ECHA | Newsletter

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ECHA
European Chemicals Agency

Thinking about January

Greetings from sunny Helsinki where we continue to receive REACH registration dossiers well ahead of the November deadline. Congratulations to those of you who have received your registration numbers already – you must have a great sense of achievement and relief to have complied early with the legislation. In Helsinki we are already turning our attention to the deadline in January for companies to notify us of the classification of their chemical substances. We are expecting millions of notifications with many of them potentially needing to come from companies who aren't involved in REACH, which presents a particular communications challenge for us. Individual member states are working on awareness raising with companies and we will be doing our part to support them. Either way, the message is clear – you need to register and notify in time.

I would like to thank the 392 of you who took part in our last Stakeholders' Day (you'll read more inside). You were kind enough to give us excellent feedback on the new format of the day which provided one-to-one sessions for registrants with questions. We got a tremendous sense of satisfaction that you left the sessions with your questions answered and better able to complete your registrations. We want to go a step further at our next day on October 4th and have an extended one-to-one period so that we can speak to even more of you. Details of the day and the registration process will be on our website shortly.

And finally, thank you too to the 1 000 of you who participated in our first stakeholder survey. We are looking forward to hearing the feedback from the survey and to tailoring our services better to meet your needs.

I wish you success with your registrations and an enjoyable summer break.

Lindsay Jackson,
Head of Communications

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Stakeholders´ views and Helsinki Chemicals Forum

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ready?

Who has an obligation

to submit a notification on classification and labelling?

The REACH Regulation is by now familiar, but in the midst of registration preparations, have you had time to consider whether you also have duties under CLP – the Regulation on Classification, Labelling and Packaging? The CLP Regulation requires companies to reclassify, label and package their chemical substances according to the new CLP criteria as of 1 December 2010. In addition, this new classification and labelling needs to be **notified** to ECHA, to the Classification and Labelling Inventory.

The obligation to notify affects numerous companies in various industry sectors, and ECHA expects to receive millions of notifications. The deadline for notifying is approaching – are you ready?

You have an obligation to notify if your company carries out one of the following activities and places the substances on the EU market:

- **Manufactures or imports** substances subject to registration under the REACH Regulation;
- **Manufactures or imports** substances which are classified as hazardous, irrespective of the quantity;
- **Imports** mixtures containing hazardous substances, irrespective of the quantity involved, and the mixture is classified due to the presence of the substance;
- **Imports** articles containing substances which are subject to registration under REACH Article 7 – Substances in Articles.

If you are importing chemical substances, mixtures or certain explosives into the EU, you are considered an importer under the CLP Regulation. Only EU-based manufacturers and importers can submit a notification to ECHA. If you are a non-EU company, you can appoint one of your importers to notify on behalf of all the others (notification as a group). Only Representatives may not submit a notification but can provide the information needed for notification as part of the registration dossier of the substance. In this case, the importers covered by the registration are released from their obligation to notify to the Inventory.

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How to find more information?

The CLP section on the ECHA website in 22 languages: **http://echa.europa.eu/clp_en.asp**

CLP leaflets for downstream users and importers in 22 languages: **http://echa.europa.eu/publications_en.asp**

Practical Guide – How to Notify Substances to the Classification & Labelling Inventory: **http://echa.europa.eu/publications_en.asp**

National helpdesks in all EU Member States: **http://echa.europa.eu/help/nationalhelp_en.asp**

- Substances placed on the EU market must be classified, labelled and packaged according to the new CLP criteria as of 1 December 2010.
- The Classification and Labelling Inventory is a database of basic classification and labelling information on chemical substances.
- From 1 December 2010, a notification should be made within one month of placing a substance on the market.
- The first notification deadline is 3 January 2011.
- Notification is free of charge.
- For substances that are registered under REACH by 30 November 2010, notification can be done as part of the registration.
- Manufacturers and importers can notify as a group.

Guidance updates frozen

As of 1 June, ECHA has postponed further guidance updates until after the first registration deadline. The last eight pieces of guidance on registration and classification and labelling notifications were issued before 31 May, and the publication of other work on guidance in 10 instances will be postponed until after the registration deadline. "That is how we wish to ensure stability of guidance," says Executive Director Geert Dancet.

