ECHA
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Newsletter

The big push towards 2013

Greetings from an autumnal Helsinki. As the days start to shorten and the winter beckons, I realise that the next REACH deadline will be over by the time we experience our next wonderful 24 hour day of sunshine here in Helsinki. So the big workload for us, as well as for many of you, lies ahead!

With that in mind, just last week we had our second lead registrant workshop. We welcomed around 100 participants and 200 online who are preparing for the upcoming 2013 REACH deadline to share best practice with ECHA and with each other about leading a SIEF, sharing data and preparing joint submissions. The event was organised together with a number of our Accredited Stakeholder organisations and much of the content was provided by stakeholders, particularly lead registrants with experience from the 2010 registration deadline. Their practical input was invaluable and we're very grateful for their help. You can read about the workshop on pages 3-5.

In this edition of the newsletter, we are also talking about the importance of data sharing and introducing the new possibilities offered by the upcoming update to REACH-IT, the Co-registrants page, which will support potential and existing registrants in sharing data and preparing joint submissions. In addition, we highlight the problems contained in many intermediate dossiers – where the substance is arguably not an intermediate and therefore should not benefit from the reduced information requirements (and costs) under REACH. We are following all of those dossiers up as we speak.

In the beginning of September we took a major step towards the target of having 136 substances of very high concern (SVHC) on the Candidate List for authorisation by the end of 2012. As you will recall, this target was set by Commission Vice President Tajani and Commissioner Potočnik in 2010. We launched our biggest public consultation yet of 54 potential SVHCs asking for your comments on the identity and properties of the substances. Currently, there are 84 SVHCs on the Candidate List. After the consultation, which ends on Thursday (18 October), the proposal will go to the Member State Committee for agreement. You can learn more about the next steps on page 6.

Finally, we are hoping that you will have an extra little "gift" in our December Newsletter. Acting on your feedback, and in particular, your desire to have the Newsletter in a more user friendly format, we will be going 'online'.

We hope that the new format will help you find and share the stories that are relevant to you and your colleagues more easily. We're always on the lookout for ways to make the Newsletter more valuable for you, so please let us know what you would like to see covered in the coming issues, what has been good, and what we can improve. Get in touch with Hanna and me at echanewsletter@echa.europa.eu.

Lindsay Jackson
Head of Communications

"Acting on your feedback, and in particular, your desire to have the Newsletter in a more user friendly format, we will be going 'online'."

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Following the lead to Helsinki

ECHA welcomed lead registrants back for a second workshop

TEXT BY SUSANNA DUNKERLEY

With the 2013 deadline for phase-in chemicals fast approaching, the Second Lead Registrants Workshop provided a final opportunity for lead registrants to share their experiences, information and tips for registration.

More than 100 participants attended the two-day event in Helsinki, including newly appointed and candidate leads representing the chemical manufacturing industries. Experienced leads, industry representatives, consultants and representatives of the national helpdesks of four Member States were also present, while an additional 200 people followed online.

The event complemented the initial workshop earlier this year, which focussed on dossier submission IT-tools and lessons learned from the 2010 deadline. Workshop chair and Director of Cooperation at ECHA, Mr Andreas Herdina, welcomed the chance to discuss developments since then and practical ways to reach the May 2013 deadline and beyond.

A key message throughout the event was the need for lead registrants - those responsible for compiling lead dossiers in joint submissions – to register as soon as they can. "Registration is the start," ECHA Executive Director *Geert Dancet* said in the opening address. "You have a big responsibility, take the lead!"

Presentations covered, among others: management of substance information exchange forums (SIEFs); substance identification; confidentiality of information, communication down the supply chain; and exposure assessment. Each sparked robust discussions.

Participants also received targeted advice during one-to-one sessions and IT training sessions.

SUPPORTING DOWNSTREAM USERS

The challenges facing downstream users - right through to the customers at the end of the supply chain - was the focus of one session.

Sylvie Lemoine from the Downstream Users of Chemicals Co-ordination (DUCC) Group stressed the importance of harmonised and simple language and terminology. "It's a challenge for downstream users to manage their deadlines, given the complexity, language barriers and lack of targeted training", she said.

One useful way leads can assist is by inserting a simple table of contents in safety data sheets (SDS) listing exposure scenarios, in a harmonised format. "Providing good exposure scenarios to downstream users will avoid a lot of unnecessary questions after registration. We need your help to make the life of your customers easier!"

European Association of Metals consultant *Hugo Waeterschoot* says not enough attention was given to end users when REACH was designed. "And I think we see the consequences of that now." He suggested harmonising with already existing risk management legislation including workplace health and safety.

GETTING INACTIVE PRE-REGISTRANTS ON BOARD

Another issue raised was that of inactive or dormant pre-registrants.

The European Chemical Industry Council's *Mercedes Viñas* flagged targeted communications to inactive pre-registrants over the coming months. "Please note that we are progressing with the registrations … and if you want to change your data you can still do it," she suggested the communication could say.

CONFIDENTIALITY CLAIMS – ACT BY 31 OCTOBER

Questions were raised about the 31 October confidentiality claim deadline. From November 2012, safety data sheet information, including company names and registration numbers, will be published online. So, the 30 000 dossiers already in the dissemination portal will soon be searchable by registrant names, identifiers and tonnage bands.

NEW TOOLS AND FEATURES INTRODUCED

A number of new features were announced during the workshop, including the Co-registrants Page. The IT Tool feature will provide direct access to the contact details of co-registrants in real time, and identify potential registrants, who have successfully inquired about a certain substance. The REACH 2013 website has also been updated with links to tools, information and guidance documents for the deadline by Accredited Stakeholder Organisations.

HIGH QUALITY DATA AND REGULAR EVALUATION NEEDED TO ENSURE SAFE USE OF CHEMICALS

ECHA experts spoke about the need to provide quality data in dossiers and gave practical advice on updating them.

Registrants were reminded that the May 2013 deadline for chemicals at or above 100 tonnes a year was not the finish line. ECHA Scientific officer *Rupert Simon* described registration as a long-term commitment. "Leads should evaluate and update dossiers ideally every six months and take note of emails and information requests from ECHA", he added. "The earlier you react the earlier we can help you, and we are dedicated to do so."

Mr Waeterschoot concurred, sharing his experience of registrants missing the 2010 deadlines because they did not check their mailbox. "Act for the deadline, it may look like a Swiss watch but I can tell you the Finnish watch is just as precise in timing."

- As of September 2012, ECHA has received 1 949 self-nominations as lead registrants for the 2013 deadline. They are published on the ECHA website. These nominations came from 568 legal entities. More than a quarter of these lead registrants have no previous experience of being a lead registrant.
- A total of 2 607 lead registrant nominations are listed, including those intending to register for the 2018 deadline.
- ECHA has received an authorisation from 425 lead registrants to disclose their names. That is 16% of total nominations.
- Intentions to register for 2013 deadline: 2 968 substances, and of these 75% already have leads.

Adding colour, *Dr Rene Hunziker* from the Dow Chemical Company, told a tale of crossing the 'roaming river REACH' to the new frontier. "Imagine there are no maps, no-one has ever gone there. Many have told stories of … an agency somewhere far off in the north."

"Everybody knew they had to cross the river REACH … and the promise, if you succeed, was a land of safe chemicals, a public with confidence in the chemical industry and its products."

"This land exists, it's not a dream."

The presentations and a video recording of the event are available on ECHA's website: http://echa.europa.eu/en/view-article/-/journal_content/2b6c9ef3-b8c8-4ee1-a15d-bee72a3b47ea

Smaller companies taking the lead

INTERVIEWS BY VIRGINIA MERCOURI & HANNA-KAISA TORKKELI

At the Lead Registrants Workshop, ECHA Newsletter interviewed few of the participants on their experience with REACH registration, managing substance information exchange forums (SIEFs) and the challenges for smaller companies of being a lead registrant.

Mariano Alessio Verni from SILC Fertilizzanti Srl, is the co-ordinator of the Potassium Phosphites Consortium. His company has experience as a member registrant from the 2010 deadline and recently stepped in to become a lead registrant for 2013. He is quick to point out that there is a substantial change in communication within the SIEFs from two years ago. "It is not like in 2010 registration, when we had a couple of big companies with enough people to work on REACH inside the company itself. Smaller companies usually have to outsource this work. It is not profitable to train people internally if you have to register only a couple of substances." He explains that usually the lead registrants call on an external consultant and the companies that are members also call on consultants. "The dialogue is between the consultants themselves and not between companies, so it is an indirect communication. Moreover, different consultants have different approaches on how to make the gap analysis. This makes it very hard to manage the consortium."

