH implementation in Slovenia

Breaking barriers through cooperation

INTERVIEW BY PIA FALLSTRÖM-MUJKIC

While implementing the REACH Regulation, Slovenian authorities realised that they did not have enough competence to tackle all the requirements that REACH had placed on them. A solution to this issue was the development of a unique cooperation between Slovenia and Germany. Through this connection, Slovenia nominated a German expert as its representative in the ECHA Committee for Risk Assessment. ECHA Newsletter interviewed the Director of the Chemical Office of the Republic of Slovenia, *Alojz Grabner* to learn more about the cooperation and the implementation of REACH in Slovenia.

How has the Slovenian industry adjusted to the REACH Regulation?

The big chemical companies were already involved at the time of the old legislation and well aware of their responsibilities. They were, therefore, proactive and submitted some registrations for the first REACH deadline. They also started to cooperate with associations, for instance with the European Chemical Industry Council, CEFIC. Many companies in the chemicals sector are, however, small and medium-sized companies or even micro companies. It remains to be seen how they will manage the upcoming deadlines. Another challenge is to raise awareness among e.g. the downstream users who do not necessarily realise their obligations or consequences in this respect.

What did you learn from the REACH implementation?

This is a big project for us all. Before, we did not work as intensively as we need to work now. We needed to change our approach. We succeeded in involving partners but we had to look for outside expertise. We would have needed better planning and better strategies. ECHA has done a very good job and has understood our problems and been willing to help. The current economic crisis will present some new challenges though.

Could you tell our readers about the cooperation you've had with Germany?

It started as an informal initiative, but became very useful for both sides. We were able to combine the German expertise with Slovenian flexibility. The German expert from the German Federal Institute for Risk Assessment (BfR) representing Slovenia in the Committee for Risk Assessment was doing so well that the duration of term was extended. The decision and the cooperation itself were very pragmatic. We even jointly submitted an Annex XV dossier for the identification of a substance of very high concern (SVHC). We did not feel confident enough to nominate Slovenian experts to various ECHA boards and expert groups from the start, but we will probably nominate some national experts this year.

Alojz Grabner.

Having adjusted to REACH, what lessons do you think future new EU member countries in a similar situation could learn from your experiences?

They should try to get a good overview of who is responsible, what is required to be done and how. They should ensure good planning, study the obligations and establish scenarios on how to tackle those obligations. Without trying to impose anything on anyone, the way we cooperated with Germany could be used fully or partly as a model. We've learnt some good things and already work in Serbia on one project with Austria, Germany and Hungary. Naturally, if requested, we would be glad to share our expertise.

SLOVENIA IN A NUTSHELL

- Independent since 1991
- Member of the European Union in 2004
- First transition country that became a donor instead of borrower at the World Bank
- First new EU member to adopt euro

MAIN PRODUCTS FROM SLOVENIAN CHEMICALS INDUSTRY

- Basic chemicals
- Pesticides, other agrochemicals
- Coatings, paints and varnishes
- Printing ink
- Pharmaceuticals
- Soaps and detergents
- Perfumes and toiletries
- Man-made fibres
- Rubber and plastic products
- Tires and air-tubes for vehicles

Sources: European Commission, Invest Slovenia, Statistical Office of the Republic of Slovenia

ECHA Stakeholders have many important roles

TEXT BY MIRA BANERJEE-RANTALA, SIMON TERWAGNE

Contributing to scientific discussions, participating in technical consultations and carrying out joint communication initiatives are examples of the many ways ECHA works together with its Accredited Stakeholder Organisations. A new strategy paper has been published to give a framework for this cooperation.

Cooperation with the Accredited Stakeholder Organisations has gradually increased during the years. Stakeholders are not only invited to contribute with their scientific and technical expertise, but also to help ECHA in reaching out to the field through their networks.

"Cooperation through events, workshops and the Committee work is important for having a good dialogue between the Agency and the field. With this strategy in place, ECHA's commitment to working together with the stakeholders is more clear", says *Christian Schaible* from European Environmental Bureau (EEB), which is one of ECHA's Accredited Stakeholder Organisations.

BENEFIT FOR BOTH PARTIES

The overriding principle for working together with the stakeholders is to join forces on activities where mutual benefit can be reached. This is an approach also appreciated by the stakeholders.

"We share a joint interest to achieve the objectives of REACH and CLP, and to promote chemical safety. It is very important that we work together", says *Sylvie Lemoine* from International Association for Soaps, Detergents and Maintenance Products (A.I.S.E), another Accredited Stakeholder Organisation.

TRANSPARENCY AND INDEPENDENCE IMPROVING

Both A.I.S.E and EEB noted that ECHA's corporate values are reflected in its relations with the stakeholders, and that the cooperation is developing towards a positive direction.