Study says: Stakeholders share

a common vision on REACH

An American Fulbright scholar, Alison Cohen, has recently conducted a study on stakeholders' perspectives on the implementation of REACH. According to her study, an overall consensus exists as to the good intentions of REACH and the positive work ECHA has done as an implementation agency. The greatest divergence in opinions exists in relation to authorisation and data dissemination.

For the last eight months, Alison Cohen has worked in Europe with joint funding from the US and the EU to study the implementation of REACH. She has met and interviewed over 60 stakeholders from different sectors of government, civil society and industry. Her overall findings are that there is a high level of consensus across these three sectors and that in general people think that REACH is working well.

"The majority of stakeholders think that having a centralised chemical regulation and ECHA as a centralised implementation agency is useful, and that a lot has been done in a short period of time. Technology is what has made the implementation of REACH possible in the first place. Among the stakeholders there was also agreement about the vision of REACH: its successful implementation will protect and enhance public health, occupational and worker health, the environment, market competition and innovation," explains Allison Cohen.

Challenges remain

Whilst the study recognised the overall consensus on REACH, challenges remain in relation to the SIEFs and their functioning, and the role of the Candidate List and data dissemination – in particular the confidentiality of business information. Language barriers have also been identified by SMEs as problematic as has the lengthy process involved in the production of guidance documents.

"Despite these challenges, I've been impressed with the consensus that has emerged. It really seems that there is a lot of potential moving forward. In terms of the future, I would encourage you to make SIEFs work, continue to progress towards harmonised enforcement, clarify policies on confidentiality and continue to be responsive to each other," emphasises Alison.

Interest for REACH

Trained as an environmental health scientist, Alison Cohen reveals that she has learned a lot about REACH in the last year alone.

"I knew more about the science behind REACH than I did about the policy itself – so it has been a great experience. The United States, where I come from, is definitely looking towards Europe and REACH as a model for them to consider in their own chemical policies. There are a lot of people who are very interested to see how REACH is working, how it is being implemented and what lessons can be learned".

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US-EU Fulbright *Scholar Alison Cohen explained the results of her study on REACH implementation.*

Advantage for early Lead Registrants

Lead Registrants who create a Joint Submission Object in REACH-IT and intend to submit their lead dossier well ahead of the deadline can profit from a special service from the ECHA helpdesk. The Joint Submission Object is a functionality in REACH-IT whereby the Lead Registrant creates the technical framework for the joint submission. This includes identification of the substance to be registered, the members of the joint submission and other related information. Creation of the Joint Submission Object is a pre-requisite to making a joint submission to ECHA and can only be done by the Lead Registrant.

After creating the Joint Submission Object, and thus confirming their intent to submit as lead, the Lead Registrant can request assistance for their registration from ECHA´s Helpdesk. These requests are handled as a priority. When appropriate, ECHA Helpdesk will contact the Lead Registrant by phone.

"A lot on our plates"

ECHA's Executive Director Geert Dancet highlights issues around the first registration and notification deadlines.

Is ECHA prepared for the first registration deadline?

Yes, we are ready but of course no one can offer guarantees ahead of the big flow of registrations. We have detailed contingency plans, we are recruiting additional staff and we have back up IT preparations. I can assure you that we are doing everything possible to ensure that we are able to meet our commitments.

How was the Stakeholder Day feedback?

The feedback was very positive. We had a new initiative of one-to-one sessions with Lead Registrants and candidate Lead Registrants. It was really welcomed by industry, and we definitely want to have direct discussions with registrants and be more approachable also in future.

There were some issues regarding blocked dossiers: at times, we have a dossier that gets stuck in the IT system without us being able to solve the problem. The proportion of dossiers stuck in the business rules or further down in the process is still too high, but we are working to find the reasons and solutions. But we also received extremely good feedback from industry which have registered successfully and said that everything went smoothly and better than they had anticipated.

Register early

Why should companies register early and not just before the deadline of 30 November?

The new version of REACH-IT allows Lead Registrants and SIEF members to register at the same time. But I would strongly recommend that all SIEFs try to register in two stages. First the Lead Registrants should register in the summer to be able to verify with us whether their dossier is complete. If the Lead Registrant has passed successfully, then there is a much bigger chance that the members will also get their dossiers through.

It is an advantage for companies to have their registration number as soon as possible and have their correctly registered substance on the market. The expected volume of registrations is huge and from October we have three months to check the completeness of their dossiers. Companies need to remember that dossiers which fail of correctness may not be verified until well into 2011.

