ECHA Newsletter

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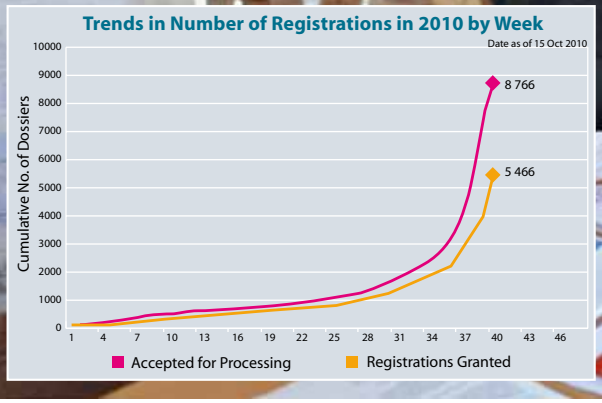

ECHA
European Chemicals Agency

ECHA engines humming

In their June and August editorials, Executive Director Geert Dancet and Head of Communications Lindsay Jackson highlighted the fast approaching REACH registration and CLP notification deadlines.

Now, six weeks from 30 November, ECHA's engines are humming. As of 25 October, 8,502 dossiers have been registered. Thanks to the Technical Completeness Check (TCC) and fee calculation plug-ins, dossier submission is running smoothly. Many Lead Registrants enjoyed shorter handling times by submitting the joint parts of their dossiers by the end of September. The result was ECHA's first prominent peak which triggered the Agency's staff deployment mechanism. The handling of incoming submissions has now been further automated.

In September, we held a series of training events for national REACH and CLP helpdesks on the various IT tools available to facilitate registration. National helpdesks are the first point of call for enterprises, able to respond in local languages and with a detailed knowledge of the domestic context. Much of the training material is publicly available around the clock on ECHA's website in the form of webinars.

ECHA provides access to around 4,000 translated pages in your language, which are mainly guidance documents aimed at SMEs in particular and available on our website.

This edition reports on the work of the Directors' Contact Group (DCG) in which our Executive Director, together with Directors of the European Commission and decision-makers of six industry associations, have been addressing potential obstacles in the registration process. (more on p3)

A concern remains about manufacturers and importers of chemical substances who need to ensure that the supply of their customers is not disrupted by failure to register in compliance with REACH. Downstream Users need to know if their supply chain is legally assured.

In summary, we are well prepared for the challenges of the upcoming deadline, and I hope and believe that our December editorial will reflect on the first REACH registration as having been a success.

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Andreas Herdina
Director of Cooperation

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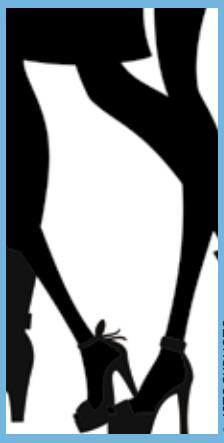

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ready?

Preparing together for the 2010 deadline

The Directors Contact Group, set up to monitor industry preparedness and to resolve issues that could hinder a successful registration process, recently published the results of its work so far. They are available on ECHA´s website. In the following interview, ECHA Directors Christel Musset and Andreas Herdina comment on the results.

Ms Musset and Mr Herdina, why was it necessary to set up this group?

Mr Herdina: ECHA, industry associations and the Commission realised at the end of last year that it would be better to prepare ourselves early in 2010 for any eventuality, instead of taking the risk of facing surprises towards the end of the registration period. It was for this reason that the Directors´ Contact Group was formed, with the consent of ECHA´s Management Board and under the chairmanship of the European Commission.

The Group started off by narrowing down our estimates of the possible number of dossiers and substances to be registered.

Ms Musset: Yes, both ECHA and industry associations have really made great efforts to find out which substances will actually be registered. The downstream users are quite worried in cases where their suppliers are not confirming their intention to register a substance. This is the issue we are trying to tackle now. For downstream users it is important to see on our website that the substances that are intended to be registered have their Lead Registrants in place.

This is why we have made several pleas to industry associations and to large companies, asking industry to nominate themselves as Lead Registrants. If there is a Lead Registrant associated to a substance, this shows that the SIEF is working. It gives certainty to industry and in particular to downstream users. Looking at our website at this point, it seems that there will not be any major disruption of supply.

Mr Herdina: The other major activity was for industry associations to identify issues that could be a challenge in the registration process. We then went through all the 28 issues raised by the industry associations in March, and found solutions for all of them by the end of September.

Were you surprised by the problems that industry reported?

Mr Herdina: ECHA had already taken decisions in relation to some of the issues, such as the decision not to introduce updates of REACH-IT at a late stage just before the registration deadline. Industry also wanted us to have a special Helpdesk service for registrants and REACH-IT available at weekends whenever there is need. These things were planned by ECHA in any event. The Directors´ Contact Group could provide the comfort of knowing what our intentions were.

Ms Musset: We knew informally about industry concerns, because we are in regular contact with the associations. The Directors´ Contact Group was a channelled and efficient way of discussing relevant matters with all interested parties. Some issues were not in our sole remit, and we needed to work together with the Commission to identify solutions.

Solutions were found for several exceptional cases. Do these change the legal requirements?

Mr Herdina: Evidently, everything that the Directors' Contact Group could agree had to be within the legal framework. We were able to provide solutions for companies who have done everything they can to fulfil their obligations to register but still find themselves in an unexpected and exceptional situation. The Directors´ Contact Group was dedicated to facilitating the implementation of REACH, not to changing it. So, with regard to the deadline, those who snooze, lose, and that continues to be the case.

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Christel Musset, *Director of Registration and IT Tools.*

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Andreas Herdina,
Director of Cooperation.