"We consider transparency and independence as very important values. Failing to respect them can be an obstacle to efficient policy making. These values as well as trustworthiness are built over time", says Ms Lemoine.

"We can see signals that ECHA has learnt from past mistakes and that they aim to improve on transparency and independence", Mr Schaible comments. He also points out that ECHA has an important task in keeping REACH's objective to ensure a high level of protection of human health and the environment in focus, and in this way demonstrating ECHA's commitment to well-being.

Accredited Stakeholder Organisations are umbrella organisations from different fields and sectors, all working at EU level and representative of their area of competence. They also have a legitimate interest in the work of ECHA and are thereby a natural link between the Agency and the relevant field.

ECHA has revised its External Communications Strategy

The strategy, among other things, highlights the objectives for ECHA's global communication, which support the successful delivery of the Agency's four key services. The updated strategy was endorsed by the Management Board in December.

Read more on the External Communications Strategy of the European Chemicals Agency:
http://echa.europa.eu/documents/10162/17208/mb_66_2011_external_communications_strategy_en.pdf

eu2012.dk

Danish EU presidency working towards a green economy

INTERVIEW BY TIIU BRÄUTIGAM

Denmark took over the EU presidency on 1 January 2012. Promoting green and sustainable growth is among the Danish key priorities and closely linked to chemicals policies. To achieve better regulation of chemicals, specific areas of concern will be addressed, such as nanomaterials, combination effects of chemicals and endocrine disruptors.

Mr Henrik Søren Larsen, Director for Chemicals at the Danish Environment Protection Agency emphasises that REACH - when fully implemented - has already improved the EU chemicals policy: "I would highlight the industry's obligation to provide standard information on the intrinsic properties of substances and the public availability of this data. Other important developments are the duty to communicate throughout the supply chain as well as the obligation to document and implement safe manufacture and use, based on a systematic assessment of risks."

Despite the progress, the Danish authorities point out that there are still areas of special concern that are not fully covered by the existing regulation: in particular issues related to endocrine disruptors, combination effects of chemicals and nanomaterials. "Industry could act proactively on these issues and show that they take responsibility for the substances they manufacture and place on the market", Mr Søren Larsen says. "For example in the registration dossiers, very little information is available on nanomaterials. Nothing prevents companies to address the specific properties of nanoforms of their substances. The industry has a huge interest in preserving their investment. The best way to do so is to show that they take chemicals safety seriously - also for nanoforms. By taking up such responsibility, the industry could prevent that different national regulations will be put in place in the Member States until EU-wide legislation is agreed."

© DANISH MINISTRY OF THE ENVIRONMENT

Henrik Søren Larsen highlights industry's obligation to provide standard information on the properties of chemical substances, and encourages ECHA to accept scientific progress, and work proactively for the use of new test methods.

PROACTIVITY NEEDED FROM INDUSTRY AND AUTHORITIES

Mr Søren Larsen continues that companies should also take the initiative on endocrine disrupters and combination effects on chemicals: "On endocrine disrupters, industry could voluntarily propose testing using the extended one-generation reproductive toxicity study (EOGRTS) and also address neurotoxicity and immunotoxicity. Regarding combination effects, the industry could ensure that their exposure scenarios show safe use even when assuming that other substances will contribute to toxicity. That could happen, for example, by showing that the risk quotient in the risk assessment of that use is significantly lower than one."

"Also ECHA should always accept the scientific progress and proactively work for use of new test methods such as the EOGRTS. These address whether substances have endocrine disrupting properties and at the same time save a huge number of laboratory animals. As regards nanomaterials, ECHA should continue to pursue information - or lack of information - in registration dossiers and investigate the need for substance evaluation. Concerning combination effects, I encourage ECHA to revise its guidance promoting the use of a risk quotient smaller than one to be able to show safe use even if other substances and uses contribute to the total risk. ECHA could also identify groups of substances that should be assessed together in e.g. substance evaluation. This would be based on the assumption that the total risk of these substances should be assessed by dose addition of the individual substances belonging to that group", he adds.

INITIATIVES FOR 2012

For 2012, Denmark has provided additional funding for establishing an inventory on nanomaterials and to investigate consumer exposure and environmental effects of nanomaterials. Another initiative is to map out the potential need for further regulation and information of 40 substances and groups of substances on the Danish List of Undesirable Substances. "We expect that the outcome of such a project will result in proposals for restrictions, substances of very high concern, harmonised classification and labelling or substance evaluation for some of these substances", Mr Søren Larsen clarifies.