So my strong advice is: all those that are well prepared, do it in time, register in time as Lead Registrants and thereby make your whole SIEF happy.

What can companies do if there is no Lead Registrant?

A list of active SIEFs is published on our website, and we are checking with downstream users whether there are missing SIEFs. If a SIEF is missing – which is rare – we advise a potential registrant to move ahead as fast as it can, simply start preparing the dossier and let us know that it is doing it. The company can use the SIEF web form to say that it is a one-company SIEF preparing a separate registration, and if others would like to join, they can let us know and a SIEF can be created.

Solutions foreseen

What is currently happening in the Directors' Contact Group?

We have set the 1 June as the deadline for resolving open issues, and in our last meeting in May, we concluded six of the seven priorities. Now Member State Competent Authorities and inspection authorities are being consulted. We have informed the Forum for Exchange of Information on Enforcement about interim solutions that might be needed in instances that under REACH were not foreseen or are not covered sufficiently. If the situation arises where registrants will not be ready with their dossier in time for registration, they can submit an incomplete dossier. We have now identified how they can do this and how they can inform the inspection authorities of this.

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"I would strongly *recommend that all SIEFs try to register in two stages," says Geert Dancet.*

Awareness not yet there

How is the situation with the notifications of classification and labelling?

It is very important that the Commission is clarifying the outstanding

Continues on next page

Continued – Geert Dancet

question: *Who* has to notify? Many downstream user companies working in research and development may have obligations. We hope to receive the clarification in the coming weeks.

Not all companies that need to notify are aware of their obligations. We are planning different awareness raising measures, but many of these companies are out of our reach. Associations need to make sure that the big companies notify early enough, so that we can publish an inventory around 1 December and launch a sort of "last call" for downstream users.

As was explained at the Stakeholders' Day, the notification tool allows you to agree with the notification of someone else just by pressing the button "I agree", if a notification of the same substance is in our database.

How is ECHA trying to assist small and medium sized enterprises?

That is enormously important, and translation has been a big tool for this. For the classification and labelling notification, we have translated one of the tools in all languages. The combination of practical guides and webinars and translations will help SMEs to overcome the difficulties. And last but not least, there are the national helpdesks!

How is your own work as Executive Director of ECHA now that we are approaching the important deadlines?

It remains a tremendously challenging job. Also there is a considerable degree of uncertainty in this whole enterprise, so this is a sort of burden that you have to carry all the time. You can try to narrow down the uncertainty, but we simply do not have control over all the variables.

So there is a lot on my plate, just as there is for companies throughout Europe. For the first five years the Agency needs to build up, and during this time we need to make sure we keep on delivering on the ever-increasing agenda and programme, which is a constant challenge.

ECHA´s fourth Stakeholders´ Day

Hands-on advice and one-to-one discussions

ECHA´s fourth Stakeholders´ Day brought 392 participants to Helsinki on 19 May. The programme focused in particular on advice to registrants and those who need to notify the classification and labelling of their chemicals. All presentations are available as videos and presentations on ECHA´s website under "Events".

In the various sessions of the day, ECHA's scientists presented the latest tools that are available and gave tips on the preparation of a Chemical Safety Report and classification and labelling. ECHA hopes that registrants and notifiers will use the tools and provide ECHA with feedback.

Participants were able to present their questions during the Question and Answer sessions, and a new approach where Lead and candidate Lead Registrants had the possibility to book, in advance, one-to-one sessions with ECHA's experts was introduced for this stakeholders' day. This opportunity was welcomed by the stakeholders, and ECHA intends to offer the sessions at the next Stakeholders' Day as well. For both the stakeholders and ECHA, the event provided a chance for networking and to get to see the faces behind the names.

"Want to hear your concerns"

"We are leading the world in our quest for safer chemicals that will protect human health and the environment and enhance competitiveness and innovation," said Executive Director Geert Dancet in his opening speech.

"This year is crucial for you and us. Many of you need to register and even more of you need to notify your chemicals to ECHA. Around 65 000 manufacturers and importers still need to react this year, and hundreds of thousands of downstream users will be affected."

The Executive Director said that we all know that REACH and CLP are rather demanding, but the deadlines are fixed and ECHA asks the registrants and notifiers to respect them. He congratulated the SIEFs that are active now but stated that the number of received dossiers so far is not high.

