ECHA
EUROPEAN CHEMICALS AGENCY
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Newsletter

ECHA takes on new tasks

This summer has been marked by three important dates for ECHA. Firstly, 1 June was special for us in terms of marking what has been achieved so far in our work. It has been five years since REACH came into force, and ECHA started its activities in Helsinki to manage the implementation of the regulation. In these five years, we have achieved a lot, in good cooperation with industry, the Member States and the European Commission, in ensuring good-quality information is available on substances and in addressing chemicals of concern. I want to thank you all for this.

The second date marks the beginning of important new work for us. The EU Biocidal Products Regulation entered into force on 17 July 2012, and the coordination of the current EU biocides scheme is transferred from the Commission to ECHA. Therefore, ECHA is actively preparing to take on its new responsibilities that will formally begin on 1 September 2013, i.e. when the regulation comes into operation. By that date, we have to prepare the IT systems to receive biocides dossiers, to create the Biocidal Products Committee and to recruit and train experts.

The new regulation builds on and improves the current Biocidal Products Directive; in particular a new EU authorisation scheme for biocidal products is introduced. The scheme for biocides is in certain aspects more complex than REACH, and although the number of dossiers will be smaller, the workload will still be significant, in particular for the Biocidal Products Committee, who will deliver the opinions on Union authorisation. There is a tight timeline for our preparations, but we can build on our experience with setting up the REACH and CLP processes, and fortunately there is considerable expertise among the ECHA staff on the current Biocidal Products Directive.

A key element of the preparations for the improved biocides scheme will be to inform industry of the upcoming changes, giving special attention to the needs of small and medium-sized enterprises. You can read more about the Biocidal Products Regulation on page 8.

The third summer date for us was 16 August 2012 when the revised Prior Informed Consent (PIC) Regulation entered into force after being formally approved. This recast of the PIC Regulation will transfer the implementation tasks of notifying export and import of hazardous chemicals from the European Commission to ECHA from 1 March 2014. As we will be responsible for most of the administrative tasks of the Regulation, we are now beginning preparations for the necessary tools and processes. An update on PIC can be read on page 15.

These new activities must not be allowed to take our attention away from our existing priorities with REACH. Therefore, I encourage you to push forward with progress on your 2013 registrations – the May deadline is getting ever closer. The lead registrants should be ready to submit their dossiers already in March 2013 to allow time for the member registrants to follow. To that end, we are organising a lead registrant workshop on 11 to 12 October here in Helsinki, with the aim of providing hands-on assistance to the lead registrants in working with substance information exchange forums (SIEFs), preparing their dossiers and communicating down the supply chain.

We are concerned that those substances due for registration next year really will be registered by the deadline. In particular, on 30 July 2012, there were still 778 substances identified to be registered by the May 2013 deadline for which ECHA has not received a lead registrant nomination nor a registration. I call on the missing lead registrants to make themselves known to ECHA in order to benefit from our targeted support. You can notify yourselves on our REACH 2013 campaign page: http://echa.europa.eu/reach-2013

Finally, I wish our various stakeholders and colleague regulators strength for the busy autumn.

Geert Dancet
Executive Director

"I call on the missing lead registrants to make themselves known to ECHA in order to benefit from our targeted support."

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ECHA five years

From a start-up to a well-established authority

TEXT BY HANNA-KAISA TORKKELI, COMPILED FROM ECHA REPORTS

The European Chemicals Agency was set up on 1 June 2007 in Helsinki to ensure the effective management of the REACH Regulation. In five years, the Agency has successfully managed the pre-registration phase, the first registration and classification and labelling deadlines, published safety information on registered substances and introduced new REACH processes. Along the way, ECHA has grown from 37 seconded European Commission officials to 500 statutory staff. Yet, the work continues to maintain the credibility and the leadership of REACH in the world.

2007 - SETTING UP THE AGENCY

The Agency was founded in the centre of Helsinki, in a building owned by the Finnish insurance company. A handful of experienced officials from the Commission came to Helsinki to set up the Agency and develop its processes. The Commission appointed Mr Geert Dancet as the Interim Executive Director to lead the work. Later in December, Mr Dancet was officially appointed as Executive Director by the ECHA Management Board.

Over the year, the REACH and IUCLID helpdesks were transferred from the Commission to ECHA. Guidance documents, which were prepared by the Commission and the stakeholders, were translated and published by ECHA.

The Agency also launched its website to serve as the main source of information regarding REACH and set up three Committees and the Enforcement Forum. At the end of the year, the Agency had 102 staff.

2008 - PRE-REGISTRATION

ECHA became financially independent from the European Commission on 1 January 2008 and officially joined the cluster of European Institutions and Agencies. The major challenge in the first half of the year was to get ready for the entry into operation of REACH on 1 June and support companies in applying the new regulatory procedures of the REACH Regulation.

The main activity for 2008 was to inform companies about the pre-registration period for phase-in* chemical substances. In collaboration with the Commission, ECHA launched an awareness campaign, organised its first Stakeholders' Day and published tools to support companies in their pre-registration efforts. Pre-registrations began on time, reaching a high peak in October which put pressure on the Agency, but they were successfully concluded by 1 December. A list of pre-registered substances was published in December containing more than 2.7 million pre-registrations, a number that exceeded 15 times the original estimates.

In addition, ECHA launched a public consultation on the first substances proposed by Member States to be identified as substances of very high concern (SVHCs). A list of 15 substances to be included on the candidate list of substances for authorisation was unanimously approved by the Member State Committee and published at the end of October 2008.

*substances subject to transitional arrangements in the REACH registration

2009 - PREPARING FOR THE FIRST REGISTRATION DEADLINE

The year 2009 was challenging for everyone involved in REACH - industry, Member States, the European Commission and ECHA. It was a race against time to prepare for the first REACH registration and the new classification, labelling and packaging (CLP) notification deadlines. ECHA launched a campaign to assist companies in getting the substance information exchange forums (SIEFs) functioning and tidied up the list of pre-registered substances to make the SIEF groupings more useful and accurate. It also streamlined the dossier submission process and launched a technical completeness check (TCC) IT tool. The Agency's aim was to assist companies directly by organising workshops and events, contacting registrants individually and running online webinars.

Continues on the next page...

Official inauguration in June 2008. Commission President José Manuel Barroso and Vice-President Günter Verheugen handed over the list of substances considered registered under REACH at a symbolic ceremony to Geert Dancet.

The public online portal of registered chemical substances was launched in December 2009 providing information on the hazards and safe use of 129 substances. By the end of year, the number of statutory staff had grown to 320.

2010 - FIRST MILESTONE

To improve efficiency in submitting and handling registrations, the dossier submission tool REACH-IT was re-engineered in 2010 to improve its functionalities. Other IT tools were developed to allow companies to compile and check their dossiers efficiently. The TCC tool proved a success: after its release in December 2009, the TCC success rate increased to above 98%.

The first landmark in the implementation of REACH was reached with the first registration deadline. By the deadline, on 30 November, ECHA had received 25 000 registration dossiers for 4 300 substances that are either commonly used in Europe or are the most hazardous. Another major achievement for the Agency was to receive over three million classification and labelling notifications from industry for over 100 000 substances that are classified and have to be labelled to protect the user.

ECHA's ambitious vision is to become the world's leading institution on chemicals management.

In 2010, ECHA concluded its first cooperation agreements with third countries. A Memorandum of Understanding was signed with Environment Canada and Health Canada in May and a Statement of Intent later in the year with the US EPA Office of Pollution Prevention and Toxics. By the end of the year, the number of statutory staff had grown to 450.

2011 - FOCUS ON EVALUATION AND DISSEMINATION OF DATA

After the first registration and notification deadlines, the focus of the Agency shifted to evaluation and dissemination of the received information. In 2011, the emphasis was on examining dossiers containing proposals from companies to test substances on animals. However, unclear substance identity in many of the corresponding dossiers prevented a meaningful examination of testing proposals and forced the Agency to perform a targeted compliance check first. This almost doubled the number of planned compliance checks and slowed down the examination of testing proposals.