BETTER REGULATION OF CHEMICALS

Innovation and development of new products are necessary for growth in the future, but this also entails health risks, in particular in connection with developing chemicals and technologies whose impact on health are as yet unknown. Therefore, the EU environmental policy should be continually tightened so as to provide maximum protection to humans, animals and nature against harmful drugs and chemicals. In the future, there will be a particular need to focus attention on regulating combinations of chemicals that affect human health. The EU must be able to act quickly and translate new knowledge into specific prevention and common policies as soon as harmful effects on human health can be documented. (*From the Programme of the Danish presidency*)

Both projects run over four years. "We also have a project where we look at whether the 22 potential endocrine disrupters on the Danish SIN list and four other substances meet the criteria that Denmark has proposed for identifying endocrine disrupting chemicals. If they meet the criteria, we will consider to propose them as substances of very high concern to be included under Article 57(f) of REACH."

To further explore ideas on sustainable chemicals during the Danish presidency, a conference is planned by the European Environment Agency in the spring of 2012.

More information about the Danish EU presidency:
http://eu2012.dk

Communication on the safe use of chemicals

The European Chemicals Agency has submitted to the European Commission its study on communication of information on the safe use of chemicals to the general public.

The study provides insights on how to further improve hazard communication to EU citizens. Changes to the CLP labels themselves are not recommended as it is more beneficial to allow the public to get used to the new system – now in use globally - steadily improving their overall understanding of the hazards posed by chemicals and encouraging a safer use of household chemicals in particular.

The European Commission will, on the basis of the study, submit a report to the European Parliament and the European Council in order to present, if justified, a legislative proposal to amend the Regulation.

Further information on the ECHA Press release of 23 January:
http://echa.europa.eu/view-article/-/journal_content/37a61697-8fbe-4766-baa6-22fdad2ba1f6

Study on Communication on the safe use of chemicals to the General Public, submitted to the European Commission on 20 January 2012:
http://echa.europa.eu/documents/10162/17203/clp_study_en.pdf

Industry experience with the QSAR Toolbox

Nearly 30 QSAR Toolbox industry users participated at the first QSAR Toolbox workshop held at ECHA on 24 November 2011. ECHA Newsletter asked four industry users who attended the workshop to share their experiences and express their needs for further development of the tool. They all agreed on the wide application of the Toolbox and its increasing importance for the next registration deadlines.

TEXT BY EDUARDO ALONSO

The Toolbox, developed by OECD in collaboration with ECHA, is a software to fill (eco)toxicological data gaps for chemical hazard assessment. It uses existing information to estimate missing experimental values and help address REACH information requirements to reduce the use of additional testing on animals.

Companies have found that the Toolbox provides practical support for preparing registration dossiers, even though it cannot and should not replace expert judgement. *Grace Patlewicz* from DuPont said that they find the Toolbox particularly helpful in providing supporting data as part of a weight of evidence approach; for example in the case of a substance with data derived from a study not conducted under current standards, but where there would be little scientific merit in repeating. "In such cases, the Toolbox permits the substance to be evaluated further by reference to mechanistically similar analogues and typically the outcomes evidenced by the original study are confirmed", she said.

For the substances to be registered in 2013 and 2018, less experimental data are available and this makes non-testing approaches and predictions within the QSAR Toolbox more relevant. The representatives from industry expressed their wishes of achieving a better understanding on how non-testing approaches are applied for registration purposes. "Regulators and registrants need to build a comfort level such that substantial non-testing approaches can be applied to read across Annex VIII endpoints including 28-day studies", said *René Hunziker* of Dow. *Geoffrey Hynes* from Givaudan agreed: "There can be future problems for the longer term tests. However, the data obtained from the Toolbox could be of real benefit for a weight of evidence argument."

Users of the Toolbox would also like to see how ECHA evaluates the results of non-testing approaches. Dr Patlewicz admitted that her company lacks concrete case studies from which to benchmark whether their scientific justifications are sufficiently detailed and reasonable. "We just don't know how these approaches are going to be evaluated", she said and continued: "Obviously, it is not the role of ECHA to provide an approval, but we do need more dialogue to share and exchange best practice both with ECHA and within industry so that ultimately registrants have a clearer understanding of what is fit for regulatory purpose. In this way, submissions should become more consistent, instead of each registrant having their own interpretation of what ECHA Guidance requires." *Stéphanie Ringeissen* from L'Oréal joined this petition:" If ECHA can share what is acceptable, more people can be convinced of the usefulness of the Toolbox."

In view of these challenges, users of the Toolbox welcomed initiatives from ECHA to increase the dialogue between the users and the Agency. "The support of ECHA is good and the organisation of this workshop is a good example", stated Dr Ringeissen. "The possibility for industry players to be able to give feedback on the development of the tool shows how ECHA is willing to adapt the tool to the needs of the users", she continued. Besides workshops and documentation, the OECD hosts a discussion forum on its website to maintain an ongoing dialogue with users of the Toolbox. "On the forum it is easy to speak to someone from ECHA or the OECD and any questions are answered in one or two days. New users of the forum could benefit from this great help", appreciated Dr Hynes.