"We want to hear your concerns and answer your questions on the spot as much as we can and explain why we do things like we do" Mr Dancet stressed.

Useful tools

In view of the obligation to notify classification and labelling, Terhi Kuljukka-Rabb from ECHA's Classification and Labelling Unit reminded the audience that the first deadline is approaching fast. Substances on the market on 1 December 2010 must be notified to the Classification and Labelling Inventory, by 3 January 2011. All information concerning the notification is available on ECHA's website in the "CLP/Notification to the C&L Inventory" section. Ms Kuljukka-Rabb discussed in detail the obligations and who is concerned. She also presented an option in the online notification tool, a button which allows the notifier to simply agree with a notification made by another registrant or notifier. In this case the classification and labelling fields will be automatically filled in.

Sandrine Lefèvre-Brévart from the Scientific IT Tools Unit presented the IT tools which have been developed to assist notifiers. ECHA expects millions of notifications, and different types of users will be using the tools, from small and medium sized companies to large

companies with huge databases of classification and labelling information. Ms Lefèvre-Brévart explained which tool is suitable for which type of submission and said that the Bulk Excel Tool has also been translated. "Do not wait until the last minute with your notification," she stressed.

Registration explained

"Every registrant has to know what is a Chemical Safety Report," emphasised Andreas Ahrens from the Guidance and Helpdesk Unit. He focused on the information requirements for the Chemical Safety Report, especially the practical conditions for safe manufacture and use, as well as risk characterisation and exposure estimation. He presented examples of the type and content of exposure scenarios and introduced the guidance available.

Hélène Magaud from the Scientific IT Tools Unit described Chesar, the IT tool developed by ECHA in consultation with industry to support the preparation of the Chemical Safety Assessment and the Chemical Safety Report. She stressed that the tool helps prepare the assessment in an effective and efficient way and ensure a transparent assessment and harmonised structure. The Chemical Safety Report is created from the information in the database, which facilitates the process and makes updates easier. With Chesar, you can currently manage your substances, report uses, manage assessment, build exposure scenarios, generate Chemical Safety Reports and perform administrative tasks, Ms Magaud explained.

Kevin Pollard, Head of the Registration and Dossier Submission Unit said that on the basis of the latest estimations, ECHA has scenarios for receiving 25 000–75 000 registration dossiers by 30 November. One assumption is that there could be around 40 000 dossiers submitted for 5 000 substances. The Head of Unit said that all the tools and information are already in place for a successful registration and explained the different phases of the submission process. Registrants should make sure they understand what business rules verification means and submit all necessary information as required. They should use the Technical Completeness Check tool to check the completeness of their dossier. It is also important to remember that if the invoice is not paid by the extended due date, the IT system will reject the registration.

Dossier evaluation update

Wim De Coen, Head of ECHA's Evaluation Unit 1, explained the division of work in the evaluation process under REACH. Substance evaluation is a responsibility of Member States whereas ECHA is in charge of dossier evaluation. The latter covers both the compliance check as well as testing proposal evaluation. The compliance check aims at verifying compliance with the information requirements and checking whether adaptations are justified. The compliance check is done to at least five per cent of dossiers in each tonnage band. Testing proposal evaluation deals with examining registrants' proposals for tests specified in Annex IX and X of REACH. All testing proposals received are being evaluated, and this process provides a way for ECHA to avoid unnecessary animal testing.

Mr De Coen also made some recommendations concerning the registrants' commenting options and shared recent experiences of the dossier evaluation process.

REACH from the outside

Alison Cohen, a US-EU Fulbright Scholar, presented results of her study on REACH implementation and attitudes of stakeholders towards the legislation. One of her main findings was that there is a joint will to comply. Read more on page 4.

Informing about chemicals

As a result of the REACH implementation, a lot of information on chemicals will be publicly available. ECHA is publishing information from registration dossiers. Catherine Cornu, the project manager of the dissemination project, explained in her presentation which information is made available and which will remain confidential.

The dissemination site is in the "ECHA Chem" section on ECHA's website and was published last December. It has been viewed around 115 000 times by altogether 32 000 viewers. A IUCLID 5 plugin which allows the registrants to

The popular sessions *between companies and ECHA staff will also be in the programme of the next Stakeholders´ Day.*

The Stakeholders asked *ECHA details about registration and notification.*

Hélène Magaud, Andreas *Ahrens, Christel Musset, Antonello Lapalorcia and participants.*

see which information in their dossier will be available for the public is planned to be released in June. This information is defined in Article 119 of REACH. All kinds of registration dossiers are disseminated and the information from joint submissions will be merged into one dossier.