The Member State Competent Authorities went along with the approach that the Group took and were consulted once solutions had been established. As the enforcement of REACH is the sole responsibility of the Member States, we have also been keeping the Forum informed about a number of cases.

Ms Musset: Indeed it is essential that companies contact us via the DCG contact form as soon as they become aware of their situation. The fact that a company has informed ECHA about their situation and received an incident number for their communication is something that the enforcement authorities know they should be looking for.

I would also like to emphasise that companies who believe themselves to be affected by these issues have to provide documentary evidence of their problem. For instance, if the Lead Registrant faces an exceptional set of circumstances before the deadline because of a merger or a change of company organisation, then the merger or acquisition must be documented.

Have we already received this kind of information? By when do companies need to submit such information to ECHA?

Ms Musset: We have had some initial contacts. Companies must send us the information and supporting documentation before they submit their registration dossier. Once we have the documentary evidence, we will explain how to indicate their situation in the registration dossier which has to be submitted within the legal deadline by 30 November. There is no way to come back to us after 1 December saying that it was not possible to submit a dossier or that information is lacking.

Who can one turn to if the solutions are not clear?

Mr Herdina: The list of solutions we provided on the ECHA website should be self-explanatory, but you can still as always get help from the national or ECHA Helpdesk. Companies who are in an exceptional situation should also consider the Note on the DCG web section which outlines a set of prerequisites and also the consequences related to the solutions.

Are you satisfied with the results? How will the work proceed?

Mr Herdina: General feedback received from industry has been that this is very useful for them. It was also important for the Commission and ECHA to have clarity on these issues. The mandate of the Group ends in March 2011. After the registration deadline the focus will be on lessons learnt from this registration deadline, with a view to the next registration period.

Ms Musset: As for the rest of the year, ECHA will continue to monitor the situation. For example, currently REACH-IT is open from Monday morning until Friday evening, also overnight, and companies have the opportunity of submitting their dossier during current working hours. If we begin to see that this is not sufficient then we will extend our opening hours.

Mr Herdina: The special service for registrants is also up and running. It is an outbound telephone service, and when it is clear that it would be more useful to telephone the registrants, this is now done.

How are the submissions of registrations going?

Ms Musset: We have had increasing success rates of dossier submission. However, these were the Lead Registrant dossiers, from large companies who already have experience of the system. Now we are starting to see dossiers from SIEF members being submitted, and obviously it is the first time that they are using REACH-IT. We are observing more problems than we did with big companies. Therefore our message is: "Register early so that we can help you and you will have the chance to re-submit your dossier quickly if necessary! The national helpdesks have been trained on all the available tools and are ready to provide help."

Summary of the issues and solutions:
http://echa.europa.eu/doc/reach/echa_dcg_solutions_summary_en.pdf

Downstream users need assurances

Downstream users need assurances that the substances they are using have been properly registered and that their supply chain is legally assured. A meeting with downstream users, organised by the European Commission on 27 September in Brussels, was held to discuss this important issue. On 21 October, ECHA published a list of all phase-in substances registered thus far and will further ensure that the list is regularly updated until the 30 November deadline. ECHA also appeals to Lead Registrants to make themselves known to ECHA through the Lead Registrant webform. An overview of Lead Registrants may be the only mechanism through which downstream users will be able to check if a high volume substance or a CMR is legally on the market from December onwards.


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The President
of the Republic of Finland visits ECHA

On 28 September, the President of the Republic of Finland, Tarja Halonen, visited ECHA, where she met with ECHA´s senior management and attended a meeting of the HelpNet Steering Group.

The President was very interested to hear how the consistency of legal interpretations could be guaranteed in the European Union given its many languages and legal traditions. She was also impressed by the multicultural and multinational cooperation taking place in HelpNet and ECHA and said she felt encouraged by the clear commitment of everyone she met.

The President appreciated the fact that ECHA is located in Helsinki. She hoped that staff members and their families who have come from abroad will feel at home in Finland. "I hope you enjoy your work, it is very important! But I also hope you enjoy being here in Finland," said the President. Her message to the staff was: "Work hard, keep your hearts warm and your heads cool!"

The Forum: Formulators of mixtures in focus in 2011

At its 8th meeting held in Helsinki 12–14 October 2010, the Forum for Exchange of Information on Enforcement approved a new enforcement project focused on downstream users who formulate mixtures.

The new Forum enforcement project "REACH-EN-FORCE 2" aims to ensure compliance with duties placed on formulators of mixtures. Specifically, the inspectors will control the supply-chain related obligations for substances in the mixtures prepared by formulators as well as the CLP notification requirements. They will also check if the substances placed on the market in mixtures are registered or pre-registered. In addition, the inspectors will raise awareness of the future obligations for downstream users with relation to the extended safety data sheet.

In addition, the Forum acknowledged the progress made regarding the project on compliance with the restriction regarding extender oils containing polycyclic-aromatic hydrocarbons (PAH) in tyres. The enforcement tools for assessing compliance with this REACH restriction have been successfully applied.

The next Forum meeting will take place in Helsinki from 1 to 4 March 2011, and will include the Forum´s second Stakeholders' workshop.

In your language!

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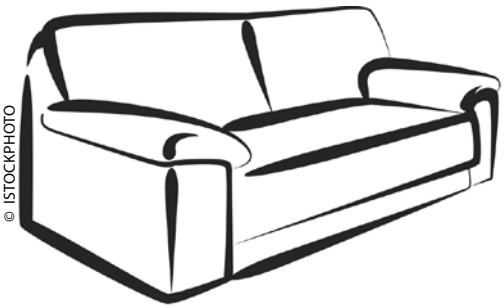
First four restriction reports under consultation

Since April 2010 ECHA, together with its committees, has been working on the two first reports proposing restrictions under REACH: Lead and its compounds in jewellery and Dimethylfumarate (DMFu). In June, two other proposals were received, one on Mercury in measuring devices and another on Phenyl mercury compounds. The four restriction reports are currently undergoing public consultation. All interested parties are invited to send in their comments as early as possible. Information on potential alternatives would also be valuable.