FUTURE IMPROVEMENTS

The participants at the first QSAR Toolbox workshop also discussed the needs for further development. Apart from improvements in the user interface and better possibilities of data exchange between the Toolbox and IUCLID, most of the participants mentioned the availability of more data as the key feature to increase the usefulness and reliability of the software.

Dr Ringeissen acknowledged that there is a need for more good quality data, with more reference papers and a bibliography. According to Dr Hynes, one of the shortcomings of the Toolbox is the lack of some specific data. "For example, on fragrance substances, there are lots of data out there, but we would like to see more. REACH should help to fill in these data gaps when the dossier result data for 2010 substances is entered into the Toolbox in the next version", he said.

Increasing the available databases would also increase the reliability of the predictions and outputs of the Toolbox. "It is very important to be able to assess how the data was generated to give an overall confidence that the data is relevant to your substance. Sometimes there are data, but we cannot use it because the reference cannot be substantiated", Dr Hynes explained.

WIDER APPLICATIONS

The QSAR Toolbox has a much wider application than its use for registration purposes. It has become a tool used everyday for many companies, especially in the research and development phase. Dr Patlewicz explained that her company uses the Toolbox to evaluate substances at a research and development level to gain a perspective of the likely hazards for prioritisation purposes. In a similar way, Dr Hunziker said that the Toolbox helps develop an understanding of the effects of potential chemicals. "For our R&D molecules, not linked to existing businesses", he explained, "we really appreciate the Toolbox because it can be used as an internal screening tool when we come with chemistry that we have not seen at all in our company. We can gain an understanding of potential effects of new candidates in a very rapid way."

Further information, presentations and a summary of the workshop on the ECHA website:
http://echa.europa.eu/news-and-events/events

QSAR Toolbox
http://www.qsartoolbox.org

Geoffrey Hynes from Givaudan (left), René Hunziker of Dow and Stephanie Ringeissen from L'Oréal shared their experiences with the QSAR Toolbox to industry colleagues and ECHA scientists during the first QSAR Toolbox Workshop held at ECHA.

Event calendar

March-April 2012

- Conference on REACH and CLP Enforcement: 1 March, Brussels
  http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm
- ECHA Management Board: 22-23 March

Tentative dates:

- Forum for Exchange of Information on Enforcement: 28-29 February, Brussels
- ECHA Committee for Risk Assessment (RAC): 6-9 March
- ECHA Committee for Socio-economic Analysis (SEAC): 13-15 March
- HelpNet meeting: 17-18 April
- ECHA Member State Committee: 23-27 April

Webinars - preliminary plan
http://echa.europa.eu/support/training-material/webinars

Coming up:
- ECHA Stakeholders' Day: 23 May 2012
- Helsinki Chemicals Forum: 24-25 May 2012
  www.helsinkicf.eu
- EUROTOX 2012 Congress, Stockholm: 17 June
  http://eurotox2012.org/?id=40

Ongoing consultations:

Harmonised classification and labelling
http://echa.europa.eu/harmonised-classification-and-labelling-consultation

Restrictions
http://echa.europa.eu/restrictions-under-consideration

Testing proposals
http://echa.europa.eu/information-on-chemicals/testing-proposals/current

ECHA reporting on nanomaterials to the European Commission

TEXT BY SANNA AIRAKSINEN, HANNA-KAISA TORKKELI

ECHA has analysed the extent to which companies included information about nanomaterials in their REACH registration dossiers and classification and labelling notifications. A report of the analysis has been sent to the Commission, which will use it in reply to the European Parliament.

In April 2009, the European Parliament asked the Commission to compile information on how nanomaterials are covered in all legislation across the European Union. In 2010, the Commission made an official request to ECHA for assistance in gathering information on nanomaterials reported by chemical companies either in their REACH registration dossiers or in notifications to the classification and labelling inventory under the CLP Regulation.

CHALLENGE WITH NANOMATERIALS

ECHA has a very large repository of REACH registration and C&L notification dossiers that could in principle provide information on nanomaterials registered or notified and therefore on the market. However, the REACH and CLP Regulations do not have any specific requirements for registrants and notifiers of substances that are nanomaterials or nanoforms of a substance. There is also no definition for nanomaterial[1] within REACH and CLP legislations. The European Commission has, however, addressed nanomaterials in a series of papers endorsed by the REACH and CLP competent authorities (CARACAL).

For REACH registrations, the position of the Commission[2] is that nanomaterials are covered by the definition of substance under Article 3(2) of the REACH Regulation, and that REACH requirements are applicable to nanomaterials. It has also been agreed that nanomaterials could be considered as substances in their own right and thus registered as such, or as forms of a substance and included in the registration dossiers of corresponding bulk substances. For C&L notifications, the Commission considers that the classification and labelling of nanomaterials should follow the rules set in the CLP Regulation.