Twofold impact

Tony Musu from the European Trade Union Confederation (ETUC) said that chemicals provide jobs for 1.3 million workers and many more millions in the downstream industries, but there is also growing evidence of their links to diseases like cancer and allergies. He quoted ETUC statistics that around 30 percent of all occupational diseases recognised in the EU each year are related to exposure to chemicals. According to the EU Agency for Occupational Health and Safety, 74 000 work related deaths in the EU per year are due to exposure to hazardous substances. Therefore workers, industrial hygienists, medical doctors, researchers, inspectorates, general public, poison centres – and competitors – are interested in information on chemicals. Mr Musu listed information which ETUC thinks should be published, including the REACH registration number, the CAS number, the most common uses, the contact details of the manufacturer, importer or downstream user, and uses advised against by the supplier.

For informed decisions

Antonello Lapalorcia, Deputy Chair of ECHA's Management Board, discussed in his presentation the importance of public information on chemicals for citizens and the requests for nondisclosure. "We in the Management Board consider of course that dissemination is a corner stone of REACH," said Mr Lapalorcia. He explained that the Management Board have already decided on a review of partial or full rejection of a confidentiality claim and has created an Advisory Group on Dissemination to provide the dissemination and to provide strategic advice to ECHA's management.

Mr Lapalorcia encouraged the participants to look for information gaps in the way ECHA presents the information on its dissemination site and to react. "We need advice from citizens and enterprises", said the Deputy Chair of the Management Board.

Practical help needed

Marko Sušnik from the European Association of Craft, Small and Medium-sized Enterprises (UEAPME) discussed the importance of making information available. The association has 84 member organisations, representing 12 million enterprises which employ 50 million people. The level of knowledge and awareness on REACH varies among the members. Most of them are downstream users or distributors. The information sources offered by ECHA are very important for them and the association.

Mr Sušnik said that the members ask for sector-specific information in their own language. SMEs are overburdened with the legal obligations and often do not have a scientific background on testing of chemicals, competition law or legal issues in consortia. He called for translations of important sections on ECHA's website, easier guidance and practical assistance by helpdesks.

Keeping research and development in Europe

The chemical industry in Europe still remains the most important chemical industry in the world, said Erwin Annys from the European Chemical Industry Council (Cefic). However, its world market share decreased from 32 to 28 percent in five years. Cefic agrees that innovation is one of the major goals of REACH. Mr Annys stressed that confidentiality and respect for research and development are preconditions for innovation. "There is no remedy possible if the wrong information is becoming publicly available."

Cefic is looking forward to the ECHA software that will allow companies to check in advance which data will be public and the fee calculator to estimate the cost of confidentiality claims. Industry expects that old confidentiality claims accepted before REACH are maintained and that registrants will be given sufficient time to update the claims. The dissemination database should be easy to use and contain information that the public can understand. Industry will contribute to dissemination by publishing their own safety summaries, Mr Annys said.

More work to be done

"We will do more work on resolving the confidentiality question with regard to classification and labelling," promised Executive Director Dancet in his closing remarks. "We also would like to progress in reaching the Only Representatives and responding to their needs." Mr Dancet also promised that ECHA will translate as many documents as possible. He addressed the downstream users and said that it is in their interest to provide information on their uses and the volumes. Otherwise they may need to prepare a Chemical Safety Report themselves. It would also be important for them to check whether the substances they need are on the list of substances to be registered in 2010.