France was the first country to send in restriction reports in spring 2010. One of the proposals is to restrict lead and its compounds in jewellery. The main reason for the proposal is the exposure of children to lead and/or its compounds resulting from unintended use (ingestion/mouthing) of jewellery. Effects of lead on children are severe and may be irreversible. No safe threshold can be scientifically determined for the effects on the central nervous system.

The other proposal submitted by France concerns DMFu. It is used in furniture, clothing, shoes and other articles to prevent moulds that may deteriorate the product during transport and storage. DMFu is used in little sachets which are in contact with the main article. In addition, a DMFu preparation can be sprayed on the articles or inside the containers. Articles containing DMFu can cause severe skin problems (dermatitis).

The biocidal use of DMFu is already prohibited in the EU under the Biocides Directive (98/8/EC). However, this does not apply to imported treated articles. Currently there is a temporary ban in place that requires Member States to ensure that articles containing DMFu are not placed on the market. With the current restriction proposal the ban could be made permanent.



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In June 2010, ECHA received another two restriction proposals. They both aim to reduce mercury emissions in the EU. Norway is suggesting the restriction of five phenylmercury substances. These substances are mainly used as catalysts in the production of polyurethane coatings, adhesives, sealants and elastomers. The manufacture and production of polyurethane systems as well as the waste handling of them lead to a release of mercury to the environment estimated to correspond to around 4% of total European mercury emissions.

Norway suggests that these substances should not be manufactured, placed on the market or used as a substance or in mixtures in a concentration above 0.01 % weight by weight (w/w). The same concentration limit would apply for substances in articles or homogenous parts of articles. In order to give time for the replacement of the substance with safer alternatives Norway proposes that the restriction takes effect after five years of the entry into force of the restriction.

Finally ECHA has, on the request of the European Commission, prepared a report proposing to restrict mercury in several different types of measuring devices that either contain or use mercury. The report covers thermometers, sphygmomanometers, barometers, manometers, metering devices for the determination of a softening point, pycnometers and strain gauges in industrial and professional uses. With the proposed restriction, mercury containing measuring devices would be prohibited from being imported or placed on the market in the EU. This restriction would count for around 1.5% of the current mercury use in the EU. The placing on the market of mercury containing measuring devices for the general public is already restricted.

Public consultation – provide your input!

The public consultation on the two first restriction proposals ends in December 2010. The ECHA Risk Assessment Committee (RAC) should give its opinion on the proposals by the end of March. At the same time the ECHA Committee for Socio-economic Analysis (SEAC) is to deliver its draft opinion. This is followed by another 60-day public consultation on the SEAC draft opinion, after which the final SEAC opinion is due in June 2011.

For the two Mercury related restriction proposals the public consultation started on 24 September. Although the public consultation is open for six months, interested parties are encouraged to send their comments before Christmas in order to provide input to

France has proposed *a restriction for DMFu which is used in furniture, clothing, shoes and other articles to prevent moulds during transport and storage.*

the detailed discussion of the restriction proposal in January 2011. The earlier comments are received the better use can be made of them. Besides the comments directly related to the substances and suggested restrictions, information on potential alternatives would be valuable.

The invitation for the public consultations as well as the proposal on specific requests for comments can be found at: **http://echa.europa.eu/consultations/restrictions_consultations_en.asp**

The opinions of the committees will be forwarded to the Commission who will take them into account when deciding on whether to introduce a new restriction into Annex XVII of REACH.

Restrictions under REACH

Restrictions within the REACH Regulation are a Community wide tool to protect human health and the environment from unacceptable risks relating to chemicals. Restrictions can be introduced to reduce the risks arising from the manufacture, use or placing on the market of substances on their own, in preparations or in articles. They can also apply to imports. Restrictions can be regarded as a safety net when other risk management measures do not give sufficient protection to human health or the environment.

A Member State, or ECHA on request of the Commission, may prepare a restriction report and suggest a restriction if it finds that the risks needs to be addressed on a Community wide basis. The intention to prepare a restriction proposal is made public before the proposal is provided: **http://echa.europa.eu/chem_data/reg_intentions_en.asp**

The restriction reports contain the background information and justifications for the proposed restrictions. They include the identified risks, any information on alternatives and the costs, as well as the environmental and human health benefits, resulting from the restriction.

In the last 30 years, many EU-wide restrictions have been introduced under the previous legislation (Directive 76/769/EC). While REACH continues this work it also brings some new features to the restriction process. One of the main differences is that the risks related to the substance and benefits and costs of the suggested restriction are covered by one report and assessed in a parallel process. ECHA's Risk Assessment Committee assesses the proposal and gives its opinion on whether the suggested restriction reduces the risks to human health and/or the environment. At the same time, the ECHA Committee for Socio-economic Analysis prepares an opinion about the socio-economic impacts of the proposal. Besides the two groups above, the Forum for Exchange of Information on Enforcement (Forum) may provide advice on the enforceability of the suggested restriction.

All interested parties have the opportunity to give comments during the process. Any suggested restriction conforming to the Regulation will be forwarded for a six month public consultation where interested parties can comment on it. Later in the process an additional 60 day public consultation is held on the SEAC draft opinion.