On the dissemination front, safety information from more than 23 000 registration dossiers covering more than 4 100 substances were made freely available through the registered substances database on ECHA's website.

The Agency also delivered its first five-year report on the operation of the REACH Regulation. The first three-year report on the status of implementation and use of non-animal test methods and testing strategies was also produced.

ECHA's organisational structure was changed at the beginning of the year to better respond to the increasing workload and the demanding scientific tasks. A more horizontal organisation with three new directorates was created. The reorganisation was complemented with the launch of a revised corporate identity and a new visual identity that highlights the service-orientation and ambitions of ECHA towards its customers. The new website showcasing the new visual identity was launched in December. At the end of the year, ECHA had 503 statutory staff members.

2012 - REACHING MATURITY AND SETTING FUTURE PRIORITIES

ECHA has now grown to one of the largest EU regulatory agencies with an ambitious vision of becoming the world's leading institution on chemicals management. In five years, it has managed to put in place the regulatory processes introduced by the REACH and CLP Regulations. To steer the work onwards, the ECHA Management Board has prolonged the mandate of the Executive Director for another five years and agreed on four strategic long term goals to set priorities for the activities of the Agency.

The first strategic aim is to improve the quality of the data submitted by industry and published by ECHA to enable the safe manufacture and use of chemicals. The second goal is to mobilise authorities to use REACH and CLP data intelligently to identify and address chemicals of concern with the most appropriate risk management measures.

The third aim is to address the scientific challenges by serving as a hub for the scientific and regulatory capacity building of Member States, European institutions and other actors. Finally, the fourth strategic aim is to embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.

"The achievement of the four strategic aims in the coming years is essential for the success of the entire REACH system. In order to achieve them we need to cooperate constructively with all our stakeholders", says ECHA Executive Director *Geert Dancet*.

Bjorn Hansen:

"ECHA is centrally important for the EU"

INTERVIEW BY HANNA-KAISA TORKKELI

Head of Unit for Chemicals, Biocides & Nanomaterials at DG Environment, *Mr Bjorn Hansen*, was one of the European Commission Officials who were seconded to Helsinki to set up ECHA in 2007. Now, five years later, he looks back on his time at the Agency and reflects on the years to come.

Bjorn Hansen.

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You worked at ECHA during 2007-2008, setting up the Agency. What was the experience like? In your opinion, how has ECHA developed in five years?

My year at ECHA was one of the most exciting professional experiences I have ever had. It was fantastic to have met the challenge of 220 completely unpredictable days in the office with a group of very motivated, fun and professional colleagues. Five years later, I am back in Brussels seeing ECHA develop to full size, from the outside. It is a luxury position to judge ECHA from my office window in Brussels, but I would say that ECHA has grown according to my expectations.

There have been numerous successes in ECHA's life span from pre-registration to the first registration deadline, the Classification and Labelling Inventory, evaluation decisions and Annex XIV proposals. The Committees take decisions and the ECHA Helpdesk never fails. But these milestones are steps in a bigger picture.

At every step you need to look at what can be improved, what can be simplified, what work was crucial and what was not. Each of these milestones were expected to be reached – REACH would be a failure had any one of them not been met.

You have said that there are four key factors for the success of REACH implementation: "scientifically respected ECHA; an industry, which takes its responsibility and cooperates with the Agency; Member States that never lose sight of what REACH intends to do and a Commission that works efficiently, coherently and closely with ECHA". Are we on the right track?

The right track has two components: direction and distance. I think the direction is right, but there is still work to do to get the distance right. There is 'a scientifically respected ECHA', which does not mean the best science, but rather the best science-based decisions. REACH is constructed to make efficient science-based decisions and not to make the best science. It does, however, require good scientific knowledge to implement such a regulation and in my opinion this is an area where more work is needed.

The industry has taken the challenge and done their work but what we should not forget is that industry is an economic operator and the way in which the sticks and carrots are built into REACH is based on that logical, market oriented business fact. I remember at a conference where a person responsible for safety in a company praised the arrival of REACH as it will give them the legal basis to get the test data they have wanted for years, but could not make the business case for. To me, this is in a nutshell what REACH is about.

With the enormous implementation work being driven by an Agency of 500 staff, a lot of pressure is placed on the Member States and the Commission to keep up and they sometimes seem to forget the big picture of REACH. One example is evaluation. For me REACH intended to have compliance check as a fast, efficient and simple information generation machine, rejecting poorly justified derogation statements. We are not there yet, but we need to get there to obtain the information to promote the safe use of registered substances as well as to create a knowledgebase that will help us understand toxicity well enough to reduce testing on animals in the long run. As for the Commission, we could definitely improve in efficiency!

How do you see the role of ECHA in the framework of all EU Agencies?

Chemicals are important for Europe and important for the European citizens in terms of the quality of life they bring; jobs, innovation and research, which the industry stimulates. The chemical industry contributes to the wealth of Europe. On the other hand, chemicals are important because of the safety concerns related to their use. So, ECHA is centrally important for the EU - and beyond - and will gain in importance as the chemicals legislation develops.

What are the future challenges of ECHA?

The workload will increase, the expectations will rise and resources will be cut. Against this reality, the biggest challenge is to become more efficient.

ECHA's second lead registrant workshop prepares industry for the 2013 registration deadline

TEXT BY ADAM ELWAN

ECHA has the pleasure to welcome companies to Helsinki from 11 to 12 October for its second workshop for lead registrants who are preparing for the 2013 registration deadline. The event takes place in ECHA's new conference room.

INFORMATION SESSIONS EXCLUSIVELY FOR LEAD REGISTRANTS

The workshop is part of a series of information sessions directed towards lead registrants. It is a key milestone in the REACH 2013 campaign and enables lead registrants to receive information and guidance on how to best fulfil their roles and prepare high quality registration dossiers ahead of the deadline.

The event will cover three main topics:

- **2013 registration and SIEFs** - update on the status of substance registration and lead registrant nomination;
- **Dossier preparation and submission** – information requirements, dossier preparation, classification and labelling and the chemical safety report;
- **Information in the supply chain** – downstream user obligations and practical advice, exposure scenarios and safety data sheets.

INDUSTRY LEARNING FROM INDUSTRY

The majority of the workshop programme will be chaired and presented by ECHA but some of the content will also be provided by industry associations and lead registrants with experience from the 2010 registration deadline. The content of the workshop also includes training/live demonstration of IT-tools (IUCLID, REACH-IT, Chesar). The training sessions have been adapted based on feedback from participants of the previous workshop in February 2012.

ONE-TO-ONE SESSIONS

Participants have the opportunity to book one-to-one discussions with ECHA staff about topical issues and receive guidance on specific problems they are facing.

SME REIMBURSEMENT

To support the participation of SME lead registrants, the Agency is offering a limited number of free places to cover the costs of their travel and accommodation. In order to qualify for reimbursement, SME lead registrants must indicate their SME status during online registration for the workshop by submitting a self declaration.

REGISTER BY 21 SEPTEMBER

A total of 300 places are available for the workshop. Attendance to the event is by invitation only for lead registrants that have notified the Agency about their role through the lead registrant notification webform on the ECHA website.

WEBSTREAMING

The majority of the presentations and training can be followed live via web streaming. A video recording of the workshop will be available on ECHA's website.

FURTHER INFORMATION

Second lead registrant workshop
http://echa.europa.eu/en/view-article/-/journal_content/2b6c9ef3-b8c8-4ee1-a15d-bee72a3b47ea

Lead registrant notification webform
https://comments.echa.europa.eu/comments_cms/LeadRegistrantNotification.aspx

SME verification
http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/sme-verification

Participants following presentations at ECHA's first lead registrant workshop in February.

More information on chemical substances to be published on ECHA's website

TEXT BY VASILEIOS TSIFOUTIS

From November, ECHA will start publishing more information from registration dossiers, including the name of the registrant, the registration number of the substance, and other items normally contained in a safety data sheet (SDS). Registrants can request for the information to be kept confidential by updating their dossiers by 31 October 2012.