Published in May–June

General	
General Report 2009[1]	Read
Publications catalogue	Read
REACH timeline brochure (update)[1]	Read
Classification, Labelling and Packaging brochure for importers[2]	Read
Classification, Labelling and Packaging brochure for downstream users[2]	Read
Guidance	
Guidance on the preparation of dossiers for harmonized classification and labelling	Read
Guidance on waste and recovered substances[1]	Read
Guidance on information requirements and chemical safety assessment – Exposure Scenario Format[1]	Read
Guidance on information requirements and chemical safety assessment – Chapter R.14: Occupational exposure estimation	Read
Guidance on information requirements and chemical safety assessment – Chapter R.16: Environmental exposure estimation	Read
Definition of intermediates as agreed by Commission, Member States and ECHA on 4 May 2010 (under Guidance on Intermediates)[1]	Read
Practical Guide 7: How to notify substances in the Classification and Labelling Inventory[2]	Read
Practical Guide 9: How to do a registration as a member of a joint submission[1]	Read
Practical Guide 10: How to avoid unnecessary testing on animals[1]	Read
Guidance Fact Sheet on waste and recovered substances[1]	Read
Frequently Asked Questions on REACH (version 3.1)	Read
IT Manuals	
Data Submission Manual 5 – How to complete a technical dossier for registrations and PPORD notifications (update)[1]	Read
REACH-IT Industry User Manual 6 – Dossier submission (update)[1]	Read
REACH-IT Industry User Manual 7 – Joint Submission (update)[1]	Read
Chemical Safety Assessment and Safety Reporting tool (CHESAR) User Manuals	Read

[1] Being translated into 22 languages
[2] Available in 22 languages

Risk Communication Network – current activities

▸ The Risk Communication Network is a voluntary network of the Member State Competent Authorities who are in charge of managing communication to the general public on the risks from chemicals and their safe use. The Network was established by ECHA to provide a platform for the Authorities to coordinate their activities and exchange experience and best practice.

Currently, among other projects, the Network is closely following the development of the "Study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels".

The "CLP Regulation" (Art. 34) requires that ECHA carries out this study by 20 January 2012. On the basis of the results, the European Commission can then propose amendments to the Regulation. In preparation for the Communication Study, ECHA has commissioned a Eurobarometer Survey to be carried out in all 27 EU countries as well as in some EEA and Accession Countries. It will assess how citizens understand the new label symbols and hazard pictograms, signal words and hazard phrases.

The questionnaire for the Eurobarometer survey is being prepared as we write.

The Eurobarometer survey is expected to be completed in October 2010, and ECHA should receive the report by the end of 2010.

Readers' opinion

▸ In spring, ECHA launched a Newsletter reader survey to hear whether the publication meets your needs and how we can improve it. We also wanted to find out more about you, our readers, in order to target better our articles. Around 310 readers replied to the survey, one third of them from non-EU countries.

Most of you have a professional interest in ECHA and chemicals legislation. EU-readers work mainly in downstream user companies (18%), manufacturers of chemicals (17%), or are consultants/law firms (15%). For them, news, guidance, events, statistics and enforcement were the most interesting. The great majority would like to read more about REACH and the Regulation on classification, labelling and packaging of substances and mixtures (CLP).

Around 29% of replies came from non-EU countries, mainly from Asia. The non-EU readers were mainly interested in news, guidance, events, IT tools, statistics, enforcement, CLP and REACH.

The quality of the articles was rated good or excellent by 58% of the EU-readers, and 74% found the articles relevant or very relevant. 76 % rated the articles in the latest issue to be well written and easy to understand. The rating of the non-EU readers was either good (44%) or satisfactory (31%). 79% considered the articles to be relevant or very relevant.

Readers were happy to have a chance to comment and want to read more on substances in articles; the impact of REACH on downstream users and article producers; substances of very high concern, "the experiences of other registrants" and why dossiers are rejected.

Many readers wished to have more direct contact with ECHA. The difficulty in getting in touch with us clearly frustrates many of you.

We will take the comments into account as far as possible and will focus especially on topics that are relevant for registrants and notifiers.

We thank you all most cordially for your feedback and would be happy to receive your comments at anytime to our Newsletter mailbox: **echanewsletter@echa.europa.eu**

ECHA-Canada

Memorandum of Understanding signed

The European Chemicals Agency (ECHA) and Canadian authorities from the Federal Department of the Environment and the Federal Department of Health are about to start working together in the area of chemicals safety.

The purpose of ECHA's first bilateral agreement is to strengthen the scientific dialogue between the EU and Canada and increase cooperation on technical matters and other issues of common interest, including emerging risks from chemical substances or guidance development. By putting into force a detailed work plan, the regulatory authorities hope to benefit from the knowledge gained and best practice developed by both parties from their respective chemicals safety legislation.