To address this challenge, Mariano Alessio Verni considers that the lead registrant's company or a core group of companies should have sufficient expertise to guide the consultants. "I have enough expertise in the sector, so I can help our consultant not only with the chemical issues, but also with the technical, marketing and commercial issues." He is convinced that good knowledge of the market is also important. "I already know other SIEF members from my past commercial

experience. I have already met most of our members in congresses or trade exhibitions in and outside Europe and that helps a lot in the communication." He advises that it is not good to forget the commercial aspects when dealing with REACH, especially when the consortium involves SMEs.

Attending ECHA's Lead Registrants' workshop provided the opportunity to have a one-to-one session and to clarify the sameness of the substances that will be registered. Following this, he is planning a meeting with the consortium to do final preparations before submitting the lead dossier before the end of February 2013.

Mariano Alessio Verni.

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Stéarinerie Dubois, a French medium-sized company manufacturing fatty esters, is registering for the first time in 2013 as lead registrant for several substances. Regulatory Affairs Manager *Laetitia Halbeisen* says that her company became a member of a consortium several years ago to be able to manage the registration process. The consortium is managed by an external consultant. "We don't have the internal resources especially for the eco-toxicological and toxicological parts, so the support of the consultant is very important. It is still somewhat difficult to decide strategies since it requires a lot of background in these fields, but we are learning" Ms Halbeisen says.

Stéarinerie Dubois is exporting products all over the world and has to comply with many different legislations. "Our products have to conform to legislations in Europe, Asia, America… and we need to adjust to the changes they introduce. For example, we might have to register a substance under REACH and commission tests according to certain methods. To export the same substance to China, we would have to do other tests which are applicable to their legislation. The overall context is complex," Ms Halbeisen explains.

From ECHA, Ms Halbeisen would also like to receive positive, reassuring feedback, to know that her company is on the right track. "For example, when you put in a confidentiality claim, which requires a detailed argumentation, it would be good to know that it is being assessed and what the result is. At present, there is a waiting period during which you may receive messages in REACH-IT if there are comments or problems. It is the same with dossier updates. It would be great to receive some proactive signals from ECHA," she concludes.

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Darren Abrahams is an environmental lawyer working with REACH and related legislation at Steptoe & Johnson LLP in Brussels. He helps his clients interpret the REACH Regulation and guides them on strategies. "But we are also an Only Representative. We are actually registering for a large number of non-EU manufacturers; companies, which are exporting chemicals subject to REACH onto the European market. So I get to see everything from pre-registration right through to registration, which will be leading us to 2018", he mentions.

Although many of Mr Abrahams' clients are large companies, he also helps clients who are engaging with REACH for the first time in 2013. According to him, the 2013 deadline is not – and should not be – a repetition of the 2010 deadline. "We are dealing with a very different audience. These are people who have made sincere efforts to try and prepare properly for REACH but may not have the resources nor time that are required to really do this properly", Mr Abrahams explains. As specific problematic issues for all registrants, Mr Abrahams mentions supply chain management and communication within the SIEF. Supply chain problems occur both upstream and downstream. "Our clients need the information on the substances they register. A lot of these suppliers are not based in the EU and do not have a legal obligation to provide that information. We spend a lot of time trying to help our clients to extract that information and also provide a way to give reassurance to their customers downstream without disclosing commercially sensitive information." Although there are supply chain requirements within REACH, a lot of the practical elements are not directly addressed by the legislator. "All of these issues, where there is a legal requirement but not very much explanation from the legislator create issues for our clients. ECHA is of course doing its best trying to fill the gaps", he says.

Mr Abrahams says that communication within SIEFs is now very different compared to the past deadline. "We are actually not just educating our lead registrant clients but everyone they need to engage with. Joint registration is a collective process. There is no magic formula for SIEFs really. You need to be transparent and treat everyone fairly. You also need to repeat the same thing over and over again. It is a drip-drip effect and eventually you get through", he explains. Darren Abrahams advises lead registrants to keep a paper trail of all their actions showing that they have done everything required to bring the SIEF together.

Candidate List – the way ahead

TEXT BY ELINA KARHU

Having 136 substances on the Candidate List of substances of very high concern (SVHC) by the end of 2012 is the policy target set out by the Commission in spring 2010. This target is likely to be achieved. The focus has now shifted to how to use the REACH and CLP information to identify new substances and uses which would require regulatory risk management actions and how to choose the best approach to tackle the concerns in each case.

The eighth round of SVHC identification is currently under work. Out of the 17 proposals submitted by the Member States, five are based on PBT/vPvB* properties and six on equivalent level of concern considerations: three on endocrine disruption properties and three substances classified as respiratory sensitisers. In addition to these Member State proposals, in August the European Commission requested ECHA to prepare SVHC dossiers for 37 CMR** (Cat 1A/B) substances.

With this request, the Commission aimed to achieve the policy target set out by Vice President Tajani and Commissioner Potočnik in spring 2010 to have 136 substances on the Candidate List by the end of this year. The Commission has started further discussion with the Member States and ECHA on how to reach the policy target of getting all relevant SVHC substances identified by 2020.

REACH places the primary responsibility for ensuring the safe use of chemicals on industry: manufacturers, importers and downstream users of substances. Regulatory interventions can be seen as complementary measures where the actions taken by industry are for one or more reasons insufficient. The main focus of the further developments and discussions is how to make the best use of the REACH and CLP information and of the regulatory risk management tools that REACH provides.

In other words, how to guarantee that the concerns are identified as early as possible and addressed by a set of tools which ensure efficient, timely and proportionate regulatory actions.

Registration and classification and labelling notification requirements have and will continue to bring in new information. However, in order to have sufficient basis to address concerns related to new types of substances, which are not yet regulated for instance due to their recognised CMR properties, often requires further information. Substance evaluation starts to take its role in filling the data gaps where necessary to support regulatory risk management.

Furthermore, ECHA has established a PBT expert group bringing together experts from Member States, industry, NGOs and ECHA to support the work of identifying information needs and assessing the information related to potential PBT and vPvB substances. Shifting the focus on new substances and concerns provides a possibility to achieve a real difference in human health and environmental protection but also requires considerable work and resources both from industry and authorities.

The Candidate List and the other parts of the authorisation process are new regulatory tools. While restrictions are not new – the first ones were adopted in 1976 – REACH provides a better information basis and a well structured and transparent framework to establish new restrictions. The challenge of the coming years is to ensure that these tools are implemented in an effective and proportionate manner as part of the wider Union regulatory framework for managing risks related to chemicals.

Candidate List table:
http://echa.europa.eu/candidate-list-table

* PBT - persistent, bioaccumulative and toxic chemicals
vPvB - very persistent and very bioaccumulative

** CMR - carcinogenic, mutagenic or toxic to reproduction

CANDIDATE LIST

The identification of a substance as substance of very high concern and its inclusion in the Candidate List is the first step of the authorisation procedure.

Companies may have immediate legal obligations following such inclusion which are linked to the listed substance on its own, in preparations and articles.

Further documentation or more detailed information on the identification process of substances of very high concern can be found on the web pages of ECHA's Member State Committee.

IT screening of intermediate dossiers

ECHA finds over 2 000 potentially non-compliant dossiers

TEXT BY HANNA-KAISA TORKKELI

The IT-based screening of all REACH intermediate dossiers conducted by the Agency has raised serious quality and potential compliance concerns. As a result of the screening, ECHA identified 2 388 potentially non-compliant dossiers from 574 registrants, representing 760 substances registered with intermediate use.

The concerned registrants have been directly informed about the findings for their dossier(s) along with information on how to update their dossiers via REACH-IT. They are requested to review and update their dossiers with correct information by the end of the year. ECHA intends to screen these dossiers again and identify those that require further regulatory action.

"We have already reported on the previous screening exercise done in 2010 and 2011, which raised concerns in terms of compliance. This new approach identifies additional substances through our IT-screening tools and focuses on inconsistencies in the information on uses provided in the dossier with regard to the intermediate status or strictly controlled conditions", explains *Mike Rasenberg*, ECHA's Head of Unit for Computational Assessment. The Agency has excluded all substances that have already received a clarification request (Article 36 letter) or are about to receive one in the near future as a result of the initial screening. However, the previously screened dossiers, which had not received clarification requests, were included in this screening.

Registrants affected by the findings have received a letter via REACH-IT asking them to carefully review the reported uses and update their registration dossiers. In the letter, the Agency also offers practical advice for registrants on how to better report intermediates in IUCLID 5.4 or how to update the registration to a full (Article 10) Registration. "We hope that the support and information in our letters will provide enough information for the registrants to update their dossiers either by providing correct information to register their substance as an intermediate under Articles 17 and 18, or by doing a full registration by submitting information as specified in Article 10 of REACH," Mr Rasenberg states.