The decision to publish this additional information was taken by ECHA in 2011 and is in line with Article 119(2)d of REACH. Information made available will include the identities of the registrant(s) of a registered substance, the registration number(s), an indication of whether a chemical safety assessment (CSA) was performed and the results of the PBT (Persistent, Bioaccumulative and Toxic chemicals) and vPvB (very Persistent and very Bioaccumulative) assessment. Companies wishing to request confidentiality on these items need to update their dossiers and justify their requests for confidential treatment.

ECHA encourages all registrants to review their dossiers and to use the upgraded IUCLID 5.4 dissemination plug-in which will help in identifying the data that will be published. The plug-in is available free of charge on the IUCLID website. Other sources of help are the questions and answers document on dissemination and confidentiality claims of safety data sheet information in IUCLID 5.4 published in June and the updated Data Submission Manuals 15 (on dissemination) and 16 (on confidentiality claims) now available on the ECHA website.

Dossiers that need to be updated with confidentiality requests **should be resubmitted by 31 October 2012**. From November onwards, ECHA will publish all safety data sheet information that has not been claimed confidential. At the same time, registrants are also encouraged to complete the newly introduced section on the PBT and vPvB assessment of their substance. This information will also be made public. Information from registrations of previously notified substances (NONS) will similarly be made available on the website.

FURTHER INFORMATION

Additional information on chemical substances to be published, ECHA news alert 24 July
http://echa.europa.eu/view-article/-/journal_content/acde6540-cfbc-420c-b0cf-0b58485c7da9

ECHA refines its methodology for calculating "total tonnage" bands

ECHA has identified some shortcomings in the implementation of the rules for determining the total tonnage for each chemical substance manufactured or imported in the EU. These shortcomings arose from the fact that the REACH Regulation is based on the concept of legal entities rather than companies, which in some situations could lead to involuntary disclosure of confidential business information.

ECHA has now decided to modify the envisaged methodology on how to calculate aggregated tonnages, leaving out the four registrants rule before publication of any tonnage band data on the ECHA website. This rule foresaw that the tonnage data, which has been claimed confidential by a registrant, would still be included in the calculation of aggregated tonnages if there are four or more registrants in a joint submission. The modified rules are explained in a corrigendum to the initial news alert. The publication of tonnage bands on ECHA's registered substances database that took place for the first time in June already took the modifications in the calculation method into account.

The rules that ECHA decided to use to determine the total tonnages of chemical substance were originally communicated in a news alert on 18 April 2012. The "total tonnage band" is published together with other substance-specific information on ECHA's website.

Further information
ECHA to publish total tonnage band for registered substances, ECHA news alert corrigendum 25 July 2012
http://echa.europa.eu/en/view-article/-/journal_content/81cace06-43bf-4756-aa10-784f3561ea4c

The new biocides regulation offers new opportunities for business and industry

INTERVIEW BY SUSANNA DUNKERLEY

The Biocidal Products Regulation recently entered into force and the new requirements will apply from September 2013. With just over a year to go, business and industry should already be considering how the changes will affect them.


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The newly appointed Chair of the Biocidal Products Committee, Mr Erik van de Plassche (right) and his colleague Steve Hollins say that the new Biocidal Products Regulation will streamline and simplify the old directive. It is estimated that this will bring €2.7 billion in savings to industry over ten years.

ECHA established a new unit for biocides at the beginning of this year, which has become fully operational on the entry into force of the new regulation on 17 July 2012. Selections and recruitment are ongoing as the unit will expand next year to prepare ECHA for its upcoming tasks. Chair of the Agency's new Biocidal Products Committee *Erik van de Plassche* and the Committee Secretary *Steve Hollins* talk to ECHA Newsletter about how the new rules for placing biocidal products on the market will work.

Biocidal products, including disinfectants, insect repellents and many other products, have been subject to EU law under the Biocidal Products Directive since 1998. The new regulation, which ECHA has been tasked to play a central role, aims to streamline and simplify the old directive and in doing so deliver an estimated €2.7 billion in savings to industry over ten years. Under the two step approach, companies will still need to gain approval for active biocidal substances and authorisation for biocidal products to sell their products on the market. But unlike the old system where applications for authorisation of biocidal products had to be made to individual Member States, companies will for the first time be able to seek Union-wide market authorisation.

Committee Chair Mr van de Plassche says improving free movement across the market is likely to be of economic benefit to many European companies. "This opens the possibility for companies to place their products directly on the entire EU market", he says. Companies can still opt to submit applications at an individual Member State level, which may be of benefit to small and medium-sized companies operating in a smaller market.

There will be a fee to submit authorisation applications to ECHA, which is still to be determined by the European Commission but Mr van de Plassche says companies that opt for Union-wide authorisation will not have the burden of separate application fees and procedures to each individual Member State where they want to do business.

European-wide authorisation will be possible for most biocide product types but excluding a limited number of biocides, for example antifouling products used on ship hulls that will still require applications to be made only at an individual Member State level. Mr van de Plassche says it will be helpful if companies can contact ECHA to inform the Agency if they will seek Union-wide authorisation ahead of the September 2013 deadline. This functionality will be incorporated in the dedicated IT platform, the Register for Biocidal Products, which will be used to submit applications.

BINDING DEADLINES AND ANIMAL WELFARE

Another positive change that the new regulation delivers to industry are the fixed timelines, Committee

Secretary Steve Hollins points out. For example, the new Biocidal Products Committee will have to consider new active substance approvals within nine months and new biocidal product applications for Union authorisation within six months, in contrast to the open-ended timeframe under the old system. This means that "industry will now have predictable timelines in which to get their products onto the market", Mr Hollins says. "But meeting these strict deadlines is going to require a considerable cultural change for everybody involved", he says.

Another important change business needs to be mindful of is the compulsory sharing of data to reduce animal testing. Similar requirements are already in place under the REACH Regulation.

Committee Chair Erik van de Plassche says it would be helpful if companies can contact ECHA to inform if they will seek Union-wide authorisation ahead of the September 2013 deadline.

NEW RULES FOR TREATED ARTICLES AND ALTERNATIVE SUPPLIERS

Articles treated with biocidal products, such as furniture treated with wood preservatives, will now be covered by the regulation. Mr van de Plassche says this will also impact companies based outside of Europe and wanting to operate in the EU market. In order to be able to place treated articles on the European market, companies will have to use biocides that have already been approved within EU.

Another key feature of the new regulation is aimed at alternative suppliers: persons placing biocidal products on the EU market will have to hold the data on active substance, either by submitting their own data or via a letter of access. ECHA will compile a full list of companies that have followed the requirements and from September 2015 onwards those that have failed to comply will be forced to take their products off the European market within a year.

ECHA is working on a new IT tool (Registry for Biocidal Products) to submit dossiers, which is scheduled to be operational by September 2013. The whole application process will be online and ECHA will provide training and information sessions ahead of the IT tool's launch. In addition, ECHA is preparing together with the Commission the necessary guidance. "We are preparing guidance for new elements in the regulation but also considering to restructure the guidance already available under the old system to make it more user friendly", Mr van de Plassche says.

A separate section of the ECHA website containing basic information on the new regulation and processes is already up and running. ECHA will also in 2013 deliver a focused Helpdesk and email address for business with

Steve Hollins highlights that to efficiently implement the new regulation ECHA, the Member States, industry and other stake-holders will have to work together.

questions and queries about the new regulation.

In summing up, Mr Hollins says successfully implementing the regulation will be a real team effort between ECHA, the Member States, industry and other stakeholders. "ECHA will be sitting in the centre of this, coordinating and facilitating, but we would like to construct a strong partnership with the Member States and the applicants to be sure we can all deliver what the new legislation intends."

FURTHER INFORMATION

Biocidal Products Regulation web pages on the ECHA website
http://echa.europa.eu/regulations/biocidal-products-regulation

Biocidal Products Committee
http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

Registrants play a role in the substance evaluation process

TEXT BY VIRGINIA MERCOURI & PIA KORJUS

Organising informal interaction between the evaluating Member States and the registrants of substances on the Community Rolling Action Plan (CoRAP) list was discussed during the substance evaluation workshop arranged by ECHA from 4 to 5 June 2012.