Restriction procedure

- Notification of intention
- Submission of the proposal
- Checking of its conformity
- Public consultation of the restriction proposal (6 months)
- Advice on enforceability by Forum
- Opinion by RAC & draft opinion by SEAC
- Public consultation of the SEAC draft opinion (2 months)
- Opinion by SEAC
- Draft amendment of Annex XVII by the Commission
- EU Decision

The two opinions of the ECHA Committees contribute to the Commission decision making a balanced overview of identified risks and of the benefits and costs of the suggested restriction. This, combined with tight deadlines, is to speed up the handling of the proposals compared to the previous legislation.

After receiving opinions from ECHA the Commission must also act promptly. Within REACH, the Commission has three months to prepare a draft amendment on whether to introduce the suggested restriction in the Annex XVII of REACH. The final decision is taken in a comitology procedure involving the Member States and the European Parliament.

All restrictions from the previous legislation (Directive 76/769/EC) as well as all new restrictions and possible modifications are incorporated into Annex XVII of REACH. The national enforcement authorities are responsible for ensuring that the restrictions are followed by the actors concerned. For further information on restrictions, please, visit the ECHA webpage at: **http://echa.europa.eu/reach/restriction_en.asp**

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The Dutch Helpdesks *are well equipped for REACH and CLP deadlines.*

Good preparations are paying off

There is no panic in the air at the Dutch REACH and CLP Helpdesks, despite the approaching deadlines. Coordinators of the helpdesks, Ms Margaret Wouters and Mr Richard Luit, say that good preparations have taken off a lot of the pressure. Recently the workload has even been decreasing at the REACH Helpdesk.

Ms Margaret Wouters and Mr Richard Luit from the Dutch REACH and CLP Helpdesks are very satisfied with the way the regulations have been introduced in their country. Companies, citizens and consumers have been informed through large campaigns and much information material, and the campaign for consumers is still ongoing.

"Our stakeholders were involved in developing the helpdesk. This made very clear the role of the national helpdesks of the government and the branch helpdesks," explains Mr. Luit. A great deal of material and a helpful website were created to assist registrants and notifiers from the start. Since then, the pressure at the helpdesks has been relieved, particularly by the frequently asked questions which are updated three times a year at EU level.

Dutch companies seem already to be well-informed about REACH, but questions on C&L notification are increasing. "The workload at the REACH Helpdesk has been decreasing in 2010, but we expect an increase later this year", says Ms Wouters.

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Margaret and Richard.

Ms Wouters says that companies are now asking very specific and complicated questions about REACH, but there are still also companies who contact the Helpdesk saying: "We have heard about REACH; what should we do?" "These are small and medium sized companies, and we advise them to focus on the most important substances for the company and to establish their role for these substances. We do our best to help them move forwards," says Ms Wouters. The helpdesk is also preparing a webpage targeted at small and medium sized companies.

The CLP Helpdesk started its work in March 2008, well before the CLP Regulation entered into force. Mr Luit is now coordinating the Helpdesk in close collaboration with a colleague from another government institute, which has proven to be very effective since both have complementary knowledge and skills. He expects questions on CLP notification to increase until the first notification deadline in early January 2011 but then to decrease, as the next deadlines are only in 2015. Many are asking about transitional periods, Safety Data Sheet requirements, re-classification, re-packaging and re-labelling, he says.

"We also receive some practical questions on how to notify. I think that it is really helpful that there are several options for doing this. Different companies have different roles, and it is necessary to have these different tools available," says Mr Luit.

Ms Wouters and Mr Luit are employed at the Dutch National Institute for Public Health and the Environment (RIVM). They say the Dutch helpdesks are closely connected with the Dutch Competent Authorities and therefore helpdesk employees are in general well trained on REACH and CLP and informed about the latest developments. Nevertheless, they are also happy to attend the HelpNet Steering Group meetings at ECHA, to meet colleagues and to receive and exchange information, especially on issues that have proven difficult to solve nationally or by exchange of ideas in the web-based discussion platform, HelpEx.

In the Netherlands, the Ministry of Housing, Spatial planning and the Environment (VROM) is the Competent Authority for REACH, and the Helpdesk is run by the Dutch National Institute for Public Health and the Environment (RIVM) in a joint effort with another government Agency, Agentschap NL. The Ministry of Health, Welfare and Sport (VWS) is the Competent Authority for CLP, and the CLP Helpdesk is also run jointly by RIVM and Agentschap NL. The Helpdesks cooperate on a daily basis.

Make sure the argumentation is well documented

What is needed to successfully initiate a data sharing dispute procedure with ECHA? And when does ECHA reject such a request? A key factor to bear in mind is that ECHA can only help if you are able to demonstrate that you have made every effort possible to reach an agreement and have appropriate documentary evidence of this.

If (potential) registrants cannot agree on the sharing of data, there are remedies for such a situation. After exhausting all possibilities to find an agreement, the potential registrant who has requested the data can ask ECHA to be granted a permission to refer to that data. Several web forms are available on ECHA´s website to indicate failure to reach an agreement.

Different procedures apply for companies within a SIEF (having pre-registered phase-in substances) and for those who have not pre-registered or have non phase-in substances. Please keep in mind that data submitted more than 12 years ago can be used for registration free of charge.

No automated fast track

The data sharing dispute procedure is not an automated fast track to get access to data. Under REACH, both parties concerned by the sharing of the data must make every effort to reach an agreement. A company submitting a claim must demonstrate to ECHA that they have made every effort to come to an agreement on how to share the data and costs in a fair, transparent and non-discriminatory way. Judging by the claims received so far, it seems that often there have not been sufficient efforts made by the parties and that the possibilities to negotiate on the access to data were not all exhausted.