FOLLOW-UP ACTIONS WILL ALSO COVER UPDATED DOSSIERS

So far, ECHA has received 84 updates for the intermediate dossiers included in the recent screening. In addition, several industry associations have contacted ECHA for additional support for updating dossiers, or for advice on how to integrate the information from the ECHA letters in the overall approach to update intermediate dossiers. ECHA continues to monitor the situation. "Take care! The fact that a company updates their dossier by simply removing incorrect uses does not mean that we forget about the dossier. As we receive more updates, we are reviewing where best to put our efforts to be as effective as possible", Mr Rasenberg says.

TOWARDS A COMMON UNDERSTANDING

The definition of intermediates and the interpretation of strictly controlled conditions have been popular topics of debate. ECHA has been, and will continue to be, in dialogue with industry to facilitate a common understanding of the Guidance on Intermediates and the related legal obligations. "It is important to us to ensure the safe use of chemicals, including intermediates. We are therefore taking industry concerns for intermediates seriously and are open to further discussions", Mike Rasenberg concludes.

Further information:
News alert, 14 September 2012
http://echa.europa.eu/view-article/-/journal_content/0d1a14fe-9c63-4807-a3de-380c0dbffdf5

INTERMEDIATES IN REACH

Substances used as an intermediate are intended to be transformed into another substance, and shall be manufactured and used under strictly controlled conditions at chemical manufacturing sites. Due to these special circumstances, the exposure to humans and the environment is considered to be minimised. On that basis, REACH allows intermediates manufactured and used under strictly controlled conditions to be registered with reduced information on their properties and without a chemical safety report (Articles 17 and 18 of REACH).

ECHA steps up evaluation of dossiers containing nanomaterials

Reaching the nano scale

TEXT BY VIRGINIA MERCOURI

ECHA is moving ahead with the evaluation of nanomaterials, following the agreement of the Member States' competent authorities during its workshop on nanomaterials at the end of May. The common approach is pragmatic and step-wise, balancing the scientific uncertainties with the legislative framework of REACH. The Agency is a focal point for the nano-related discussions through the establishment of a nanomaterials' working group and by taking over the coordination of the Group Assessing Already Registered Nanomaterials (GAARN). Both involve the Commission, national authorities and other stakeholders.

The nano particles, which represent a giant leap in modern chemistry and which have formed a growing multi-billion Euro industry, have intensified the scientific and regulatory discussions in REACH. *Wim De Coen*, ECHA's Head of Unit for Evaluation I and the leader of the Agency's task force on nanomaterials, is quick to point out: "The scientific uncertainty of nanos forces the regulator to be more cautious, but it does not mean stigmatising nanos." He clarifies that ECHA's approach responds to the recommendations of the Scientific Committee which advises the European Commission on Emerging and Newly Identified Health Risks (SCENIHR) to assess nanoforms on a case-by-case basis.

"From an early stage, we have not considered nanos to be more hazardous than any other substances." Dr De Coen explains that the classical principles of toxicology (i.e. hazard assessment) do not necessarily apply to all types of nanomaterials because of their tiny size and their relatively large surface area. Furthermore, experts involved in the work of the Organisation of Economic Cooperation and Development (OECD) on the safety of manufactured nanomaterials have acknowledged that adaptation of current test guidelines may be necessary in some cases and that specific guidance will have to be developed, for example, on sample preparation and dosimetry.

REACH AND CLP NANO BASICS

The starting point is the REACH and CLP definitions for substances. They are not explicit about nanomaterials, but apply to them as to all other forms of chemicals. This was again confirmed by the Second Regulatory Review of Nanomaterials, published this month*, which states that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures.

The next step was the recent recommendation** of the European Commission on the definition of nano, which provides more clarity in the debate between regulators and registrants regarding the size (in the range of 1 nm-100 nm) and number (50 % or more as default) of particles in a nanomaterial. ECHA will use this definition as the benchmark for registration and evaluation.

From the GAARN forum, where companies shared their experience from the registration of nanos for the first REACH deadline, and the recent workshop on nanomaterials, another important message for current and future registrants came forward: nanos are synthesised by design; they do not occur by accident. If companies make them, they know what specific properties they want them to have in order to achieve their market objective. These properties should be documented in the registrants' dossiers and the information provided should be in line with the new harmonised definition for nanomaterials. ECHA and the Member States are in agreement on this approach.

DEALING WITH THE NANO INFORMATION GAP

Following the first REACH registration deadline in 2010, ECHA has been screening the dossiers containing nanos in a common project with the European Commission's Joint Research Centre (JRC). Since nanomaterials are registered together with bulk materials, the project team expected that many of those substances, which exist both in the bulk and in the nanoform, would be reported on both types of properties in the registration dossier. "We have found a surprinsingly low number of explicit claims that the substance is used in a nanoform.

This is the case even for substances, which are included in the OECD list of manufactured nanomaterials", says *Frank Le Curieux*, who is a member of ECHA's task force on nanomaterials and represented the Agency in the tenth OECD Working Party on Manufactured Nanomaterials.
This lack of nano-specific information prompted ECHA to act using both the carrot and the stick. The Agency is now implementing a two year programme for internal and external capacity building, sharing experience, participation in and contribution to international regulatory activities.

ECHA is providing feedback and advice to registrants on nanos and supporting the preparations for REACH 2013. This advice is based on compliance checks of registration dossiers, the results from the ongoing JRC project and the good practice of registrants taking part in the GAARN initiative. ECHA has also released new annexes to the Guidance on Registration specific for nanomaterials.

Regulatory actions are also now under way. ECHA has sent draft decisions requesting nano-specific information from registrants of dossiers in which nano properties were not sufficiently documented (under Art. 41 of REACH). Registrants who may be manufacturers of nanos, but did not indicate this in their dossiers, have received letters under Article 36 of the REACH Regulation, which imposes on registrants the duty to gather and provide on request 'all the information the registrant requires to carry out his duties under this Regulation'. "These Article 36 letters by no means request the generation of new information," Wim De Coen points out. "This is their main difference with the draft decisions. An Article 36 decision is asking a company to submit to ECHA already available information regarding a specific property, in this case particle characteristics; because we have reason to believe that the company may already have such information. Of course, this is legally binding and registrants need to reply. Not replying means enforcement actions", Dr De Coen stresses and advises registrants to update their dossiers.

To support industry in providing complete information, ECHA has developed a questionnaire. "The more information you give already, the more unlikely you are to receive a draft decision" , Wim De Coen highlights and insists that ECHA has a pragmatic approach. "Currently, we are looking for a constructive and proactive response from registrants to provide us with information on their nanomaterial properties. This is also a wake-up call for future registrants: it is necessary to include nano-specific information in the dossiers."

STEPPING UP NANOMATERIALS' SAFETY

Both the draft decisions and the Article 36 letters request registrants to characterise their nanomaterials. "Our aim is to provide clarity primarily on the particle characteristics. This is the first step. What we want at this stage is for companies not to go away and say they cannot characterise their material. Yes, this is scientifically challenging, but we know from the discussions with registrants that it is possible", says Dr De Coen. For example, the manufacturers will tend to know which properties they need: size, form, surface, volume, surface treatment. This is exactly the type of information that ECHA requires.

"Currently, we are not instructing registrants which method to use. There are many methods available and we let them decide which ones are the most suitable to describe the characteristics of their specific nanoforms. Our aim is to develop a matrix approach, so that all registrants who wish to cover nanomaterials in their registration should be able to document it with the best available methods", says Dr De Coen. One of the most important messages from the last GAARN meeting was the 'can do' approach. "Documenting the characteristics of your particles is just a start. If the registrants do not do it, we will not achieve any breakthrough in the nano discussion."

Focusing on the physico-chemical properties is the first step in ECHA's strategy and one of the main outcomes from the workshop with the Member States. This will be the approach to follow through evaluation. "First we want to clean up the landscape", says Dr De Coen, continuing "Let's resolve in the first place the uncertainty about the particulate aspects such as size, shape and surface treatment. Then we can go further towards addressing the potential hazards. The hazards will be largely driven by the physico-chemical characterisation, so it will only be possible to do this gradually." By knowing the properties of the substances and their characteristics better, it will be easier for registrants to find the best approach to start testing and address the potential hazards strategically, from a risk perspective.
In parallel with the work done by the

registrants, ECHA is setting up a working group on nanomaterials to informally provide scientific advice on any aspects of nanomaterials under REACH and CLP. Frank Le Curieux and *Ofelia Bercaru*, who are in charge of gathering the nominations and preparing the first meeting of the group, stress that the activities of the working group should not interfere with ECHA's decision-making. On the contrary, it aims to facilitate ECHA's functioning by bringing in scientific expertise that can clarify nano-issues at the Member State Committee level. "With the increased knowledge, it should be possible in the future to identify and test the nanoforms that are relevant for the safe use of a given chemical", says Wim De Coen. "We aim at setting up, collectively with the Commission, Member States and stakeholders, a level playing field for manufacturers of nanomaterials. Where needed, dossier and substance evaluation are crucial for getting this job done. If we can achieve this, we will improve European competitiveness and innovation, as well as safeguard chemical safety to protect human health and the environment."