During the workshop, representatives of the national competent authorities and ECHA's accredited stakeholder organisations discussed practicalities for the substance evaluation procedure. One of the topics was how to organise informal interaction between the evaluating Member States and the registrants of substances on the CoRAP list. Such interaction can provide transparency and facilitate the process as well as improve the quality of the information in the dossiers to ensure sound scientific analysis of the potential risks for which the substances will be evaluated.

The workshop participants agreed that in order to make this new process successful both the Member States and the registrants need to be proactive. Member States should contact the lead registrant of a specific substance and be ready to start the interaction as soon as it is evident that they will evaluate the substance. On their part, the registrants should organise themselves for the dialogue so that one registrant, presumably the lead registrant, coordinates the views and remains in contact with the evaluating Member State. The registration dossier of each substance under evaluation has to be complete and up-to-date. If the registrants plan to update their dossier, this should be done before the substance evaluation starts. Legal timelines for the evaluation are short and stringent, making it difficult to take new information into account during the process. If updating the dossier is not possible before starting the substance evaluation, the lead registrant should clearly communicate to the evaluating Member State the plans for the update and the type of new information that will be provided.

During the evaluation phase, the dialogue with registrants can focus only on the technical information of the substance.

Where substance evaluation results in a draft decision, registrants of the same substance are advised to coordinate their views and submit only one set of comments on behalf of all of them.

René Korenromp from the Dutch Competent Authority is convinced that both registrants and the evaluating Member State will benefit from interactions early in the process. "Registrants have already been approached by us to share studies underlying the robust study summaries for the substances that we are evaluating. This is essential information for our work and it is very important that we get this information at the right moment." He explains that the twelve months given to the Member States for substance evaluation may seem long, but the actual time for analysing the dossiers and, where available, additional information from literature is short. "It is not possible to take updates of the registration dossiers into account once the evaluation has started", says René Korenromp and reiterates that it is of mutual interest that updates of the information happen before the evaluation starts.

Member States may contact registrants as soon as they know they will evaluate the substances and it is recommended that the registrants in response share their plans for updating the dossiers at that time. Mr Korenromp believes that in this way interactions for the next round of substance evaluation in 2013 will make an efficient start at the very beginning of the evaluation work.

In October, ECHA will organise a dedicated webinar on substance evaluation and the role of registrants in the process.

ECHA Guidance - Why? Who? How?

TEXT BY PETER MEGAW

ECHA guidance provides readers with a deeper understanding and better knowledge of the obligations under the REACH and CLP Regulations. The work on guidance has recently been particularly intensive to provide the registrants valuable support in preparing for the upcoming deadline of 31 May 2013. As with the first deadline, the publication of relevant guidance will be 'frozen' six months prior to the deadline to provide registrants stability and certainty in their preparations.

Why write guidance?

REACH and CLP are complex regulations. Those with obligations under these regulations need help in complying with them. This is particularly important for those who will be registering substances under REACH by the second registration deadline of 31 May 2013. ECHA's guidance aims to provide this help. Guidance is not legislation but those following it can be considered as taking reasonable steps to comply with their duties.

Who is our audience?

The audience for the 2013 and 2018 deadlines will increasingly be small and medium-size enterprises and therefore the guidance needs to be more accessible, compared to the audience for the first registration deadline of 1 December 2010. A key audience for this registration deadline was registrants of substances at the 1 000 tonnes or more level – i.e. usually large companies with internal knowledge and expertise.

How will ECHA cater for the new audiences?

We are learning from experience. ECHA recognises the need for stable guidance in advance of a registration deadline. We will impose a six month moratorium on the publication of new final guidance from 30 November 2012 until 31 May 2013. We have already published key guidance updates by May 2012 (a full year before the next REACH deadline), which included, for example, major revisions of the guidance on registration and on data sharing and a series of new annexes to existing guidance to help registrants dealing with nano-materials.

Will ECHA stop work during the moratorium?

No! Firstly because REACH provides for only part of ECHA's guidance work. We are already working on major updates to the CLP guidance, for example to take account of the provisions of the second adaptation to technical progress of CLP, which apply to substances from 1 December 2012. Guidance updates on this are not subject to the REACH guidance moratorium, but are still desirable as soon as practicable. Secondly there is much other guidance on REACH that needs updating, either because of changes in REACH or because it was written when there was little or no actual experience of the processes which it described. Examples of this include guidance for downstream users on communication in the supply chain, including how to deal with exposure scenario information, especially for mixtures. We have been aware of these issues for some time, but with the given resources we have had to focus on the most immediate needs concerning substances first rather than mixtures. Another issue is how to improve the integration of the "formal" guidance discussed above with various other types of documents produced by ECHA to improve the accessibility of all of them e.g. via improved correlation, cross-referencing and consistency.

For more information on Guidance please see the article "The Nature of ECHA's Guidance" which was published in the August 2011 Newsletter (page 13) by Director of Cooperation, Andreas Herdina.

ECHA Newsletter August 2011
http://echa.europa.eu/documents/10162/13584/echa_newsletter_2011_4_en.pdf

Guidance on ECHA's Support section
http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation

ENES discusses good practice in deriving and communicating exposure scenarios

TEXT BY LISA LOCCHI & ANDREAS AHRENS

The debate of the second meeting of the Exchange Network on Exposure Scenarios (ENES) focused on how to develop exposure scenarios describing realistic conditions of use and the challenges that industry is facing today. The event, which took place in May in Helsinki, brought together more than one hundred representatives from the chemicals industry, downstream user industries, competent authorities and EU scientific bodies.

During the plenary session, the presentations from ECHA, the French competent authority and DUCC (Downstream users of Chemicals Coordination Group) gave their perspectives on the lessons learnt from the 2010 REACH registration deadline. The presentations focused on the quality of the chemical safety reports (CSRs) and exposure scenarios.

After these presentations, small workshops allowed all participants to enter into practical discussion. A first batch of working groups analysed the environmental part of an extended-safety data sheet to facilitate a discussion on how to develop and use environmental information in the exposure scenario. The participants addressed three key questions. The first one identified challenges in interpreting the environmental operational conditions and risk management measures in an exposure scenario from a downstream user perspective. The second question focused on how a downstream user can check if a use is covered in the environmental part of an exposure scenario. The final question aimed to identify what appropriate or inappropriate risk management measures are and how the registrant should describe and communicate them in a clear and meaningful way.

A second batch of four working groups gathered experience and solutions on several topics. The participants looked at the role of downstream user organisations in creating consolidated and well-structured sets of information on the "realistic conditions of use". They also discussed how to organise the environmental information inputs for a joint CSR, and how to keep the exposure scenario sufficiently flexible for the downstream user without impacting on the integrity of the registrant's CSR. Lastly, the groups considered the challenges in deriving and communicating the exposure scenarios of inorganic substances and metals.

The ENES coordination group is now reviewing the key points, conclusions and the resolution of issues from all of the working group discussions. Actions identified will be set out in a plan to be published in autumn.

The exchange of practical experience and proposals for solutions led to a number of conclusions regarding good practice in deriving and communicating exposure scenarios. As one of the actions, ENES publishes these conclusions, which refer to the structure and presentation of information in the exposure scenario, the content essentials on environment in the exposure scenario for communication, and the required interactions among the registrants of a substance.

ENES aims for such conclusions to help manufacturers and importers, distributors, and downstream users in their process for continuous improvement in the development and use of the REACH exposure scenario. **The conclusions are presented on pages 13 and 14**.

Feedback from the meeting was very positive – participants welcomed the opportunity to network and to learn from one another as well as the chance to explore ideas.