Therefore, it was expected that nanomaterials would be reported in the dossiers as any other substance or form together with their hazardous properties and the appropriate risk management measures. Registrants and notifiers were encouraged to make explicit in their dossiers if they believed their substance was a nanomaterial or a nanoform of a substance.

RETRIEVING INFORMATION FROM ECHA DATABASES

The databases holding the REACH registrations and C&L notifications were screened at the end of June 2011 for retrieving information on nanomaterials. The screening strategy included retrieving those registrations and notifications that had reported "nanomaterial" as the form of the substance in the appropriate fields of the dossier, as well as those that contained the word "nano" in any part of the dossier. The retrieved dossiers were further assessed to verify whether they were likely to contain relevant information on nanomaterials.

The term "nano" was chosen as the search criterion because without a definition for nanomaterial in REACH or CLP, information on particle size could not be used as a clear-cut criterion. The use of "nano" by a registrant or a notifier in a relevant context was considered to be an indication that the dossier may include nanomaterials or nanoforms within the scope of the substance.

CONCLUSIONS OF THE ANALYSIS

The screening retrieved dossiers for 78 registered substances which contained some information on nanomaterials. Of these, five substances clearly included nanoforms within the scope of the substance. For most of the dossiers, however, "nano" was found in the context of read-across from studies carried out on nanomaterials, but the company did not specify whether the registered substance included nanoforms or not. The C&L database search yielded 18 notifications with nanomaterial selected as the form of the notified substance. One substance was common to both lists.

The retrieved substances included many of those that are on the list of manufactured nanomaterials compiled by the OECD Working Party on Manufactured Nanomaterials (WPMN). In some cases though, when a registered substance was on the WPMN list, the registration clearly excluded nanoforms from the scope of the registration. In addition, it is possible that some of the substances on the WPMN list are not manufactured at a level that would already require registration; e.g. no registrations or notifications were found for fullerenes. It may have been also unclear to companies whether to treat their substances as nanomaterials due to the lack of consensus on the definitions for particulate nanomaterials at the time of registration or notification. Nevertheless, the analysis was able to retrieve from the registration and C&L databases the substances which companies had explicitly identified as nanomaterials.

Further information:

European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials:
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0328&language=EN

Second Commission communication on the Regulatory aspects of nanomaterials:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:en:PDF

Nanomaterials in REACH. Document endorsed by the REACH and CLP Competent Authorities in December 2008:
http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

Classification, labelling and packaging of nanomaterials in REACH and CLP. Document reflecting the discussions within the REACH and CLP Competent Authorities in December 2009:
http://ec.europa.eu/environment/chemicals/reach/pdf/classif_nano.pdf

List of manufactured nanomaterials and list of endpoints for phase one of the sponsorship programme for the testing of manufactured nanomaterials: revision
http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2010)46&doclanguage=en

[1] In October 2011, the European Commission adopted the recommentation on the definition of a nanomaterial and published the reports from the REACH Implementation Projects on Nanomaterials (RIPoNs). The screening reported here was carried out at the end of June 2011. Therefore, the screened registrations and notifications were submitted before the official recommendation was adopted.

[2] Document CA/59/2008 rev.1 "Nanomaterials in REACH"
http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

Latest news from ECHA

ECHA launches the Classification and Labelling Inventory of chemicals on the EU market
ECHA Press release 13 February 2012
http://echa.europa.eu/view-article/-/journal_content/07005f81-abf1-4081-973b-6c7c526c39df

Pre-submission information sessions for authorisation applicants
ECHA website 6 February 2012
http://echa.europa.eu/applying-for-authorisation/pre-submission-information-sessions

2 300 substances already identified for registration by 2013
ECHA News alert 3 February 2012
http://echa.europa.eu/en/view-article/-/journal_content/ab06aa2b-8c2f-4273-a628-e2fdfaf2a6f4

ECHA renews its support to Lead Registrants in preparation for 2013
ECHA News alert 19 December 2011
http://echa.europa.eu/en/view-article/-/journal_content/bc5be3d5-82cb-4310-933d-cb3a1936c224

A REACH story: The tale of a political success

INTERVIEW BY M. E. LOCCHI

Guido Sacconi, former Italian MEP, has resigned from the ECHA Management Board. ECHA Newsletter talks to him about his experience as the Parliament's lead Rapporteur on the REACH proposal.

I would agree with Martin Schultz, the newly-appointed President of the EU parliament when he says that Guido Sacconi "has a great sense of humour, determination and a deep respect for the European institutions". On the verge of his resignation as an ECHA Management Board member, he talks humorously about his work on REACH as the "great adventure of his political life and a titanic effort." He explains that he is resigning because he is "fed up of being an icon as the REACH rapporteur" and then starts laughing in the interview at his own words.