When receiving a request for assistance in a data sharing dispute, ECHA will assess the argumentation that has been exchanged between the disputing parties to decide whether every effort possible has really been made. Companies who try to get data from a data owner should therefore carefully document the communication that has taken place. This documentation must be attached and submitted to ECHA at the same time as the claim.

Good to remember:

- **Starting a data sharing dispute procedure should be seen as a last resort** in your negotiations. First you should try to make every effort possible to reach an agreement with the other party.
- **Initiate the dispute procedure before you submit your registration dossier**. You need a decision from ECHA granting the permission to proceed **before** submitting a registration with a missing study. However, **continue preparing your registration dossier**, in order not to be delayed.
- **Make a strong case.** Make every effort to come to an agreement and document your efforts thoroughly. Challenge the justifications that you may receive from the other party in response to your argumentation. Demonstrate that you are right.
- **Do not send an insufficiently documented claim and do not rely on automatically receiving a positive decision**. A premature claim can cause a loss of valuable time you need to register. You might miss the registration deadline and fail to be in compliance from 1 December 2010.
- If ECHA accepts your claim, you are still **expected to pay a share of the costs to the data owner**.
- If the Lead Registrant has already submitted his dossier, **this is not an obstacle** for a data sharing dispute procedure.

> **"A company** submitting a claim must demonstrate to ECHA that they have made every effort to come to an agreement on how to share the data and costs..."

Please read detailed instructions on ECHA´s data sharing web page. At the bottom of the data sharing page you will find a link to a Q& A and the web form for a claim.

http://echa.europa.eu/datasharing_en.asp

Successful alternative methods in Canada

In June, Mark Bonnell from Environment Canada visited ECHA and gave lectures on the use of alternative testing methods by the Canadian authorities. "We have achieved good results so far," says Mr Bonnell.

Mr Bonnell´s visit to ECHA was the first follow-up event after the Canadian Government and ECHA signed a Memorandum of Understanding in May to increase their cooperation and exchange of information.

The EU´s new chemicals legislation is also designed to reduce animal testing and promote alternative assessment methods. In Canada, health and environment authorities already have a lot of experience in alternative methods, such as computational modelling and read-across, ie. predicting the properties of chemicals on the basis of their structural similarities to another group of chemicals. For ECHA staff, it was interesting to hear how alternative methods are applied in Canada in practice.

Mark Bonnell, Senior Science Advisor at the Ecological Assessment division in Environment Canada explains that Canada adopted computer-based "*in-silico*" methods and similar approaches for their new chemicals programme as early as 1994, with a view on the considerable experience that the US had acquired on these methods. The law allows Canadian authorities to accept data produced with alternative methods as data requirements for new chemicals.

The authorities can challenge alternative testing strategies if in doubt. "Not for all data requirements but for judgement cases. If industry has used a QSAR model to provide data for an aquatic toxicity test, for example, we will judge on a case by case basis as to whether that is acceptable or not," adds Mr Bonnell.

Public expects rapid action

He says that the public expects governments to act rapidly on priority chemicals. "In Canada, we had to prioritise a large number of chemicals, around 23 000, for which 95 percent of the data has been lacking. That is why we use models to fill data gaps. We have prioritised 4 000 substances and selected 200 to start with. The timeline for assessing any given substance is relatively short, months rather than years."

Mr Bonnell has been doing risk assessment for 20 years and has an extensive background in applying environmental models which help determine the hazards or risks to the environment.

In Canada, the authorities carry out the regulatory assessments. Industry must provide information, but much of the information on hazards is provided voluntarily if they have it. "That is a big difference to REACH. A lot of times we do not get the information we want. Then we conduct the assessment ourselves and make the decision on how the chemical should be managed," explains Mark Bonnell.

"Another big difference is that we typically do not ask for additional data in the Challenge program because of time constraints. In REACH you can ask for data through testing proposals, compliance checks and substance evaluation.

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Mr Mark Bonnell *was interested to see how REACH is being implemented. "There is nothing like being in a place to see how the machine works", he says.*

However, the Canadian Environmental Protection Act is not as prescriptive as REACH. But this allows us some more flexibility for decision making and more room for interpretation."

Weight of evidence, precaution and uncertainty are the three big corner stones in chemicals assessment. "Their relationship reflects our decision making. There are still some challenges to do this in a manner which is transparent to stakeholders", adds Mr Bonnell.

He remarks that the push for reduced animal testing is stronger in Europe than in North America. "We do not have a formal integrated testing strategy. But we have more or less had an *informal* integrated testing strategy for new chemicals in Canada, because we accept alternative data for properties of chemicals and as the basis of toxicity testing."

Mr Bonnell estimates that under REACH, the registrations of high production volume chemicals will contain a lot of empirical data, but at lower tonnages there will be chemicals for which it has not been economically viable or necessary to generate similar data. "So there may be an increased need for alternative methods to fill data gaps," he says.

Correct decisions

Mark Bonnell says that Canadian authorities have achieved good results with alternative assessment methods: "We have had a lot of success with modelling QSARs and analogue processes, and these lead to sound decisions. We feel that despite not having perfect data sets for all of our chemicals, we have made the right decisions on the information we have had. In some cases we have had objections to our conclusions, but very few with the 200 chemicals so far," summarises Mr Bonnell.

He thinks that industry coordination would be needed to familiarise companies with methods like computational modelling, read-across approaches or the QSAR toolbox.

Mr Erwin Annys, CEFIC

Confident that majority will register in time

Mr Erwin Annys, Director of REACH / Chemicals Policy at CEFIC, presented feedback from the Directors´ Contact Group at ECHA´s Stakeholders´ Day. Mr Annys believes that many companies will submit their registration relatively late but that most companies will make the deadline.