Further information on ENES
http://echa.europa.eu/en/about-us/exchange-network-on-exposure-scenarios

CONCLUSIONS FROM THE SECOND MEETING OF THE EXCHANGE NETWORK ON EXPOSURE SCENARIOS (ENES) HELD FROM MAY 21-22 IN HELSINKI

Conclusions on good practice in deriving and communicating exposure scenarios

STRUCTURE AND PRESENTATION OF INFORMATION IN THE EXPOSURE SCENARIO (ES)

- **Include a table of contents** into the extended safety data sheet to provide an overview on the exposure scenarios contained. This ToC should be structured according to life-cycle stages and user groups (see next point), and should include short titles and use descriptors. The table of contents should help the downstream users in comparing the ES they receive with their own use mappings. The table of contents should include:
  - ES number/code
  - Short, intuitive title in the terminology of receiving downstream users (e.g. title taken from DU associations' use mappings)
  - Short generic title based on use descriptors
  - List of the relevant use descriptor codes

- **Differentiate exposure scenarios** according to life-cycle stages and user groups:
  - ES for manufacture
  - ES for formulation
  - ESs for end-use at industrial sites
  - ESs for wide dispersive uses
    - workers (professionals)
    - consumers
  - ESs for article service life

- **Optimise** the number of ESs and the number of contributing scenarios within an exposure scenario. Easy identification of practically relevant information for the single addressee should be one of the major drivers of this optimisation.

- **Simplify**: Limit to information that is practically relevant to the addressee. Keep in mind who is receiving your safety data sheets (SDS) and who is looking at your ESs. Important to remember that the ES is substance-related and should be written for those that have to use the information and to implement the measures.

- **Find the right balance / level** between generic and specific information (depends on nature of the substance and addressee of ES). Consider that different parts of the supply chain may have different needs.

- **Clearly differentiate** in the ES between the conditions of use the downstream user is expected to implement and non binding additional advice.

- **Be realistic and consistent** with the risk management measures (RMMs). Avoid conflicting information within the ES itself and between the ES and the core of the SDS.

- For presenting the information, **use harmonised formats**:
  - Make yourself aware of with which tools the ES information can be efficiently communicated down the chain. Use the IT formats of these tools (e.g. ESComXML).
  - Harmonise your ES with the basic structure suggested by ECHA (* = to be used if relevant for downstream user):
    1. Title section
    2. Conditions of use
       - Environmental contributing scenarios
       - Human health (worker or consumer) contributing scenarios
    3. Information on release and/or exposure and/or risk*
    4. Guidance to DU on how to establish whether they work within the boundaries of the ES (e.g. scaling method/information) *

CONTENT ESSENTIALS ON ENVIRONMENT IN THE EXPOSURE SCENARIO FOR COMMUNICATION

- **Provide a clear description of processes/activities** covered in a single ES: Intuitive ES titles (standardised at DU sector level) and additional information on the scope and boundaries of ES (if needed).

- Include information on the **daily tonnage** (and annual tonnage) – applicable to uses at industrial sites.

- **Describe the conditions of use at a site** driving the release:
  - conditions driving the initial release from processes
    and if needed:
  - conditions driving the subsequent release to the environment
    (on-site RMMs and their required effectiveness)
    Please note: Release rates (kg/d) to air and water alone are not sufficient.

- Provide information on the assumed **capacity of municipal sewage systems** – applicable to uses at industrial sites.

- Provide information on the assumed **local dilution capacity** – applicable to uses at industrial sites.

- **If relevant:** Provide information necessary to understand the **underlying assessment parameters** (to enable complementary "assessment" ("verification") work at DU level e.g. scaling, whilst ensuring consistency with the CSR in the registration dossier).

Please note: ENES may in future also publish conclusions regarding content essentials on human health in the exposure scenarios for communication.

PROCESSES FOR OBTAINING AND GENERATING INFORMATION FOR THE EXPOSURE SCENARIO

- **Launch communication and cooperation** at different levels:
  - Member registrant and lead registrant;
  - Registrant and customers;
  - Registrant's sector organisation with DU sector organisations;
  - DU organisations with their membership;
  - DU organisation (formulator) to DU organisation (end-use sector);
  - Lead registrant to authorities.

- **Formulator organisation together with end-use sectors** are in a key position to generate meaningful information on conditions of use for registrants.

- Organise **joint CSR** development and maintenance/update:
  - If needed, define role of trustee (third party solution) to facilitate discussion amongst registrants e.g. on information needs and issues of confidentiality;
  - potentially include ES for communication;
  - ensure arrangements for updates;
  - involve DUs (organisation, key customers); discuss with your DUs to learn as early as possible if the language you are using is understandable, and how realistic the anticipated RMMs are;
  - establish mechanisms to enable transparency about which uses are covered in the joint CSR and which are not.

PIC Regulation enters into force

The revised Prior Informed Consent (PIC) Regulation has now been formally approved and entered into force on 16 August 2012. The EU level regulation on the import and export of hazardous chemicals will apply from 1 March 2014 onwards.

ECHA has been nominated as the responsible body for administrative and technical tasks related to the new regulation. ECHA's main tasks will be managing notifications from industry on their intentions to export chemicals included in Annex 1 of the regulation and transmitting the notifications to the importing (non-EU) countries. The Agency is now starting the preparations to put the necessary tools and processes in place.

The revised PIC Regulation will not bring major changes for industry. Responsibilities related to exporting and importing chemicals remain similar to the ones under the current legislation which is implementing the Rotterdam Convention within the EU. As before, industry is required to notify their designated national authorities in advance concerning their intention to export hazardous chemicals.

Further information

ECHA press release, 16 August 2012
http://echa.europa.eu/view-article/-/journal_content/7e56e812-fa37-4f78-be0d-07489916ff2b

ECHA joins forces with European trade unions to promote employers' obligations under REACH

The European Trade Union Confederation (ETUC) and the European trade union IndustriAll have launched a joint campaign with ECHA and the European Agency for Health and Safety at Work (EU-OSHA) to call on worker representatives to act as ambassadors for REACH in their companies. The aim is to ensure timely registration for the REACH 2013 deadline. The campaign also raises awareness about the new elements in the safety data sheets that aim to enhance the protection of workers.

The campaign kicked off at the eighth annual trade union conference on chemicals and workers' protection, held from 26 to 27 June in Brussels. To pass the message forward the trade unions have - together with ECHA and EU-OSHA - produced a leaflet, which provides a simple checklist on the actions to be taken by companies importing, producing or using chemicals in order for them to comply with the EU legislation. This leaflet is available in 22 languages.

Further information

Download the 'REACH 2013 - Call to action' leaflet from the ECHA website
http://echa.europa.eu/en/view-article/-/journal_content/f2128fee-eb37-4efd-9048-68f7d3458962

ETUC press release, 26 June 2012
http://www.etuc.org/a/10089

IndustriAll website
http://www.industriall-europe.eu/

Simplifying Art. 33 (2) requests for consumers - New web tool launched in Germany

Consumers can now check if a product contains substances of very high concern (SVHCs) included in the candidate list by typing a barcode ID of the product online. A request for information is sent automatically via email to the manufacturer or the importer. This new online service was recently published by the German Environmental Agency (Umweltbundesamt, UBA) and Friends of the Earth Germany. The tool was mainly developed by an enterprise hosting a database for products of more than 140 000 clients including contact data of a responsible person.

By the end of the year, the tool will be available as an application for smart phones. The request for information will then be created automatically when scanning the E-tin.

Although the website is only available in German, requests have also been provided in English.

Further information

Dr Christoph Schulte,
email: christoph.schulte@uba.de

Online tool (in German)
http://www.reach-info.de/verbraucheranfrage.htm

ECHA reaches out to SMEs

TEXT BY ANDREAS HERDINA

As the 2013 REACH registration deadline approaches and that of 2018 already looms on the horizon; as communicating in the supply chain has duly become a prominent topic at conferences and in discussions on implementing REACH; and as labelling obligations under the CLP Regulation are to be followed, the task of reaching out to small and medium-sized (SME) duty holders is recognised as a crucial activity for many to undertake, including ECHA.

Andreas Herdina, Director of Cooperation.