They also agreed to work with the authorities in Brussels and Ottawa towards a separate agreement that would permit the exchange of confidential business information in accordance with Article 120 of the REACH Regulation, and s. 316 of the Canadian Environmental Protection Act, 1999.

Geert Dancet, ECHA's Executive Director, and George Enei, the Director General of the Science and Risk Assessment Directorate for Environment Canada, signed the MoU after their meeting in Helsinki on 21 May. Upon signature, Mr Dancet concluded "this Memorandum of Understanding opens the door for cooperation between both regulatory authorities for the benefit of companies and citizens on both sides of the North-Atlantic Ocean".

Exchange of best practice

ECHA is hoping to establish memoranda of understanding with authorities which have a similar legislative remit to ensure the safe use of chemicals. "Under the OECD umbrella, many countries have agreed common standards in terms of hazard identification and risk assessment and risk management. This permits a more productive exchange of best practice," says Executive Director Geert Dancet.

"Canada is the first country with whom we have established a memorandum of understanding, and we are now also planning similar ones with the United States and Australia."

"I think we have a good chance of getting a better exchange with equivalent authorities to learn and exchange good practice, without exchanging confidential information. For that we need a bilateral agreement involving also the European Commission.

This is an element that we can work towards in the future. But it is not necessary to have that kind of agreement to exchange good practice and information which is anyway already available or is being made available to the public."

Building experience

The first registration deadline is approaching and there are only a few months left. During the past year, ECHA and various industry associations have gathered as much information as possible to be able to make an estimate on the number of substances that will be registered before the November deadline. The number of dossiers received so far is within the range predicted by these estimates, but the current rate of registration is slower than had been expected and ECHA encourages companies to submit their registrations soon.

In order to succeed in the registration process, the dossier must first pass the "business rules" step. ECHA has prepared a detailed manual and Q&As as well as specific webinars. In addition, help is available via the Helpdesk to give support in passing the first steps of the registration process. The key to success is to familiarise yourself with the submission process well in advance. It would also be worthwhile to consider prioritising at least one registration for very early submission in order to build experience of the process. All the manuals and lots of information, for instance under Questions and Answers, are available on the ECHA webpage.

The number of failures in Technical Completeness Check has decreased significantly since the introduction of "TCC plug-in". This development has showed both ECHA and industry that checking the dossier with the plug-in tool before submitting it to ECHA really pays off. Therefore it can be said that the use of TCC plug-in is a simple and effective way to ensure a successful submission. We therefore encourage you to use this plug-in, and to note that we will soon release an updated version which will also include a larger number of the "business rules", allowing these also to be pre-checked by you.

I PRE-PROCESSING

Dossiers accepted for processing in 2010

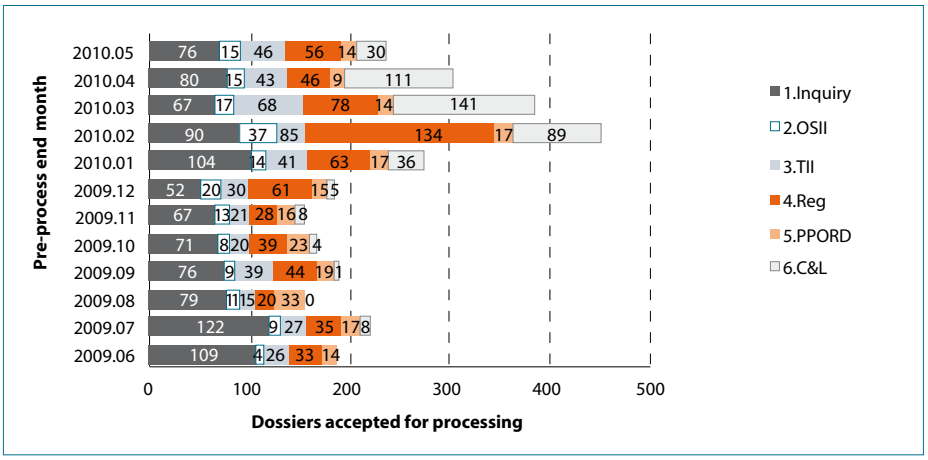
	1.Inquiry	2.OSII	3.TII	4.Reg	5.PPORD	6.C&L	Sum:
Germany	131	59	139	163	25	235	752
Spain	34	10	33	15	3	130	225
United Kingdom	53	2	27	46	4	74	206
The Netherlands	37	2	18	68	10	50	185
Belgium	30	4	21	38	8	48	149
France	38	9	24	30	6	12	119
Italy	34	9	19	11	9	2	84
Ireland	40	5	14	3	4	1	67
Sweden	16	2	8	1	2		29
Finland	6	1	1	13	2	1	24
Luxembourg	7			9			16
Austria	4		2	2	2	1	11
Czech Republic	2	1	2	1		1	7
Denmark	2	0		3		2	7
Hungary	3			2		1	6
Poland	1		3	2			6
Norway			0	5			5
Malta	1		3				4
Slovakia	0	2		1	1		4
Cyprus				2			2
Portugal				1	1		2
Romania				2			2
Greece	1						1