"I am a passionate mountaineer and if I compare working on the REACH dossier to a mountain's height, I would say that REACH is about 8000 meters high." Guido Sacconi

But then his tone becomes more serious and he adds: "It has been interesting to be a member of the ECHA board, but I am a politician and the management of an agency is not really my thing." He still asks himself why he was chosen as the REACH rapporteur by Dagmar Roth-Berendt, German MEP and head of the PSE group at the ENVI committee, but he thinks it was because of his work concerning Environmental and Public Health politics but he adds "or probably my well known negotiation skills might have influenced her decision".

He takes me back to the end of March 2002, when there wasn't much support in favour of a new chemicals policy. At the time, the REACH proposal was not only opposed by EU lobbyists but also faced resistance from the opposite side of the Atlantic from Washington. "This is something I became aware of only later", he recalls, but "the American Secretary of State at the time, Colin Powell, sent 36 members of the US diplomatic corps in a dispatch to tackle this issue with the European Economic Community as he believed that this policy would have ended in a regulatory system which was expensive, complicated and practically impossible to implement."

In the complicated puzzle of consensus building around one of the most ambitious pieces of legislation voted for by the EU parliament, the REACH saga developed around battles and swift changes of perception.

In October 2003, he explains that "a full frontal attack was launched against the main principle behind the REACH Regulation: the reversal of the burden of proof. Whereas in the past it was the responsibility of public administrations, it was now the responsibility of industry to manage the risks from chemicals and to provide safety information on substances. Industry simply didn't agree with this innovative principle. We won this battle at the end of the first reading when the parliamentary term ended and we had to start working again on the dossier in June 2004."

During the second reading, the perception of REACH's impact on industry started changing when it began to be understood that this regulation could become a tool for growth and innovation for the chemicals industry as well as for increasing its competitiveness. Another positive shift of perception occurred when German workers within the chemicals industry started to understand that this regulation would make their workplace safer, which led to German MEPs with strong links to trade unions becoming advocates for REACH. Finally, "REACH was voted on in December 2006 in a final rush. Today, I feel like a very lucky person because I witnessed the

implementation of the legislation I contributed to and the establishment of ECHA."

To conclude the interview, Guido Sacconi added: "I would like to say that something could still be done concerning the protection of the health of workers for the downstream users of chemicals. The trade union leader that is in me thinks that we can still work on improving awareness of chemical hazards especially outside of the chemicals industry sector."

Guido Sacconi has written an interesting book about his experience as Parliament's lead Rapporteur on the REACH proposal. If you want to know more, you can read the full story in "Reachstory: il racconto di un successo della buona politica" published by Edizioni Angelo Guerini e Associati, Milano, Italy, 2008.

ECHA and the Member States align views on the joint task of evaluation

TEXT BY VIRGINIA MERCOURI

Evaluation – the 'e' in REACH - is one of the main areas of cooperation between ECHA and the Member States. As the process evolves, decisions on the dossiers form a larger proportion of the agenda of the Member States Committee (MSC), while substance evaluation will be carried out by the national Competent Authorities and coordinated by ECHA on the basis of the forthcoming Community Rolling Action Plan (CoRAP).

To further align their views on dossier and substance evaluation and to see how to efficiently manage the increasing workload, 61 representatives from 24 Competent Authorities and the European Commission visited ECHA for a two-day workshop at the end of January.

The main focus of the workshop was to learn from the experience gained in the dossier evaluation and address the challenges of the increasing workload, the needs for prioritisation and shared principles by the Member States, the Commission and ECHA. These issues are crucial for generating final decisions on dossier and substance evaluation within the legal timelines.

The participants of the workshop agreed on the importance of a mutual learning process and finding new ways for reducing the administrative burden. One method could be to increase interaction between topical experts and coordinators in the Member State Competent Authorities (MSCAs) and the MSC. As ECHA presented its plans for supporting the Member States in capacity building and updating the CoRAP, the delegates confirmed their commitment to transparency and proactive communication in making substance evaluation well understood.

The workshop was mainly focused on sharing tasks between national authorities and ECHA. ECHA Executive Director Geert Dancet said in his opening speech: "Knowing the challenges ahead, it is vital that the collaboration between ECHA, the Member State Competent Authorities and the Committee works in an efficient manner." Closer cooperation with stakeholders at both national and EU level is also envisaged.

ECHA will publish the summary report of the workshop on its website.

Finnish and Swedish Ministers for Environment show keen interest in ECHA's activities

The quality of registration dossiers, preparations for the 2013 deadline and the challenges for SMEs were the key discussion topics during the visit of the Ministers for Environment of Finland and Sweden to ECHA.

The visit, which took place in January, was part of the first official visit of the new Swedish Minister *Lena Ek* to Finland. Ms Ek and her Finnish counterpart, *Ville Niinistö*, were briefed on the Agency's work and shown around the ECHA premises.