Mr Annys, now that the first registration deadline is approaching, do you feel confident?

We still feel confident. This was the message of the President of CEFIC some weeks ago and it is still the message I want to give. For the time being, we do not see any indication that many substances will not be registered. Companies are saying that it is really hard work and some might even be working through the night, so I think there will be a lot of dossiers coming in relatively late. However, we are still confident that in the majority of cases, registrations will come on time.

Are you satisfied with the results of the Directors´ Contact Group?

The Directors´ Contact Group is an ongoing project. We feel very glad that in the 28 issues that we have been handling so far, we have reached good solutions which are helpful for industry but at the same time also respect the REACH and CLP regulations. We are pleased about what has been achieved by the Group so far, and more importantly, are keen to identify any lessons learnt from the first registration deadline, so that we can take these into consideration for the 2013 and 2018 deadlines.

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Mr Erwin Annys *sees no indication that many substances will not be registered.*

Register!	30 November 2010
Classify and label!	1 December 2010
Notify classification and labelling	3 January 2011

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Stakeholders praise one-to-one sessions

The 5th Stakeholders´ Day of ECHA on 4 October 2010 gathered altogether 287 participants from 22 EU Member States and 11 non-EU countries to the Helsinki Fair Centre. The programme focused on preparing registration dossiers and notifications and on evaluation and authorisation. The feedback from participants was very positive.

In the presentations at the Stakeholders´ Day, experts from ECHA gave advice on how to prepare a registration dossier successfully. Evaluation and authorisation were also discussed. In his opening speech ECHA´s Executive Director Geert Dancet encouraged Lead Registrants to identify themselves as such, so that downstream users would know that the substance they need will be registered on time. Mr Dancet also hoped that Lead Registrants communicate with SIEF members and help them to meet their obligations.

The day´s programme again included one-to-one meetings between participants and ECHA experts. Participants were able to send in their questions to ECHA in advance and received answers from the experts in private meetings. ECHA's Helpdesk and other staff were also there to answer questions during the breaks.

Two fully booked training sessions also took place during the day, one on member registration submission and the other on the use of C&L notification tools.

The event was web streamed, and over 500 viewers followed the sessions online. Videos of the sessions and the training courses are available on ECHA´s website under Events. All presentations are also available on our website, and we invite you to take advantage of the information available.

This last Stakeholders´ Day before the first registration deadline received very positive feedback from participants. The respondents gave an overall rating between "good" and "excellent" to the content of the event and to the overall organisation. The feedback confirmed that direct dialogue is very much appreciated by both stakeholders and ECHA´s staff. The participants had the chance to express their wishes for the programme of future Stakeholders´ Days, and we are very grateful for all the suggestions received. They will be taken on board.

The next Stakeholders´ Day will take place on 18 May 2011 in Helsinki. "It will be a different world with a lot of knowledge on chemicals," said Mr Dancet in his speech, referring to the vast amount of information that will be submitted to ECHA this year.

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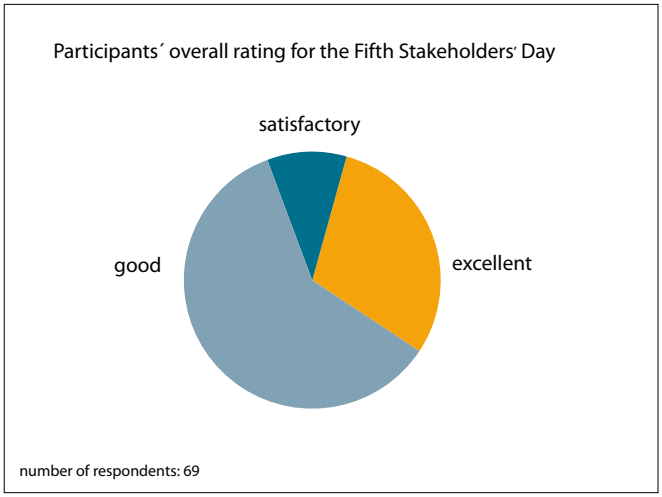
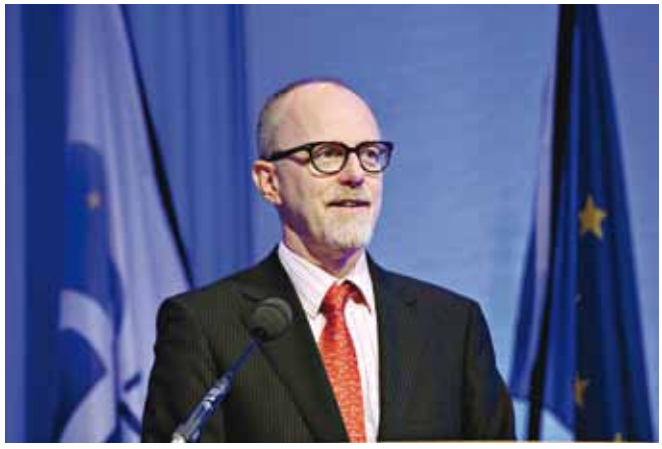
Press Officer Luca *Pettini, Executive Director Geert Dancet and Press Officer Lisa Locchi during a coffee break.*





"I hope you get *responses to your questions" said Executive Director Geert Dancet in his opening speech, and the stakeholders took the opportunity to ask a lot of questions during the Day.*

Exposure scenarios on the wish list

A Norwegian downstream user who is involved in the CLP notification attended ECHA´s Stakeholders´ Day hoping to receive answers to her very specific questions concerning groups of importers and manufacturers. She was especially interested in hearing about the role of an importer and when you can be an importer.