ECHA is starting a series of **webinars** on nanomaterials. The first one will take place on 30 October.

The Agency now has a dedicated section for nanomaterials on its website:
http://echa.europa.eu/chemicals-in-our-life/nanomaterials

Best practice on physicochemical and substance identity information for nanomaterials - Report from first GAARN meeting
http://echa.europa.eu/documents/10162/5399565/best_practices_physiochem_subst_id_nano_en.pdf

Workshop on Nanomaterials Proceedings
http://echa.europa.eu/view-article/-/journal_content/c299bea5-ccd1-495b-ba2b-c596fd8c0bed

ECHA Guidance on Information Requirements and Chemical Safety Assessment - recommendations for nanomaterials
http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

*Communication on the Second Regulatory Review of Nanomaterials (COM(2012) 572 final)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:EN:PDF

**Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

DID YOU KNOW?

The revised EU Biocides Regulation has already taken on board the nanoscale. It contains explicit requirements for the labelling of biocidal products for non-agricultural uses, by indicating the material and using the word "nano". The text refers to the EC definition of nanomaterials and asks for a separate evaluation of the risks deriving from them.

ECHA holds a scientific discussion session on *in vivo* mutagenicity tests

TEXT BY INGO BICHLMAIER

ECHA evaluates information on mutagenicity in dossiers, both for compliance checks and testing proposal examinations. A higher-tier study may be necessary to examine the potential for somatic cell mutagenicity *in vivo*.

There have been discussions on which test to use, partly triggered by the recent adoption of a new OECD test guideline, the Transgenic Rodent Gene Mutation (TGR) Assay, which is an alternative to the longer-established Unscheduled DNA Synthesis (UDS) Assay. In order to clarify the scientific considerations in selecting an appropriate *in vivo* somatic cell mutagenicity test, ECHA held a Technical Discussion Session on 4 October 2012.

Forty-four experts from sixteen Member States or Associated Member State Competent Authorities, the European Commission, the European Medicines Agency, the European Food Safety Authority, industry, consultants, contract research organisations and non-governmental organisations visited ECHA for this one-day session.

Experts provided detailed accounts on the science, limitations and practicalities of the two tests. Scientific comparisons and an in-depth analysis of concordance with carcinogenicity of the two assays were presented. The industry experience and per-

spective on the two tests was presented by one of ECHA's accredited stakeholder organisations, ECETOC.

ECHA's sister agencies, the European Medicines Agency and the European Food Safety Authority presented their views on the two tests as well as case studies demonstrating their scientific applicability.

The presentations were followed by a discussion which focused on the question of whether each assay is adequate to detect substances that cause gene mutations *in vivo* and if there were specific conditions which modified the applicability of the assay. Furthermore, it was discussed whether certain conditions could be defined under which either one of the two tests, the TGR or the UDS assay, should preferably be performed.

The event focussing exclusively on science is the first 'Technical Discussion Session' organised by ECHA. The meeting was welcomed by participants. It was in particular acknowledged that the discussion session involving experts from different backgrounds, including regulatory bodies, to share their expertise and views was a successful concept.

ECHA will publish a summary report of the Technical Discussion Session on its website.

The world is watching

ECHA at ICCM-3

TEXT BY PETTERI MÄKELÄ

Delegates participating in the triennial global chemicals management conference in Nairobi in mid-September took a keen interest in the new EU chemicals legislation and ECHA. They asked questions about the current status of REACH and CLP implementation and considered our simple CLP game as an excellent tool in teaching the GHS classification and labelling pictograms.

ECHA had an information stand - "European Chemicals Agency Working for the safe use of chemicals" - and organised a side-event - "European Union Progress towards the World Summit on Sustainable Development 2020 Goals for Chemicals" - together with the European Commission at the third session of International Conference on Chemicals Management (ICCM-3).

The objectives were to inform the conference participants about the current status of REACH and CLP implementation and how the European Union is achieving its objectives towards the World Summit of Sustainable Development 2020 Chemical Goals.

The CLP game attracted visitors to the stand.

The conference at the United Nations Centre in Nairobi was attended by over 400 delegates. Around 280 people from 55 countries visited the ECHA stand and approximately 50 attended the side-event.

The ICCM-3 documents can be accessed through the SAICM website: http://www.saicm.org/index.php?option=com_content&view=article&id=96&Itemid=485

REACH 2013, Act Now!

Make every effort to share data within your SIEF

TEXT BY DIANA ANTAL

In order to reduce animal testing, duplication of work, and to minimise costs, REACH requires the sharing of data among the registrants of the same substance. As the 31 May 2013 registration deadline is approaching, read our tips for successful data sharing.

The REACH Regulation requires the substance information exchange forum (SIEF) participants and data owner(s) to make every effort to agree on the sharing of the information and its costs in a fair, transparent and non-discriminatory way. The tips below will help you to understand how to do it.

1. If you have already registered and are part of a joint submission:

- If you receive a request for data, you must answer it. Keep in mind that potential registrants still have to go through the registration process and submit their dossiers in time.

  For 2010 lead registrants: make sure you have Letters of Access already available for 2013 registrants

- If any of the potential registrant(s) requests it, you need to provide scientific justification for the approach followed in selecting data to demonstrate the safe use of the substance. Especially if the potential registrants have not been involved in the selection of that data.

- Potential registrants are only required to share the costs of information to satisfy their own requirements. For example, if you have relied on read-across to develop different dossiers covering several substances in a category, you cannot ask a potential registrant with only one of the substances, to purchase data used for the registration of the whole category. Unless of course, you can justify the relevance of that particular data for the substance the potential registrant is interested in.

- As an existing registrant, you share an equal responsibility with the potential registrant to share data included in the joint submission.

2. If you are a potential registrant and planning to join an existing submission or your SIEF is just being formed:

- Data sharing negotiations take time. They have to be started well in advance before the deadline so that you can complete them prior to submitting the registration dossier. Whenever you bring new arguments during the negotiations, you have to consider that the other negotiating party needs time to address your arguments.

- Any disagreement you might have during the negotiations must be expressed to the other negotiating party. Any concern you may have has to be communicated directly to that party.

- ECHA is not a party in the negotiations. It is your responsibility to negotiate as far as possible and to challenge the position of the other party. ECHA does not take over this responsibility and does not negotiate on your behalf.

- It is in your interest to conduct the negotiations successfully. Keep in mind that it is always more satisfactory to reach a voluntary agreement between the parties without ECHA's intervention during a data sharing dispute.

DATA SHARING DISPUTES

If there is no agreement reached during the negotiations, there is a possibility to submit a data sharing dispute to ECHA.

The Agency first makes an assessment in order to establish whether the parties have made every effort to agree on the sharing of the information and/or its costs in a fair, transparent and non-discriminatory way.

ECHA's assessment is based on the documentary evidence of the efforts that both parties have made during the negotiations and submitted to ECHA. Therefore, we recommend recording any communication and contact taken with the other party, such as all email and letter exchange and agreed minutes of phone conversations or meetings.

ECHA will then decide to either (1) give permission to the potential registrant to refer to the data (if the joint registration dossier is already available at ECHA); (2) allow the potential registrant to proceed with the registration without the relevant data (if the dossier is not

yet available at ECHA); or (3) ask the potential registrant to continue with the negotiations.

Keep in mind that disagreements on the sharing of the costs and information are covered by Article 30(3) of the REACH Regulation. This article only refers to "any study which involves testing on vertebrate animals". Consequently, if you submit a data sharing dispute and receive a positive decision from ECHA (i.e. permission to refer to the requested endpoints), this permission will only refer to the vertebrate animal data. You will have to generate or obtain non-vertebrate animal data from another source.

Finally, bear in mind that if you submit a data sharing dispute, you have to obtain the ECHA decision before submitting your registration dossier.

In any case, we advise you to keep on negotiating while the procedure is handled by ECHA and inform ECHA if an agreement is reached.