In a lively discussion with the ECHA directors, the Ministers showed keen interest in ECHA's findings in relation to the quality of registration dossiers, the preparations for the 2013 registration deadline and the specific challenges faced by SMEs, in this regard. Other questions concerned the impact of REACH on the chemicals market, the international relations of ECHA - including those with developing countries - and the upcoming review of REACH.

The Ministers were pleased to hear that ECHA is addressing new scientific challenges, such as those related to nanomaterials, endocrine disruptors or combination effects of chemicals, and encouraged the Agency to continue to pursue the work in making public information on chemicals more understandable for consumers. Both Ministers acknowledged that the national enforcement and customs authorities have a key responsibility in the success of REACH and CLP. The risk management of chemicals in consumer products was mentioned as an area where improvements are needed in the enforcement practices.

Swedish Minister for Environment Lena Ek and her Finnish counterpart Ville Niinistö visited ECHA in January.

New Head of Corporate Services

Clemencia Widlund from Sweden started at ECHA in December 2011 as the new Head of Unit for Corporate Services. She comes to Helsinki from the European Centre of Disease Prevention and Control (ECDC) in Stockholm where she worked as Head of Section for Missions and Meetings.

Prior to her EU career, Ms Widlund was with the International Geosphere-Biosphere Programme at the Royal Swedish Academy of Sciences, spent many years in development projects under the US Assistance for International Development (USAID) and enjoyed a teaching career in economics as a part time job in the Philippines. Ms Widlund has a Master's Degree in management. In her spare time, she enjoys bowling, playing the piano, reading and cooking.

Vacancies in ECHA

ECHA is currently opening a selection for a Chair of Biocidal Products Committee, a Head of Unit for Biocides, an Information Technology Officer, an Information Technology Project Manager and a Legal Adviser on biocides.
Read more:
http://echa.europa.eu/about-us/jobs/open-positions

REACH and CLP enforcement in an Italian context

INTERVIEWS BY M. E. LOCCHI

Since the late 1970s, the Italian central administration has been devolving the enforcement activities concerning chemical substances and mixtures under Directives 67/548/CE and then the 99/45/CE to the Prevention Departments of the Regional Public Health and to the Environment Protection Agencies Services.

However 30 years later, the entry into force of the new REACH Regulation requested a more complex approach to enforcement and its management; a redefinition of the roles and competencies between the central and the local administrations took place in late November 2007[1]. "To coordinate and harmonise the REACH enforcement in Italy", says *Mariano Alessi* from the Italian Ministry of Health, "we created a new governing body: the REACH technical committee. Its organisational structure clearly indicates to what extend REACH is relevant and important to central authorities. Indeed, the committee includes four ministries and other technical taskforces[2] headed by the competent authority: the Ministry of Health. Research institutes also joined the Committee as we needed to set up a national network of laboratories to support the inspection activities: the CSC (National Center for Chemicals) and the Institute for Environmental Protection and Research (ISPRA). Last, but not least, the local operational structure of enforcement represented nineteen regions and two autonomous provinces, which were included in the REACH committee."

Furthermore, a state-regions framework agreement to manage enforcement at a local level was published in the Italian Official Journal in December 2009, followed in June 2011 by the first National Plan for enforcement to implement REACH ENFORCE-2 by the end of 2011. However, the enforcement activities had already started as Italy had from March 2010 to April 2011, taken part in REACH ENFORCE-1, the first Forum enforcement exercise. Indeed, by September 2010, pending the negotiations for the framework agreement with the regions, the central authorities trained and accredited almost 120 REACH inspectors as well as organising the training of 60 CLP inspectors. Another group of 100 inspectors is actually being trained to achieve the target of 220 accredited inspectors.

"Our inspectors are highly skilled professionals, apart from the fact that they all have a sound scientific background, allow me to say that the competitive advantage of our inspectors is that they are also in charge of a variety of surveillance and inspection activities related to the health and safety in workplaces, solvents, cosmetics, paints, adhesives, plant protection products, detergents and environmental protection as a whole. In this respect, REACH and CLP are just a part of a bigger picture. For this reason, their inspections go beyond the mere checking of the formal aspects of the compliance with the laws. Their surveillance is factual, and for example, they could ask for the reason why a substance or a mixture has been labeled as not hazardous", reports *Celsino Govoni*, the representative of the regions in the REACH technical committee.

Mariano Alessi.

Celsino Govoni.

To encourage good practice and raise awareness of REACH and CLP obligations from the industry, the Italian authorities have prioritised a strong communication approach based on a variety of information activities. In some regions, inspectors have organised information days, workshops and meetings. In other cases, companies have been pre-informed by the inspectors themselves on the surveillance activities that would take place. The National Enforcement Plan detailing the target groups and the substances and mixtures that will be under surveillance is a public document available on the internet. Regions have also set up an extensive network of local helpdesks for companies and consumers. "In general, within the framework of the enforcement project REACH-EN-FORCE-1, the Italian companies have responded positively to the inspections but we must highlight the fact that there is still much do to meet REACH safety data sheet requirements and use-related duties", says Govoni.