The downstream user, who preferred to remain anonymous, visited ECHA´s event for the first time and found it very useful. She also attended both training courses but she thought that there could have been more of a hands-on format. The Norwegian participant had posted her questions for the one-to-one sessions in advance and got the answers. "For some questions, I am not sure if the answers exist. REACH and CLP regulations are very complex, and there are some situations, which, I understand, can be difficult to foresee when you are drafting legislation," she said.

Her company has had difficulties in finding out whether the substances they need will be registered. "We are not sure. We have tried to contact our suppliers, but we have many suppliers and not all of them are certain. Yes, this communication in the supply chain is a challenge," said the participant. She would greet a standardised communication tool for supply chain communication, developed by industry or by ECHA. "Maybe this is more for industry to pick up than for ECHA. Such a tool would help tremendously."

"Will there be more on exposure scenarios on the next Stakeholders´ Day? This would be very useful for the downstream users," added the Norwegian downstream user before she left for another meeting with ECHA´s legal advisors.

Nominations

New Security Manager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Mr Arto Parviainen was appointed in September 2010 as ECHA´s Security Manager. Parviainen has a Master of Laws Degree (LLM) from the University of Turku and was trained on the bench at Helsinki District Court. He is a Finn, who before joining ECHA, worked for 13 years at an insurance company in different security and risk management positions. For the last three years he has worked as Head of the Operational Risk Management Unit.

New Head of Evaluation Unit III


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Mr Watze de Wolf was appointed in August 2010 as Head of Unit for Evaluation. Watze has a M.Sc. in Biology, a Ph.D in environmental toxicology, and is a EUROTOX Registered Toxicologist. He is Dutch and has over 15 years of professional experience working in the chemical industry and consumer products industry.

Reorganising our work

The organisation of our Agency will change in 2011 to better reflect our present tasks. From January 2011 onwards ECHA will be divided into seven directorates, resulting in the appointment of three new directors in July–August 2010.

New division of tasks:

Directorate of Cooperation.....Andreas Herdina
Directorate of Regulatory Affairs.....Jukka Malm
Directorate of Registration .....Christel Musset
Directorate of Risk Management.....Jack de Bruijn
Directorate of Evaluation .....Leena Ylä-Mononen
Directorate of Information Systems .....Luisa Consolini
Directorate of Resources.....Jef Maes

More to come in the December issue of the Newsletter.

In December issue
- Registration special
- Research on REACH
- International cooperation
- Candidate Countries and REACH

Safer management of chemicals – Submit relevant information!
Consultations: **http://echa.europa.eu/consultations_en.asp**

Management Board


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Chair Dr Thomas Jakl confirmed for a second term

The Management Board of ECHA unanimously confirmed the Austrian member Dr. Thomas Jakl as Chair for a second two year term in office at the Board meeting in Helsinki on 30 September 2010.

Dr Jakl heads the Chemicals Policy Department of the Austrian Ministry of the Environment and has been a member of the ECHA Management Board since the establishment of the Agency. He has chaired the Board since September 2008.

30 September milestone gives first clear indication that many companies are on track

30 September was a significant milestone in the REACH regulation whereby companies who submitted before this date could be guaranteed a Technical Completeness Check result within three weeks of their submission. The last two days before this deadline saw 1 840 dossiers being submitted, and there were 6 275 uploaded dossiers for the whole of September, over four times the 1 479 received in August. This was the first clear signal that many companies are on track for the 2010 registration deadline.

Regarding the processing of the dossiers, ECHA has recently implemented a further automation procedure, helping to ensure that we will be able to provide a registration outcome as quickly as possible. Dossier submissions are expected to continue to build in the coming weeks and we are confident that we are ready to deal with these promptly.

I PRE-PROCESSING

Dossiers accepted for processing in 2010

	1.Inquiry	2.OSII	3.TII	4.Reg	5.PPORD	Total:
Germany	288	216	521	2058	59	**3142**
United Kingdom	135	50	166	761	8	**1120**
The Netherlands	63	28	96	806	12	**1005**
France	103	53	144	688	11	**999**
Belgium	60	22	151	601	11	**845**
Italy	81	49	85	363	22	**600**
Spain	47	69	110	320	4	**550**
Poland	2	62	31	185		**280**
Sweden	22	19	30	178	3	**252**
Ireland	82	12	90	47	6	**237**
Finland	11	7	25	159	2	**204**
Austria	4	7	21	115	7	**154**
Czech Republic	9	10	28	102	2	**151**
Norway	4	1	12	112	1	**130**
Hungary	7	6	25	63		**101**
Greece	21	2	4	72		**99**
Denmark	4	2	3	71	1	**81**
Romania		12	6	63		**81**
Portugal	1	11	5	58	1	**76**
Slovakia	2	6	8	58	2	**76**
Lithuania	2	22		49		**73**
Luxembourg	10		4	32		**46**
Latvia	28		2	13		**43**
Bulgaria	1			36		**37**
Cyprus	2		2	33		**37**
Estonia				13		**13**
Slovenia	1	0	1	11		**13**
Malta	3		3	4		**10**
Iceland				2		**2**

Report refresh date 13/10/2010

We would like to remind companies that it is absolutely essential that the business rules step is passed prior to the end of the 30 November deadline. Particularly companies submitting a dossier for the first time should ensure that their submission is made as early as possible in order to allow time to correct any errors or inaccuracies. We encourage companies to use the detailed information on how to pass the business rules available in the REACH-IT Data Submission Manual Part 04 – How to Pass Business Rule Verification and in the webinars and manuals linked below. In particular, we would recommend two presentations given at the recent ECHA Stakeholders' Day, which outline key points to address in order to ensure a successful registration. (See links below)

Stakeholders' Day presentations: **http://echa.europa.eu/news/events/5th_stakeholders_day_en.asp**