Even if the chemicals sector is characterised by a number of well-known large and multinational manufacturers, looking at the entirety of duty holders, SMEs outnumber the rest. After all, they provide the backbone of the EU economy overall.

Before entering into the subject, however, I add a caveat. Not all SMEs need special attention. Some companies that have claimed to be SMEs turned out not to be such at all. In many cases, they were small entities of a large chemical mother company. Since 2011, ECHA has been running a check on the claimed SME status of registrants and found some confusion as to companies' actual status. Of the genuine SMEs too, not all are either struggling with or too little informed of their obligations under the European chemicals management regimes. Last year, we analysed feedback from successful registrants of the 2010 REACH registration deadline. About half of all SMEs were middle-sized companies, mostly in a position to dedicate some specialised staff to handle their obligations. Another sizeable element of the SMEs consisted in fact of micro-companies, often located in the UK. These very small actors were even more adept at using ECHA's tools and documents than large chemical companies. With this in mind, we recognised that the remaining proportion composed of small companies that may need our targeted special attention was relatively small in comparison to the totality of registrants. Finally, we often hear a statement made that small companies need attention because of linguistic difficulties although nothing indicates that their staff's educational standards differ from their national averages. It is more often the complexity of REACH and CLP that appears to be a hurdle for them.

SO, WHAT IS ECHA DOING FOR SMES?

As a starting point, one key realisation is that ECHA needs to engage intermediaries to reach out to them. There are simply too many small companies to address. The Agency has a number of platforms at its disposal to do this.

One such platform is the HelpNet: the network of national REACH and CLP helpdesks organised and chaired by ECHA. The Agency regularly provides helpdesk correspondents with information that needs to be conveyed to SMEs, trains the correspondents in the use of ECHA's IT tools so that they can advise company customers how to use them accordingly, and also involves them in specific awareness-raising campaigns, such as currently on "REACH 2013". This approach makes use of the exclusive knowledge that national helpdesks have of the structure of their domestic chemicals sector and of their established contacts with interested actors. National helpdesks are the "first port of call" for duty holders in their respective countries, and thus naturally also the first instance for guiding SMEs with regard to their obligations. Evidently, national helpdesks are also best placed to communicate with their domestic companies in the respective national language or even regional dialect – something that ECHA is neither meant nor staffed to do. National helpdesks draw on the original as well as translated version of ECHA's Guidance documents, and additionally on their own national material, to give orientations to their customer companies.

ECHA dedicated part of its latest HelpNet Steering Group meeting, held in April of this year, to sharing best practice and experience of national helpdesks in reaching out to SMEs. One realisation of this event was that the structures of national economies are very specific and require differing national approaches. The exchange of views between national helpdesk correspondents, for instance, found some significant differences even between countries with traditionally

strong chamber organisations, looking more closely at the relatively centralised French structure and the sector-wise and regionally more fragmented SME picture in the Italian economy. Involving these chambers is essential to reaching out to SMEs. The French authorities, for instance, published a dedicated brochure on REACH, sent staff to speak in French regions and followed through a programme of seminars. Similarly, the structure of the involved public authorities differs from one Member State to the other, determining the usefulness of differing national practices too. Whereas a single body can reach out to companies in Malta, Germany's federal system and size makes its administration rely on help provided at Länder level, sometimes through dislocated town-hall-style meetings.

In this light, ECHA focuses on providing the umbrella for respective activities. It acts as an initiator, catalyst and promoter of campaigns – from "REACH 2013" to awareness-raising on CLP duties or soon on authorisation applications – providing content, dedicated logos and specific campaign material. Recently, for instance, ECHA launched a joint campaign together with the confederation of European trade unions (ETUC), aimed at reaching out to companies by means of their employees. ECHA has also placed emphasis on inviting SME representatives to its annual Stakeholders' Day held in May as well as the two lead registrant workshops that it is organising this year (the first happened in February, the second is to be held in autumn). These events are web-streamed so that companies can either watch them live or on the ECHA website thereafter. Readers can also profit from the numerous webinars on a wide range of subjects when they visit the ECHA website. Moreover, ECHA's specific "REACH 2013" web page will provide links to respective information on national websites, as from September. The ECHA website also contains a dedicated SME web page.

The Agency is also cooperating with other bodies, such as the European Enterprise Network (EEN), in addressing SMEs, together with the European Commission. To animate communication in the supply chain – an obligation under REACH and prerequisite for registrations to provide correct information on the actual uses of substances – ECHA, as partner in the Directors' Contact Group (DCG), is also devising promotional means in close cooperation with industry associations as well as the Commission. ECHA runs a special network, ENES – the Exchange Network on Exposure Scenarios. This network and the CSA (chemical safety assessment) development programme engage industry associations in developing avenues to address duty holders with recommendations and support in fulfilling their obligations. In June, ECHA published a Practical Guide for Downstream Users receiving Exposure Scenarios for substances registered under REACH.

These various activities not only serve to intensify the information that SMEs may already have but also aim at "reaching the unreachable", i.e. any company that may not yet be aware of its obligations under REACH and CLP. Through ECHA's Forum for the Exchange of Information on Enforcement, the Agency has also encouraged national inspectors to use their enforcement activities to raise the awareness of companies that they visit in the course of their regular duties.

I finally want to mention that ECHA's new and totally reorganised website, launched in December 2011, has been instrumental in making information even more accessible to companies. Obviously, this is also to the benefit of SMEs. They can now make use of swift search functions; they can consult regularly updated lists of registered substances as well as those intended for registration by the 2013 deadline; they can access plug-ins that help them use ECHA's IT tools which are also regularly upgraded to match our customers' as well as the REACH processes' needs. User manuals in 22 official EU languages, with screenshots and practical advice, guide customers in using unilingual IT tools. Practical Guides and ECHA's Guidance documents relevant to SME use are made available in translated versions. Since its launch, the new ECHA website is also better accessible in 22 official EU languages, and its translated content is continuously growing. Only such web content which is short-lived or not yet stabilised, and technically complex Guidance documents are not translated; with Guidance in a Nutshell documents and Fact Sheets provided instead. Although all statistical feedback indicates that the vast majority of ECHA's stakeholders make use of ECHA's documents in their original English versions, irrespective of their home country or native language, ECHA is spending about €4 million annually on translating material as a service to its readers, with a view to helping mainly SMEs.

At this juncture, I can only provide a limited snap-shot of our activities of benefit to SMEs; so much is happening and bound to happen still. Nonetheless, even this limited summary underlines that SMEs are close to ECHA's heart.

A Member State perspective:
Activities for SMEs in France

INTERVIEW BY HANNA-KAISA TORKKELI

The Member States play a crucial role in the success of REACH. They are the ones who can convey the relevant messages in a national language and understand the political, economical and social factors affecting the industry. This is valuable in particular when reaching out to the small and medium sized enterprises (SMEs.) We spoke to *Ms Sylvie Drugeon* from the French Ministry of Ecology, Sustainable Development and Energy to learn what French authorities have done to reach the 'unreachable' for the 2013 deadline.

The French campaign for the 2013 REACH deadline began in the beginning of 2012 with the aim of informing especially SMEs about their different obligations under REACH. The selection of activities was decided on the basis of the lessons learned from first registration deadline in 2010, and in cooperation with the French chambers of commerce and representatives of the Enterprise Europe Network (EEN). "We have used some very classical communication tools, such as press releases, interviews and briefings given to general and specialised press. Our first key action was to publish a very simple 'How to' brochure in non-technical French for the SMEs. This brochure contains concrete case studies, examples and illustrations and was distributed by the local chambers of commerce", Ms Drugeon explains.

Other actions include on-location events and webinars. "We have oranised meetings with SME representatives at a regional or even local level together with the chamber of commerce. SMEs really appreciate to meet the representatives of the Ministry or the French Helpdesk on their own ground. In the future, we plan to invite the regional press to the meetings and that way hope to multiply our message to a wider audience", Ms Drugeon says and continues "we also provide industry with free webinars every other week until May 2013. There we focus not only on registration but also on communication in the supply chain and the authorisation process. According to our research from the previous deadline, webinars are one of the most effective tools. The French Helpdesk gives us useful insight for identifying the issues to be tackled in the webinars."