FURTHER INFORMATION

Web page on Data sharing, with links to supporting material
http://echa.europa.eu/regulations/reach/substance-registration/data-sharing

- Guidance on data sharing
- Questions and Answers on Data sharing and related disputes
- SIEF Formation and Data Sharing fact sheet
- Webform to indicate failure to reach an agreement according to article 30 (3)

Webinars on data sharing
http://echa.europa.eu/support/training-material/webinars

- Webinar to Lead Registrants on data sharing obligations and data sharing disputes on 17 January 2012
- Webinar to Member Registrants on the importance of proper substance identification, data sharing and related disputes on 27 March 2012

Newsletters
http://echa.europa.eu/news-and-events/newsletters

- Newsletter of December 2011: Get your data sharing activities ready and be aware of your rights and obligations
- Newsletter of April 2012: Best practice in data sharing

Presentation during the Lead registrant workshop (2-3 February 2012, Helsinki)
http://echa.europa.eu/view-article/-/journal_content/b5961cb7-ee61-4c40-9a14-9068f23f28f9

REACH 2013, Act Now!

How can I find my co-registrants?

TEXT BY LAURENCE HOFFSTADT

To support potential and existing registrants to better fulfil their REACH obligations on data sharing and joint submissions, ECHA has developed a new functionality in REACH-IT.

Multiple registrants of the same substance share two main obligations under the REACH regulation: data sharing and joint submission. While the Regulation provides a framework for interaction between registrants, it does not recommend any particular means of cooperation.

At the end of November 2012, ECHA will release an update of REACH-IT, which will help.

WHO CAN BENEFIT FROM THIS NEW FUNCTIONALITY?

ECHA will put in contact companies that either received a valid registration number or an inquiry number. Consequently potential registrants that did not successfully inquire or previous notifiers under the Directive 67/548/EEC that did not claim their registration number to ECHA will not benefit from this new functionality.

DIRECT ACCESS TO THE CONTACT DETAILS OF YOUR CO-REGISTRANTS

The new functionality will enable companies to access the contact details of existing registrants within REACH-IT. A new page, the Co-registrants page, will provide access to the identity and contact details of other existing registrants (or of their Third Party Representative, or TPR) for substances with the same numerical identifier. So, registrants can see who else has registered their substance and therefore shares obligations under REACH.

ROLES IN JOINT SUBMISSION VISIBLE

The role of the registrants within the joint submission will also be visible. To support companies to further improve their compliance with the

joint submission obligation, the Co-registrants page will display which legal entity is the lead registrant or a member of a joint submission. In addition, legal entities which have submitted within different joint submissions or even outside of any joint submission will be visible to the other registrants.

MAKE SURE YOU ARE PART OF A JOINT SUBMISSION!

ECHA urges all registrants to use this new functionality to ensure compliance with their obligations. For example, a registrant that has submitted their registration outside an existing joint submission is required to contact the lead registrant. Both parties share a common responsibility to make every effort to ensure that they are part of the same joint registration dossier.

ENSURE YOUR CONTACT DETAILS ARE CORRECT AND CAN BE DISPLAYED

The identity of the nominated TPR of (potential) registrants will be automatically extracted from section 1.1 of the IUCLID dossier. ECHA strongly recommends that existing registrants and potential registrants that made successful inquiries check the consistency of the information they have submitted in their dossiers (registrations, inquiries etc.) to avoid their own company information from being unexpectedly disclosed. In the specific case of notifications under Directive 67/548/EEC (NONS), whether claimed under REACH or not, ECHA advises the owner to assess whether their identity needs to be protected.

Companies who want to amend their dossier(s), for example to introduce updated TPR contact details or join or merge existing joint submissions, will need to update their registration dossier before the end of November 2012.

INQUIRY PROCESS STREAMLINED

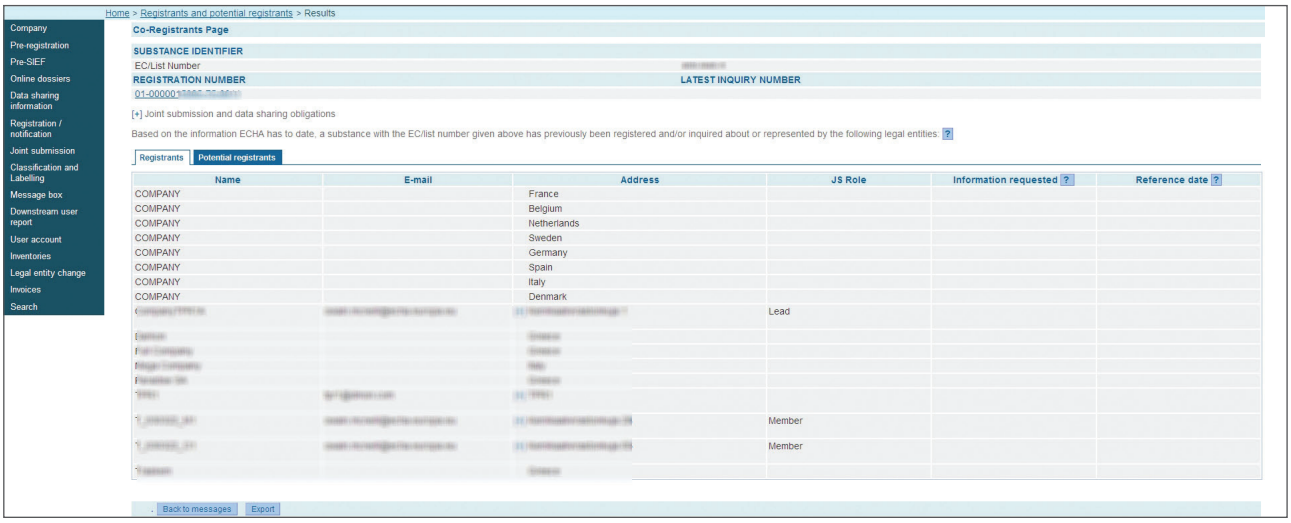
The next REACH-IT release will also enhance the inquiry process. The main requirements to prepare and submit inquiry dossiers will not be affected. However, registrants will be asked to specify their registration intentions, with regards to the expected registration date. Once ECHA has identified the substance and processed the inquiry to an end, the Co-registrants page will then provide direct access to the identity and contact details of the potential and previous registrants, so that inquirers are put immediately in touch with their fellow registrants.

Successful inquirers will access the same information related to other potential and existing registrants. Having said that, any potential difference in company details between inquiry and registration dossiers will become automatically visible to all co-registrants and potential registrants.

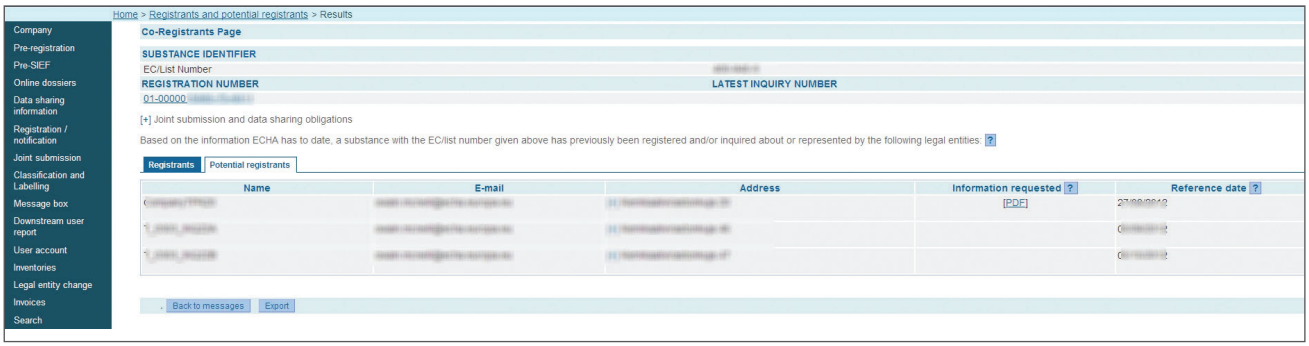
So the important benefit for the inquirers is to get up-to-date and real time information using REACH-IT. This is a major improvement to the existing procedure where ECHA sends the contact details in a paper format, reflecting the status at the sending time. ECHA will continue to improve its technical completeness check plug-in tool (TCC), so that potential registrants can increase the overall quality of the dossiers they submit and increase the success rate of their submissions. These enhancements are expected to shorten the time for succesful inquirers to get the information necessary to register.

VISIBILITY OF ENDPOINTS' DATA

The REACH-IT Co-registrants page will display the endpoints' data requested as part of an inquiry or a request for further information about a substance. This aims to facilitate data sharing between potential and existing registrants.



Screenshot 1: List of existing registrants and related information.



Screenshot 2: List of potential registrants and related information

WHAT INFORMATION CAN I ACCESS ON THE CO-REGISTRANTS PAGE?

The Co-registrants page provides different information according to the status of the registrants:

- Registrants can see the roles of all co-registrants, i.e. whether they are lead or member, of one or different joint submissions. Registrants can also view the potential registrants that successfully inquired.
- Potential registrants, during the 12 months following their successful inquiry, can see all registrants but only the leads are marked.
- Potential registrants, beyond the 12 months of their successful inquiry and if they have not yet registered, will have limited visibility.