Go to Session 1 – **Registration and Classification and Labelling Notification**

How to secure your registration part 1 – preparing and submitting your dossier

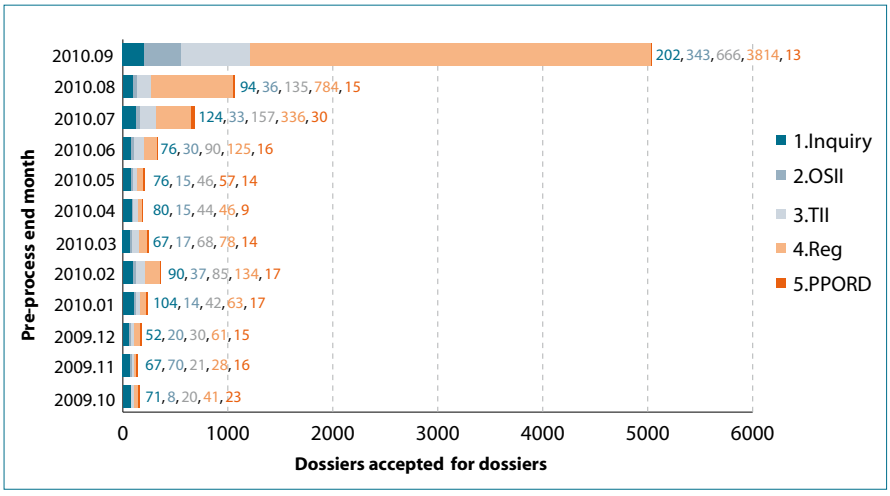
How to secure your registration part 2 – what happens next

Webinars: **http://echa.europa.eu/news/webinars_en.asp**

REACH-IT DSM 04: **http://echa.europa.eu/doc/reachit/dsm4/how_pass_business_verification_en.pdf**

REG	registration
OSII	registration of on-site isolated intermediates
TII	registration of transported isolated intermediates
PPORD	product and process oriented research and development notification
C&L	classification and labelling notification

Visit ECHA's home page for more statistics: **http://echa.europa.eu/home_en.asp**



Report refresh date 13/10/2010

Year	Dossier Type	Accepted for Processing
2010	1.Inquiry	993
	2.OSII	666
	3.TII	1573
	4.Reg	7073
	5.PPORD	152
	Sum:	**10457**

Report refresh date 13/10/2010

II PROCESSING

Processed dossiers

Processing Year	Dossier Type	Accepted	TCC Processing failure %
2010	2.OSII	458	4 %
	3.TII	1173	6 %
	4.Reg	4762	3 %
	5.PPORD	141	3 %
	Sum:	**6534**	**4 %**

Processing Month	Dossier Type	Accepted	TCC Processing failure %
2010.08	2.OSII	31	9 %
	3.TII	123	7 %
	4.Reg	491	4 %
	5.PPORD	20	0 %
	Sum:	**665**	**5 %**

Processing Month	Dossier Type	Accepted	TCC Processing failure %
2010.09	2.OSII	81	0 %
	3.TII	304	5 %
	4.Reg	1653	2 %
	5.PPORD	19	5 %
	Sum:	**2057**	**3 %**

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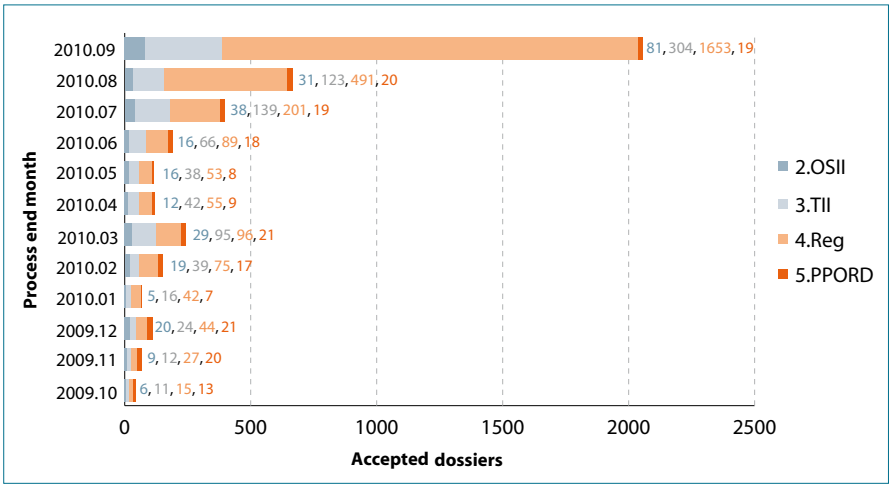
NOTE: TCC processing failure (%) is the number of dossiers that failed TCC during this period divided by the number of dossiers that underwent TCC during this period.



Report refresh date 13/10/2010

Behind the figures

The first part of the statistics reports is on dossiers that have gone through a pre-processing procedure and the second part reports on dossiers that have reached the end of the processing procedure.

The **pre-processing** is obligatory for all dossier types and includes a virus scan, file format and 'business rules' validation steps. The business rules validation checks that dossiers submitted contain all the relevant information to be able to be processed correctly. A successful pre-processing results in the issuing of a submission number.

During the **processing**, a technical completeness check (TCC) and a financial completeness check are made, and they result in the issuing of a reference number and the sending of a decision to inform the company of the outcome.

Inquiries do not undergo a technical completeness check and are therefore not included in the processing statistics.

Please note – the data provided is reported by the number of dossiers undergoing pre-processing or processing during the given period. The dossiers taken into account in the pre-processing table and in the processing table are not necessarily the same dossiers and therefore numbers can not be compared.