In addition, the Ministry holds regular meetings with the French industry associations and takes part in workshops they organise for their members. "These workshops normally bring together many companies from the same sector regardless of the size, and hence offer a useful platform for networking", Ms Drugeon points out.

REACH IMPACTS ALL SECTORS

The aim of the activities is to raise awareness among SMEs, non-chemical sector companies and among actors, which are not involved in professional networks. "We need to convince them that they are all impacted by REACH by explaining the challenges for their business. We answer their questions and advise them on where to get further assistance. Our key message is that REACH is not an issue only for the chemical industry but impacts all sectors. This also means that more and more SMEs are affected", says Sylvie Drugeon.

The efforts of the French authorities have been successful. For example, the webinars reach around 100 companies every time. "Around 50 companies take part in each of the regional meetings! They are talking to each other, sharing experience and their own 'REACH story'. The feedback has been very positive", Ms Drugeon says. To further enhance the approach of the campaign, the French Helpdesk is currently conducting a survey to identify specific needs of SMEs.

Further information

Brochure 'Take control of chemical hazards in your business' (in French)
http://www.developpement-durable.gouv.fr/Maitrisez-les-risques-chimiques.html

Webinars (in French)
http://www.uic.fr/REACH-webinars.asp

French Helpdesk (in French)
http://www.ineris.fr/reach-info/jsp/index.jsp?content=contact_cci

French Helpdesk survey (in French)
http://www.ineris.fr/reach-questionnaire-des-besoins/

MINISTRY OF ECOLOGY, SUSTAINABLE DEVELOPMENT AND ENERGY, FRANCE

(Ministère de l'Écologie, du Développement durable et de l'Énergie)

- The competent authority for REACH in France.
- Works closely with the Ministry of Labour, which is the competent authority for CLP.
- Responsible also for REACH enforcement actions.

Head of Biocides Unit appointed


© HUGUES KENINGSWALD

French *Hugues Kenigswald* joined ECHA on 16 August as the new Head of Unit for Biocides. Mr Kenigswald has worked in EFSA since 2006 in various positions, and most recently as team leader in the area of food ingredients and packaging. Before joining EFSA he worked for 10 years at a French trade organisation of food manufacturers.
Mr Kenigswald has graduated in veterinary medicine. He also has post-graduate qualifications in statistics and epidemiology, and in business management.

Head of Unit for Classification appointed


© ECHA

Dutch *Jos Mossink* started as the Head of Unit for the Classification on 16 August. Mr Mossink joined ECHA's Risk Management Directorate in May 2011, and has, since February 2012, contributed to the preparations for the Biocidal Products Regulation as acting Head of Unit for Biocides. Before coming to ECHA, Mr Mossink was with a Dutch contract research organisation, most recently in a management position in the area of risk assessment of chemicals and foodstuffs. He holds a degree in chemical engineering and information management.

Chair of the Biocidal Products Committee appointed


© ERIK VAN DE PLASSCHE

Dutch *Erik van de Plassche* started as Chair of ECHA's Committee for Biocidal Products on 1 August. Mr van de Plassche has been working at ECHA since September 2010 and is the founding father of the work on biocides at the Agency. Mr van de Plassche came to ECHA from the Commission's Joint Research Centre where he worked for almost six years in the Biocides sector of the former European Chemicals Bureau.

REACH Regulation: Scientific discussion on the adequacy of two *in vivo* tests

Date: Helsinki, 4 October 2012

ECHA will give the floor to experts from regulatory, scientific and industry backgrounds for detailed insight of using the Transgenic Rodent Gene Mutation Assay (TGR) and the Unscheduled DNA Synthesis Assay (UDS) under REACH. The aim is to produce a document about the scientific adequacy of both assays for instance to support stakeholders in their testing strategy decisions. For further information and registration, send an email by 31 August 2012 to tgr-uds-meeting-2012@echa.europa.eu.

Event calendar

August-October 2012

- ECHA Management Board: 27-28 September
- Seminar on applications for authorisation: 1-2 October
  http://echa.europa.eu/view-article/-/journal_content/01678d80-ba25-431a-91f3-36205feebb95
- Workshop on analysing alternatives and socio-economic impacts in authorisation applications: 2-3 October
  http://echa.europa.eu/view-article/-/journal_content/ab8d609b-c321-4bda-839a-58721763bd8d

Tentative dates:

- ECHA Committee for Risk Assessment (RAC): 10-14 September
- ECHA Committee for Socio-economic Analysis (SEAC): 12-14 September
- Member State Committee (MSC): 19-21 September
- REACH and CLP Helpdesk Network (HelpNet): 16-17 October

International cooperation

Visits to ECHA

14 August
China National Accreditation Administration;
China Petroleum & Chemical Industry Federation

Meetings

22 June
Eighth meeting of the chemicals subgroup under the EU-Russia Industrial and Enterprise Policy Dialogue, Brussels

Events

17-21 September
ECHA info stand and side event at the third session of the International Conference on Chemicals Management, Nairobi

Speaking engagements

18 July
Geert Dancet speaking at the Society for Risk Analysis, World Congress on Risk, Sydney

ECHA prepares Balkan region for EU accession

TEXT BY PIA FALLSTRÖM MUJKIĆ

ECHA is expecting to receive a second grant from the European Commission to prepare authorities in the Balkan region on how to work with the Agency and how to support industry to comply with the REACH and CLP Regulations.

The IPA Programme is an instrument for pre-accession assistance of the European Commission Directorate General for Enlargement that provides funding and support to the EU accession countries, candidate countries and potential candidates. ECHA's first IPA project ran from 2009 to 2011. The Agency has foreseen that it will receive €300 000 for the second project due to run between 2012-2014. During the first months, it will focus on Croatia that will become the 28th EU Member State on 1 July 2013.

The objective of ECHA's IPA support is to prepare and assist authorities responsible for chemicals legislation in the beneficiary countries. This is done by introducing and training key personnel on the role of EU Member States under the REACH and CLP Regulations, and on how to work with the Agency. In addition, knowledge transfer on regulatory science in the field of chemicals safety will take place. This is to ensure that once a country becomes an EU Member State its representatives and nominated experts can participate efficiently in Agency activities.

During the first project, 103 authority representatives took part in numerous workshops and seminars arranged by ECHA in Helsinki or in the beneficiary countries. The participants were introduced to the tasks and obligations a Member State has according to the REACH and CLP Regulations. The events also provided an insight into the role of a Member State in the three ECHA committees and information of the general procedures and practical aspects of the committees. Visits to ECHA allowed the participants to meet experts working at the Agency. The participants have provided very positive feedback on the training sessions, in particular on the practical experience highlighted by Member State representatives of the Committee for Risk Assessment and the Member State Committee.

Eva Sandberg and Petteri Mäkelä.

During the previous project, good contacts were established with the competent authorities in most countries and activities were arranged in cooperation with them. However, in some of the beneficiaries it was difficult to identify the relevant officials and their training needs. ECHA will, therefore, carry out fact-finding missions to these countries during its second project. The Agency will also arrange training workshops as well as study visits to ECHA and the national helpdesks.

Eva Sandberg, ECHA's International Affairs Officer, managed IPA support on REACH and CLP until she retired at the end of May 2012. *Petteri Mäkelä* has now taken over the coordination of the IPA project. "The support ECHA provides to the beneficiaries through the IPA programme is an efficient way to ensure that the national authorities in the countries that are joining the EU family are up to speed on how to work with the Agency", Petteri Mäkelä commented on his new task.

IPA - INSTRUMENT FOR PRE-ACCESSION ASSISTANCE

IPA provides funding and support to EU accession countries, candidate countries and potential candidates. The support can include transitional assistance and institution building, cross border cooperation as well as regional, rural and human resource development. For more information consult the Europa website at: http://ec.europa.eu/enlargement/how-does-it-work/financial-assistance/instrument-pre-accession_en.htm.