FURTHER INFORMATION

Web page on inquiry, with links to supporting material
http://echa.europa.eu/regulations/reach/substance-registration/inquiry

- Questions and Answers on Inquiries
- Data Submission Manual 2: How to prepare and submit an inquiry dossier
- REACH-IT Industry User Manual – Part 18: Co-Registrants Page will be published at the end November 2012

Webinars on substance identification, inquiry and data sharing
http://echa.europa.eu/support/training-material/webinars (November 2011, January 2012 and March 2012)

Two-week interruption of the inquiry process in November (News alert, 25 September 2012)
http://echa.europa.eu/view-article/-/journal_content/a589cd88-a28f-49f1-bb34-a1db12a4218f

ECHA advises registrants to check their company information in REACH-IT (News alert, 17 October 2012)
http://echa.europa.eu/en/view-article/-/journal_content/ab5ae030-41ed-41d0-91d0-e4ac75468406

Presentation during the Lead registrant workshop (11-12 October 2012, Helsinki)
http://echa.europa.eu/en/view-article/-/journal_content/2b6c9ef3-b8c8-4ee1-a15d-bee72a3b47ea

Web page on data sharing, with links to supporting material
http://echa.europa.eu/regulations/reach/substance-registration/data-sharing

REACH-IT
https://reach-it.echa.europa.eu/

http://echa.europa.eu/support/dossier-submission-tools/reach-it/inquiry

THE CO-REGISTRANTS PAGE gives contact information on other registrants (or of their nominated Third Party Representative (TPR)).

It provides information on registrants of the same substance (using the same numerical identifier in their dossiers).

This will help potential registrants and existing registrants to better fulfil their data sharing and joint submission obligations.

ECHA audited for the management of conflicts of interest

Taking an interest in interest management

INTERVIEW BY HANNA-KAISA TORKKELI

Independence and transparency are core values of the Agency. Every day, in all of its activities, the Agency aims to ensure that it is independent from all external interests, takes science-based decisions and that it is as transparent as possible. To ensure this, ECHA has had a system for preventing and handling potential conflicts of interest in place from the very start and has over the past two years strengthened its policy and procedures.

In late 2011, ECHA was audited together with the European Food Safety Authority (EFSA), the European Aviation Safety Agency (EASA) and the European Medicines Agency (EMA), for the management of conflicts of interest by the European Court of Auditors (ECA). The Court published the special report with its recommendations on 11 October 2012. As a relatively young regulatory Agency, ECHA appreciates the fact that it was audited and welcomes the recommendations of the Court. "We very much welcome the report, as it provides us clear guidance on what we still need to do", says ECHA's Head of Executive Office *Alain Lefebvre*. Although the Court of Auditors did not find any instances where an ECHA opinion or decision was compromised by private interests, nor any incompliance with EU legislation, there are areas where ECHA can improve. "The audit was done already in 2011 and we have made huge progress in the meantime. We started to review our practice in managing conflicts of interest in early 2011 and a new policy was adopted by our Management Board in September 2011. This new policy, which is based on the OECD guidelines, was not yet included in the audit scope. At the same time, we also introduced a more detailed declaration of interests template, which all persons that work for the Agency have to complete annually or any time their situation changes. The declarations of our managers, Management Board members, and Committee and Enforcement Forum members are published on our website", Mr Lefebvre points out.

MORE EMPHASIS ON DOCUMENTATION

One of the main findings of the Court is that the Agency has not paid sufficient attention to documenting the interest checks performed. "We have already reinforced the implementation of our policy with regard to documentation and recording of what we have done to avoid conflicts of interest in our activities. In June 2012, we prepared a work instruction on the prevention of conflicts of interest to support our process owners, mainly heads of unit, in detecting potential conflicts of interest. In addition, we have a work instruction on how to deal with potential non-conformities. We are committed to improving the implementation of the policy, checking potential conflicts of interest in each of our activities and documenting the whole process sufficiently", Mr Lefebvre emphasises.

ADVISORY COMMITTEE PROVIDES EXPERT SUPPORT

One important element of the policy is the creation of a Conflicts of Interest Advisory Committee. "On request of the Executive Director, this committee gives expert advice in complicated cases, which are difficult to resolve. It has three members: ECHA's Head of Unit of Legal Affairs, Ms Minna Heikkilä, Mr Antonello Lapalorcia, member of the Management Board and Mr Thomas Henökl who is an Austrian academic, expert in the field. The committee submits an annual report on its work to the ECHA Management Board, which will also be published on the ECHA website.", explains *Bo Balduyck*, legal advisor in the Executive Office.

PROTECTING REPUTATION AND STAFF

Having clear and flexible procedures in place to ensure independence in decision making is vital for the Agency's credibility among its partners and audiences. In addition, it is important for the staff and the external experts working for the Agency. "These procedures are there to protect people working for us from being put in uncomfortable situations. By declaring their private interests in great detail, we make sure that, whenever possible, people are not involved in decision making on issues in which they may appear having an interest. I'm glad that our staff and external experts have been proactive and acted in a very professional and trustworthy way from the very start", Mr Lefebvre says.

Making sure that the decision making is sound is a shared responsibility of managers and staff members. "We have a set of rules in place and now we need to implement it to the full extent, as stressed by the Court of Auditors, and more importantly, document the fact that

we are following the rules. We have increased training to our staff. Every newcomer is introduced to ethics and conflicts of interest. In the coming months, we will have a set of obligatory training sessions for all staff to refresh the awareness of these principles and explain in more detail how to prevent conflicts of interest. We have also held a specific workshop on this issue for all managers", says Mr Balduyck.

TRANSPARENCY IN COMMITTEES' WORK

All the committees, the Enforcement Forum and Management Board members have their declarations of interest published on ECHA's website. In addition, all specific interests are declared at the beginning of each meeting. If someone declares an interest on a topic, they will be excluded from the decision or opinion making. "Furthermore, it is important to remember that the Committees and Forum are collegial bodies that work in full transparency. Decisions are taken by consensus or by majority vote, which prevents that an individual can determine the outcome. In addition, stakeholder observers are allowed to follow the discussions and the minutes of each meeting are published online.", says Bo Balduyck.

DEVELOPING AND SETTING EXAMPLES

Introducing policies and procedures requires constant evaluation and revision. By the end of the year, ECHA will already revise its two work instructions related to conflicts of interest. If needed, improvements will be introduced in early 2013. "We have also planned an audit in 2013 on how we are implementing the conflicts of interest policy and how our procedures are working. The topic will remain a priority for our Agency, and awareness raising and training of our staff will continue", Mr Balduyck points out.

The report of the Court of Auditors could also forms a basis for shared work undertaken by the EU institutions to develop a common Union framework for the management of conflicts of interest. However, this will not happen over night. "A common framework would provide more consistency, but in the meantime we will continue to learn and develop our own practices. As a regulatory Agency, we have to be forerunners", Mr Lefebvre concludes.

FURTHER INFORMATION

ECHA news item, 11 October 2012
http://echa.europa.eu/view-article/-/journal_content/cf3b6aad-7b96-4b78-b399-9586199fbadb

ECHA's independence policies:
http://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/conflicts-of-interest

European Court of Auditors, special report and ECHA's replies:
http://eca.europa.eu/

OECD AND EU FRAMEWORKS ON CONFLICT OF INTEREST MATTERS

The OECD Framework
To effectively manage conflicts of interest in the public sector and ensure that effective procedures to resolve conflict of interest situations, the OECD has mapped "at risk" areas and positions within the public service and has identified a set of core principles and standards for the design and implementation of conflict of interest policies. The results of these analyses are outlined in Guidelines for Managing Conflict of Interest in the Public Service. The publication provides a practical framework of reference for reviewing and modernising existing policy solutions in line with good practice. EU institutions consider its principles and recommendations as an international benchmark when designing conflict of interest policies for the EU public service.
http://www.oecd.org/gov/fightingcorruptioninthepublicsector/managingconflictofinterestinthepublicservice.htm

The European Union Framework
In the European Union, the principles governing the management of conflicts of interest are set by the EU Charter of Fundamental Rights (Article 41), the code of good administrative behavior, and the public services principles for the EU civil servants. Good administration by EU institutions and bodies is a fundamental right defined in Article 41 of the EU Charter of Fundamental Rights. The code of good administrative behaviour, adopted by European Parliament in September 2001, tells citizens what this right means in practice and concretely, what they can expect from the European administration specifically mentioning in Article 8 the importance of impartiality and independence. Finally, the avoidance of conflicts of interest is an important aspect of the second of five EU public service principles: integrity. This principle states that EU Civil servants should be guided by a sense of propriety and conduct themselves at all times in a manner that would bear the closest public scrutiny.