The second enforcement project REACH-EN-FORCE-2 only started in October 2011 and is still ongoing. The priority has been given to those SMEs producing items such as paints, surfactants, detergents, varnishes, and more generally CMRs cat.1,2 and substances very toxic for the aquatic environment. Italy is also still working on the launch of a series of substance-specific inspection campaigns on the amount of polycyclic-aromatic hydrocarbons (PAHs) that can be present within extender oils and on the determination of the hexavalent chromium content of

Pre-registrations in Italy by region.

Source: ECHA, 2008.

cement with the collaboration of the Customs authorities.
For the time being, in the Italian territory, companies are requested to pay a fee of 2 000 euros for each inspection. The fine for the breach of law may vary from 2 000 to 150 000 euros in severe cases and could also include imprisonment of up to 90 days. The chemical sector in Italy - with a turnover of about 53 billion euros in 2010 - represents the third main producer of chemicals in Europe. Almost four thousand companies employ approximately 115 000 people while SMEs account for 41% of the total value of production. Companies are mainly located in the northern regions of Lombardy – the EU region with the highest density of chemical industries[3] - Veneto, Piedmont, Emilia Romagna and Tuscany.

FURTHER INFORMATION

Ministero della Salute
http://www.salute.gov.it/sicurezzaChimica/sicurezzaChimica.jsp

Celsino Govoni
CeGovoni@Regione.Emilia-Romagna.it

Mariano Alessi
alessi@sanita.it

[1] On 22 November 2007, the Italian government issued a Law Decree concerning the activity planning and the use of financial resources referred to in Article 5-bis of Legislative Decree 15 February 2007, No 10, converted into law with amendments 6 April 2007 (L46/07) concerning the obligations provided for in Regulation (EC) No 1907/2006 of the European Parliament and Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[2] NAS (Anti Sophistication task force), NOE (Operational Ecological task force), ISPESL (Institute for Prevention and Safety at Work), USMAF (Maritime, Air and Border Health departments) and Customs.

[3] Source: Federchimica "The Chemical Industry in Italy", Milano 2011.

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/documents/10162/17207/procedure_dossier_evaluation_20110329_en.pdf.
The results obtained so far can be found in the annual progress report on evaluation:
http://echa.europa.eu/documents/10162/17221/evaluation_under_reach_progress_report_2010_en.pdf.

Tables A to C report on the statistics of the dossier evaluation processes from 1 June 2008 to 31 January 2012. 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 31 January 2012.

		Phase-in*	Non phase-in	Total
No of registered dossiers [1]	containing testing proposals	521	49	570
	containing testing proposals for vertebrate animals	399	32	431
No of endpoints	covered by registered testing proposals	1 064	103	1 167
	covered by registered testing proposals for vertebrate animals	656	54	710
No of third party consultations	closed	362	29	391
	ongoing on 31 January 2012	4	2	6
	planned	76	7	83
Dossiers with testing proposals opened for examination [2]		548	55**	603
Draft Decision sent to the registrant [3]		191	15	206
Final Decision sent to the registrant		11	19	30
Terminated testing proposal examinations [4]		57	15	72

* 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). **Note:** this number changes over time as dossiers may be updated by the registrant (e.g. test endpoints added and/or withdrawn)
[2] Dossiers ever opened for examination notwithstanding their current status.
[3] Draft decisions which did not become final by 31 January 2012 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 31 January 2012.

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check[1]	187	140	327
Draft Decision sent to the registrant [2]	55	11	66
Final Decision sent to the registrant	80	37	117
Only Quality Observation Letter sent to the registrant [3]	13	46	59
Terminated compliance checks[4]	13	43	56

[1] Dossiers ever opened for compliance check notwithstanding their current status.
[2] Draft decisions which did not become final by 31 January 2012.
[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]	158
Draft Decision sent to the registrant [5]	49
Final Decision sent to the registrant	73
Only Quality Observation Letter sent to the registrant [6]	6
Terminated compliance checks [7]	8

[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 31 January 2012.
[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.

Making information on the chemicals registered publicly available

Around 90% of all dossiers and 80% of all substances registered have been disseminated by 7 February 2012. Information on registered substances can be found on the ECHA website at http://echa.europa.eu/information-on-chemicals/registered-substances.

Dissemination Progress

Data as of 7 February 2012

		Registered	Disseminated
SUBSTANCES	Phase-in*	3 687	3 556
	Non phase-in	1 691	653
	Total substances	**5 378**	**4 209**
DOSSIERS	Lead	3 160	3 057
	Member	21 071	19 264
	Individual	2 969	1 620
	Total dossiers	**27 200**	**23 941**

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