IPA BENEFICIARIES: Croatia (EU accession country); Iceland, The Former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey (EU candidate countries); Bosnia and Herzegovina, Albania, Kosovo (under UNSCR 1244/99) (EU potential candidates).

IPA project funding: ECHA: € 300 000 for 2011-2013 (€ 200 000 for 2009 – 2011).
EU total: € 11.5 billion for all projects in 2007-2013.

ECHA welcomes Croatia

TEXT BY PIA FALLSTRÖM MUJKIĆ

Croatia will become the 28th member of the European Union on 1 July 2013. During the remaining months before its accession, ECHA will support the Croatian authorities in getting ready to work with the Agency on the REACH, CLP, PIC and Biocidal Products Regulations. The main part of this support will be funded by the European Commission Directorate General for Enlargement, through the IPA programme.

Croatia has benefited from the IPA assistance since 2009 and ECHA has been working with Croatia since 2010. During the second half of this year and the first half of 2013, the Agency will work intensively with the Croatian authorities to prepare for the country's accession to the European Union.

In addition to the activities of the IPA programme, since becoming an acceding state, Croatia is already invited as an observer to the meetings of ECHA in which Member States take part, such as the meetings of the Management Board, Committees and the Forum as well as ECHA networks, workshops and seminars.

Croatia has also worked with Sweden and Italy on an IPA funded twinning project on chemicals management to harmonise its chemicals legislation with the EU legal framework. In addition, Croatia has been benefitting from another IPA funded project on chemicals safety since 2007. Thanks to those projects, much of the Croatian legislation is already in line with the REACH and CLP Regulations.

In its 2012-2014 IPA project, ECHA will pay particular attention to the Forum and Helpdesk activities, as well as the work of the Committee for Socio-economic Analysis. ECHA will also arrange REACH-IT and IUCLID training for the Croatian authorities.

During 2005-2007, the Croatian Ambassador to Finland *Dr Damir Kušen* was a member of the Croatian National Negotiating Team for EU membership. He comments on the Croatian accession: "There were 138 benchmarks in 35 chapters for Croatia and the European Union to adopt so the road to accession has been long. However, both the EU and Croatia will benefit from the EU enlargement. Enlargement is the most efficient policy tool and mechanism for extending the area of security and prosperity. Croatia is committed to contributing to these goals by providing strong support and assistance to its neighbouring countries in the Western Balkans. Enlargement expands the market potential in the EU and encourages economic growth."

CROATIA

- Population: 4.5 million
- Croatia is the second country of the former Socialist Yugoslavian republics to become a member of the EU
- Natural resources: oil, coal, bauxite, low-grade iron ore, calcium, gypsum, natural asphalt, silica, mica, clays, salt, hydropower
- Main export products: transport equipment, machinery, textiles, chemicals, food, fuels
- Main export partners: Italy 18.9%, Bosnia and Herzegovina 11.9%, Germany 10.6%, Slovenia 8%, Austria 5.4% (2010)
- During 2012-2013, Croatia will benefit from IPA projects amounting to €156.2 million

(sources: Economist Intelligence Unit, European Commission DG Enlargement)

ECHA's Management Board adopts the multi-annual work programme 2013-2015

TEXT BY TIIU BRÄUTIGAM

In its meeting on 20-21 June, the Management Board adopted an updated multi-annual work programme for the Agency, outlining activities for the next three years. It also dealt with various budgetary matters, such as subsidy needs for 2014-2020 and an amendment to the 2012 budget.

The multi-annual work programme (MAWP) for 2013-2015 includes the implementation of new regulatory tasks for ECHA under the Biocides and PIC Regulations. Other challenges in the coming years are linked to the second REACH registration deadline in 2013 and the start of applications for authorisation. The growing number of new tasks will force ECHA to focus on efficiency and priority-setting.

For the first time, the priorities of the programme were defined in line with four overall strategic aims which guide the Agency's work:

- maximise the availability of high quality data;
- mobilise authorities to use data intelligently;
- address scientific challenges and
- embrace current and new legislative tasks efficiently and effectively.

A public consulation was organised by ECHA before the adoption of the updated MAWP. The Board took into account the feedback of this consultation process when deciding on the final text, in particular the contribution received from the European Parliament's Committee for Environment, Public Health and Food Safety (ENVI).

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BUDGETARY MATTERS AND SUBSIDY NEEDS FOR 2014-2020

The Board dealt with various budgetary and financial matters, such as the amending budget for 2012 to incorporate subsidies for implementing Biocides and PIC tasks. These subsidies became available after the legislator had agreed on the final text of these new legislations in May.

Having received confirmation from the European Court of Auditors that the Agency's accounts for 2011 are regular and legal in all material aspects, the Board also adopted a positive opinion thereon. The Executive Director provided updates on the budget procedure for 2013 and the process leading to the adoption of the next EU Financial Framework 2014-2020. in particular, he informed the Board of a comparison between the level of foreseen EU subsidies for ECHA and ECHA's own estimates of registration fee income for that period. This comparison showed that ECHA's subsidy needs are likely to be higher than currently foreseen in the Commission proposal. It was noted that further reductions of the subsidy would lead to substantial problems for the Agency's long term functioning.

The Board discussed possibilities to provide the Agency with a more stable funding structure. It noted that the scheduled review of the REACH Fee Regulation by January 2013 could lead to certain adjustments, such as fees for inquiries and registration updates in response to compliance decisions.

Further topics on the agenda included, among other things, the ECHA review study, a discussion of stakeholder participation in the authorisation applications process and the next steps of the implementation of the new ECHA policy on the management of potential conflicts of interests.

Preliminary conclusions of the 26th Management Board meeting
http://echa.europa.eu/management-board-documents

Multi-annual work programme 2013-2015
http://echa.europa.eu/documents/10162/13608/mb_19_2012_echa_mawp_2013_2015_en.pdf

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/evaluation

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

		Phase-in*	Non phase-in	Total
No of registered dossiers [1]	containing testing proposals	501	62	563
	containing testing proposals for vertebrate animals	396	43	439
No of endpoints	covered by registered testing proposals	1 028	123	1 151
	covered by registered testing proposals for vertebrate animals	669	71	740
No of third party consultations	closed	390	39	429
	ongoing on 31 July2012	70	2	72
	planned	15	1	16
Dossiers with testing proposals opened for examination [2]		568	74**	642
Draft Decision sent to the registrant [3]		165	13	178
Final Decision sent to the registrant		102	32	134
Terminated testing proposal examinations [4]		107	18	125

* 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 opened for examination notwithstanding their current status.
[3] Draft decisions which did not become final by 31 July 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 31 July 2012.

	Phase-in	Non phase-in	Total
No of dossiers opened for compliance check[1]	293	142	435
Draft Decision sent to the registrant [2]	56	5	61
Final Decision sent to the registrant	116	45	161
Only Quality Observation Letter sent to the registrant [3]	13	47	60
Terminated compliance checks[4]	40	44	84

[1] Dossiers opened for compliance check notwithstanding their current status.
[2] Draft decisions which did not become final by 31 July 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]	256
Draft Decision sent to the registrant [5]	50
Final Decision sent to the registrant	103
Only Quality Observation Letter sent to the registrant [6]	9
Terminated compliance checks [7]	29

[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 31 July 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 registered chemicals publicly available

Data as of 16 August 2012

		Registered	Disseminated
SUBSTANCES	REACH registrations	4 480	4 256 (95%)
	NONS* (updated under REACH)	1 414	1 353 (96%)
	Total substances	**5 894**	**5 609 (95%)**
	NONS* (not updated)	3 838	2 054 (53%)
DOSSIERS	REACH registrations	27 218	25 981 (95%)
	NONS* (updated under REACH)	1 451	1 339 (92%)
	Total dossiers	**28 669**	**27 320 (95%)**
	NONS* (not updated)	8 511	3 055 (36%)
		Notified	Published
C&L INVENTORY	**Number of unique substances**	**119 171**	**98 898**

*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).

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