Airing new strategies for REACH implementation

TEXT BY LISA LOCCHI

On 18 September, Vice President *Antonio Tajani*, representatives of the European Commission and a high level delegation from the Chemical Industry visited ECHA to discuss REACH implementation. The focus was especially on innovation and competetiveness, and how to best support SMEs.

Recent years have been a testing time for the European economy. To better understand industry's needs at this time and to explore ways of helping competitiveness and innovation, ECHA hosted this visit. Industry was represented by a CEFIC high level delegation led by *Giorgio Squinzi* who is also President of the leading Italian Industry Association and included *Hubert Mandery*, CEFIC Director General, and *Erwin Annys*, Director of REACH Chemicals' policy.

Also attending were the DG Enterprise and Industry Director-General *Daniel Calleja*, Deputy Director-General *Antti Peltomäki* and Director *Gwenole Cozigou*. The ECHA delegation was led by Jukka Malm, Director of Regulatory Affairs, and Thomas Jakl, the then Chair of ECHA's Management Board.

CEFIC reminded participants that REACH will confront most SMEs for the last registration deadline in 2018. They felt that REACH's impact on innovation and competitiveness was not clear and commented that REACH has increased the time-to-market for new products.

Giorgio Squinzi, speaking for industry, stressed that REACH implementation needs to be compatible with the development of innovation. Other issues also put forward by Mr Squinzi concerned the high costs of REACH especially with regard to SMEs, the complexity of safety data sheets and the need for adequate protection of confidential business information.

Industry representatives showed appreciation for the recent interpretation by ECHA of the strictly controlled conditions for intermediates and suggested ECHA to amend the relevant guidance after the June 2013 registration deadline has passed.

Giorgio Squinzi, Vice President Antonio Tajani and Director-General Daniel Calleja of DG Enterprise and Industry.

In further discussion, Vice President Tajani acknowledged that REACH has posed big challenges to industry and endorsed Mr Squinzi's request to further support SMEs and more generally the innovation and competiveness of the European Chemicals industry.

Commission officials emphasised the need to provide companies with a more stable regulatory framework in which to operate and appreciated ECHA's approach of having a moratorium on the updating of guidance ahead of the next REACH deadline. Boosting competitiveness and innovation is, as reported by the Commissioner, at the heart of future EU industrial policy.

All Commission officials appreciated the results so far achieved by the Agency and acknowledged the efforts made to facilitate knowledge sharing and capacity building on REACH and CLP for SMEs by, for example, leveraging the Enterprise Europe Network for dissemination activities. Director General Daniel Calleja stressed the importance of simplification in terms of reducing the administrative burden stemming from regulatory requirements to better support the EU chemical industry competitiveness.

On the eve of the publication of the REACH Review, Commission Officials suggested a series of measures to support industry when coping with REACH requirements. Firstly, a greater harmonisation of REACH enforcement at EU level,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ECHA Director of Regulatory Affairs Jukka Malm and Vice President Antonio Tajani.

which has also been requested by Industry; secondly, a better integration with other EU regulations on chemicals including possible support for innovation by ad hoc EU funding and, last but not least, a simplification of REACH procedures for SMEs.

For ECHA the visit reinforced that it is on the right course when listening to the concerns of industry and other stakeholders, and doing its best to support all actors in their efforts to comply with REACH.

ECHA will continue to place special emphasis on SME support, especially with regard to the 2018 registration deadline. Ensuring a high level of protection of human health and the environment, and supporting competitiveness and innovation are both objectives of REACH and also included in ECHA's mission. By ensuring an effective and balanced implementation of the legislation ECHA is contributing to these policy aims.

Chair of the Risk Assessment Committee appointed

Tim Bowmer has joined ECHA as Chairman of Committee for Risk Assessment on 1 September. Over the last ten years, Mr Bowmer has been working at TNO in the Netherlands in different positions related to the risk assessment of chemicals.

He has been chairing several bodies at international level such as the United Nations Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP) and its working groups, in particular on the hazard sof chemicals in bulk maritime transport. Mr Bowmer is Irish, has lived in the Netherlands for many years and he is an ecotoxicologist by training.

© ECHA

Tim Bowmer.

Event Calendar

October-December 2012

- Member State competent authorities meeting at ECHA: 8 November
- Workshop on QSAR Toolbox version 3.0: 20 November
- ECHA Management Board: 13-14 December

Tentative dates:

- Forum Working Group - Training for the enforcement trainers 2012: 7-8 November
- ECHA Committee for Risk Assessment (RAC): 26-30 November
- Forum for Exchange of Information on Enforcement: 26-30 November
- ECHA Committee for Socio-economic Analysis (SEAC): 3-5 December
- Member State Committee (MSC): 23-25 October, 10-14 December

International cooperation

Visits to ECHA

29 and 31 October
Israeli Authorities

Speaking engagements

24 October
Shanghai Summit on Chemical Regulation 2012
Kevin Pollard

Substitution of chemicals on the Candidate List for authorisation is already happening

TEXT BY PIA FALLSTRÖM MUJKIĆ

Substitution of chemicals is not easy, but it is a process that is already ongoing, concludes a survey report on REACH. ECHA Newsletter interviewed *Mr Chris Eacott* from Stewardship Solutions Ltd, UK and *Ms Anne-Sofie Andersson* from the International Chemical Secretariat (ChemSec) to get their views on substitution.

One of the objectives of the REACH Regulation is the progressive replacement of substances of very high concern by suitable alternatives. There is already some evidence that companies have started to avoid manufacturing chemicals that have been placed on the Candidate List for authorisation with the result that some chemicals are gradually being withdrawn from the market. Although the full extent of this is still unclear, a survey commissioned by the European Commission and conducted by the Centre of Strategy and Evaluation Services (CSES), showed that 22% of European manufacturers had withdrawn a substance due to its introduction in the Candidate List.

Many well-known companies have already declared that they will phase out the manufacturing or use of substances on the Candidate List. Dr Chris Eacott, Stewardship Solutions Ltd, UK tells ECHA Newsletter that one major benefit of the REACH Regulation should be that the most toxic products will disappear from the EU market. "In one case known to me, the HBCD (hexabromocyclododecane) which is currently applied as a flame retardant to polystyrene beads used to fill some bean bags, might well be replaced by an alternative in the not-too-distant future, due to pressure from a leading UK retailer. Certainly, there have been public announcements about the imminent launch of new, alternative, flame retardants that hopefully will be less toxic than HBCD", he says.

The CSES survey indicates that companies are trying to substitute the substances with less hazardous ones. In fact, only very few respondents had said that they had decided to register a substance on the Candidate List and pay the registration costs.

According to Dr Chris Eacott, many companies are also looking at existing, less harmful chemicals to replace the most toxic ones, which is usually an easier and less expensive approach compared with introducing brand-new substances. "The challenge is often to substitute toxic chemicals with replacements that deliver the same, or at least very similar, technical effects. In practice, chemicals that are taken out from the market can often not be easily substituted. "

A recent development in this field is the SUBSPORT project jointly run by several organisations and funded by the LIFE+ programme of the European Union; the Federal Institute for Occupational Safety and Health (BAuA), Germany; and the Federal Ministry of Agriculture, Forestry, Environment and Water Management (Lebensministerium), Austria. The SUBSPORT is a free of charge, multilingual web-portal for information exchange on alternative substances and technologies. It also contains tools and guidance for substance evaluation and substitution management.

Ms Anne-Sofie Andersson, Director of ChemSec, one of the partner organisations of SUBSPORT, tells ECHA Newsletter that REACH acts as an incentive to find less harmful alternatives. "The REACH Regulation is encouraging substitution thanks to the Candidate List for authorisation as well the Article 33 pressure coming from the consumer side", Ms Andersson points out.

The CSES survey concludes that even though businesses complain about the time and resources necessary to substitute critical substances and point to the uncertainty of developing substances of similar quality, this is a development that is already taking place.

FURTHER INFORMATION

REACH Regulation (Article 33):
http://echa.europa.eu/regulations/reach/legislation

Subsport:
http://www.subsport.eu

Source: Centre for Strategy & Evaluation Services, CSES, 2012, Interim Evaluation of the European Chemical Market after the Introduction of REACH, Final Report, Appendix.

Executive Director visits authorities in Romania and Bulgaria

"More resources needed for chemicals management"

TEXT BY TIIU BRÄUTIGAM

ECHA's Executive Director Geert Dancet visited Romania and Bulgaria in September and October, meeting with the Ministers for Environment. Further improvement of cooperation, resource needs and support for industry were among the topics discussed in both countries.

The Romanian Minister for Environment and Forests, *Rovana Plumb*, discussed with him about resources and possibilities of cooperation. The Ministry staff explained to Mr Dancet that before 2002, no national law on chemicals had existed in Romania. With the help of two twinning projects with EU countries, a real framework and authorities had been established in the last ten years. Also ECHA's training, meetings, events and the continuous guidance had been helpful for the authorities.

In a meeting with the Bulgarian Minister of Environment and Water, *Nona Karadzhova*, current national priorities regarding chemicals management were outlined: support to companies with the upcoming 2013 registration deadline, providing electronic access to information and further training on REACH and CLP implementation and enforcement. The main challenge for the Bulgarian Ministry was the specific scientific expertise required for new REACH processes, such as substance evaluation.

In both countries, the Executive Director highlighted the need for sufficient resources for chemicals management: REACH, CLP and Biocides related tasks require multidisciplinary teams with scientific, legal and IT competence. Therefore, efficient cooperation with different national authorities and research institutions was needed. ECHA could support the national authorities in capacity-building through targeted training in IT-tools and legal matters, workshops, study visits to ECHA and direct contacts with the Agency's experts.

INDUSTRY CONCERNS DISCUSSED

The coordinating Ministries in Romania and Bulgaria have regular contact with stakeholders, providing helpdesks, training and information activities.

In Romania, the chemicals industry has a long tradition, but many areas had lost importance in the last years. Currently, the most important sectors were petroleum processes and petrochemicals, chlor-alkali products, fertilizers, and the manufacturing of mixtures.

During the visit to Sofia, Mr Dancet met representatives of the Bulgarian chambers and associations of chemical, metallurgical and other industrial branches as well as Bulgarian manufacturers and importers of chemicals.

The industry stakeholders raised questions concerning especially the financial burden for small companies facing the registration deadline 2013 and possibilities for training on ECHA's IT-tools. Other topics were the access to currently available registration data, details of the registration process and the guidance on nanomaterials.

Mr Dancet recommended that industry contact the national REACH and CLP Helpdesks for support. He reminded that ECHA's guidance documents were available in 23 EU languages. Furthermore, the national branch chambers and associations could organise training themselves for companies and provide also consultancy services.

Mr Dancet met representatives of six different organisations implementing distinct areas of REACH and CLP in Romania. He also visited the national helpdesk for REACH and CLP and the REACH-IT facilities in the National Environmental Protection Agency.

Highlights of the 27th Management Board meeting

During its meeting on 27-28 September, ECHA's Management Board elected Nina Cromnier as its new Chair and adopted the work programme for 2013. The Board also endorsed a new approach for the multi-annual work programme and adopted provisional eligibility criteria for the appointment of members of ECHA's bodies and key staff.

WORK PROGRAMME ADOPTED FOR 2013

The Board adopted ECHA's work programme for 2013. Among the main challenges of the "peak year" are the second registration deadline in May, the number of compliance check decisions and an increasing work in substance evaluation. The Agency will also face the first authorisation applications and a high workload related to proposals for harmonised classification and labelling. In addition, the Biocidal Products Regulation will become operational on 1 September 2013. In order to manage all challenges with the available resources, increased efficiency will be required in all areas.

The final programme will be published on ECHA's website and available in 23 EU languages.

MULTI-ANNUAL WORK PROGRAMME BUILT ALONG STRATEGIC OBJECTIVES

A new strategic approach to ECHA's multi-annual work programme was endorsed. In future, the programme covers a five-year cycle instead of three and will be structured around ECHA's four strategic objectives. This approach should help the Agency to prioritise its future work load and to allocate its reduced resources in an efficient way.

NEW ELIGIBILITY CRITERIA FOR APPOINTMENTS

The Management Board adopted provisional eligibility criteria and guidelines for the appointment of members of ECHA's bodies and key staff. These followed from ECHA's policy on managing potential conflicts of interest. The aim is to safeguard the independence, integrity and credibility of ECHA's decision-making process.

Further items on the agenda included budgetary amendments, discussion about biocides related tasks and implementing rules for Staff Regulations.

The preliminary conclusions of the meeting have been published on ECHA's website
http://echa.europa.eu/management-board-documents

Nina Cromnier, new Chair of ECHA's Management Board

The ECHA Management Board elected *Nina Cromnier*, the Swedish member, as its new Chair for a period of two years. She took up the post on 1 October 2012.

Nina Cromnier has been the Director General of the Swedish Chemicals Agency since 2010. Before that, she worked at the Swedish Ministry of Environment, her last position being the Director for Chemicals and Waste Division. Ms Cromnier has lead EU delegations in international negotiation meetings of the UN Environment Programme. During the Swedish EU Presidency in 2009, she chaired the EU's international working group on chemical issues. Previous career steps included posts at the Swedish Environmental Protection Agency and the Swedish Waste Research Council. She holds a degree in Chemical Engineering and another in Business Administration. Ms Cromnier has been a member of ECHA's Management Board since 2010.

The former Chair, Mr Thomas Jakl, the Austrian member, led the Board for two full terms from 2008. He steered the Board during the crucial set-up phase of the Agency and through a successful first REACH registration deadline. He was at the helm during the recent challenges including the start of the preparations for an extended ECHA mandate under Biocides and PIC as well as the preparations for the 2013 REACH deadline. The term of office for the Chair is two years and can be renewed once.

Nina Cromnier (left) is the new Chair of ECHA's Management Board. Thomas Jakl led the Board for two full terms, from 2008.

Evaluation statistics

REPORT ON DOSSIER EVALUATION ACCORDING TO ARTICLES 40 AND 41 REACH

Dossier evaluation covers the compliance checks of registration dossiers and the examinations of testing proposals. In the 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/evaluation

Tables A to C report on the dossier evaluation processes from 1 June 2008 to 30 September 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 30 September 2012.

		Phase-in*	Non phase-in	Total
No of registered dossiers [1]	containing testing proposals	497	62	559
	containing testing proposals for vertebrate animals	395	43	438
No of endpoints	covered by registered testing proposals	1 005	123	1 128
	covered by registered testing proposals for vertebrate animals	655	72	727
No of public third party consultations	closed	461	41	502
	ongoing on 30 September 2012	4	7	11
	planned	10	1	11
Dossiers with testing proposals opened for examination [2]		580	84**	664
Draft Decision sent to the registrant [3]		238	21	259
Final Decision sent to the registrant		111	33	144
Terminated testing proposal examinations [4]		116	18	134

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

** Some registration dossiers were opened for examination more than once, hence the difference vs. 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 30 September 2012 nor withdrawn due to termination of testing proposal examination (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 2012.

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check[1]	523	146	669
Draft Decision sent to the registrant [2]	100	4	104
Final Decision sent to the registrant	125	45	170
Only Quality Observation Letter sent to the registrant [3]	13	47	60
Terminated compliance checks[4]	59	45	104

[1] Dossiers ever opened for compliance check notwithstanding their current status.
[2] Draft decisions which did not become final by 30 September 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]	19 772
5% target for the compliance checks on registration dossiers motivated by the 2010 deadline [3]	989
No of dossiers opened for compliance check [4]	476
Draft Decision sent to the registrant [5]	93
Final Decision sent to the registrant	112
Only Quality Observation Letter sent to the registrant [6]	9
Terminated compliance checks [7]	47

[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 19 772 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 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.

Detailed REACH registration statistics now available on ECHA's website

The Agency is publishing detailed statistics on the origin and types of REACH registration dossiers and registered substances on its website. At present, the statistics provide various breakdowns of the total volume of registrations received from June 2008 until 31 August 2012. ECHA will update the statistics regularly.

Top 10 most frequently registered substances, data as of 31 August 2012.

Substance	Registrations
calcium dihydroxide	322
ethylene oxide	314
ethanol	306
iron	301
calcium sulphate	264
Fuels, diesel	240
calcium oxide	229
Ashes (residues), coal	216
methyloxirane	211
ethylene	179

! This table is based on new registrations under REACH. NONS* are excluded.

*NONS = All substances that have been notified under Directive 67/548/EEC (also called NONS) and have a recognised notification number are regarded as registered under REACH. ECHA started making information from these notifications available as of May 2012. The NONS registration dossier must be updated if at least one of the cases laid down in Article 22 or Article 24(2) of the REACH Regulation applies. This would also include any update referring to the inclusion of the information required under Article 40 of the CLP Regulation (notification to the Classification & Labelling Inventory).

Registration statistics: http://echa.europa.eu/information-on-chemicals/registration-statistics

Information on registered chemicals: http://echa.europa.eu/information-on-chemicals/registered-substances

Information on phase-in substances intended to be registered for 2013 deadline and active lead registrants: http://echa.europa.eu/reach-2013