Report refresh date 10/06/2010

Year	Dossier Type	Accepted for Processing
2010	1.Inquiry	440
	2.OSII	106
	3.TII	314
	4.Reg	418
	5.PPORD	77
	6.C&L	558
	Sum:	**1913**

NOTE: Yearly table includes all dossiers until the report refresh date.

Report refresh date 10/06/2010



II PROCESSING

Processed dossiers

Year	Dossier Type	Accepted	TCC Processing failure %
2010	2.OSII	86	9 %
	3.TII	251	11 %
	4.Reg	343	8 %
	5.PPORD	70	4 %
	Sum:	**750**	**9 %**

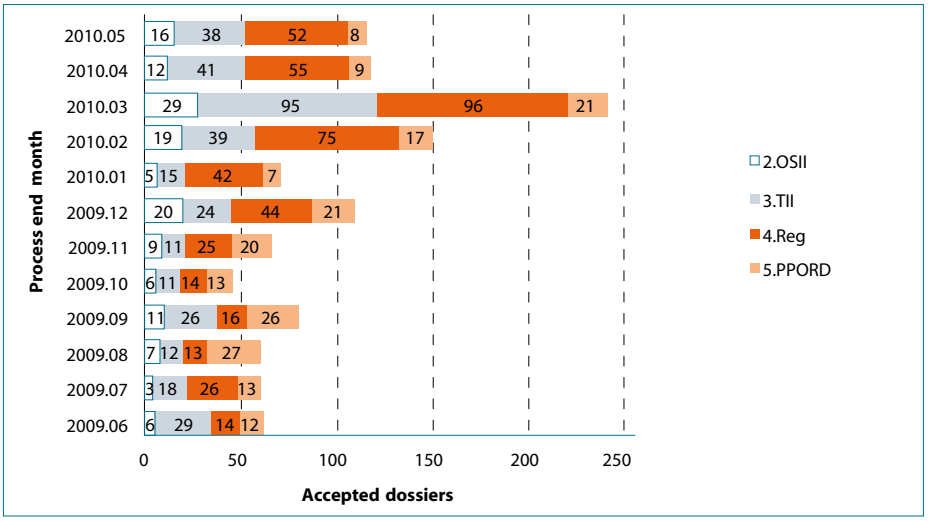
Month	Dossier Type	Accepted	TCC Processing failure %
2010.04	2.OSII	12	14 %
	3.TII	41	11 %
	4.Reg	55	7 %
	5.PPORD	9	0 %
	Sum:	**117**	**9 %**

Month	Dossier Type	Accepted	TCC Processing failure %
2010.03	2.OSII	29	6 %
	3.TII	95	7 %
	4.Reg	96	6 %
	5.PPORD	21	0 %
	Sum:	**241**	**6 %**

Month	Dossier Type	Accepted	TCC Processing failure %
2010.05	2.OSII	16	23 %
	3.TII	38	12 %
	4.Reg	52	11 %
	5.PPORD	8	0 %
	Sum:	**114**	**13 %**

Report refresh date 10/06/2010

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.



Behind the figures

After a dossier has been uploaded, REACH-IT performs various process steps. This overall processing of a dossier can be divided into two parts, namely pre-processing and processing.

The pre-processing is obligatory for all dossier types and includes the virus scan, file format and "business rules" validation steps. The business rules validation step checks if 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.

(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.)

The first part of the statistics reports on dossiers that have gone through the pre-processing procedure and the second part reports on dossiers that have reached the end of the processing procedure. Data is provided for the following dossier types; inquiries, registration of on-site isolated intermediates (OSII), registration of transported isolated intermediates (TII), "standard" registrations, product and process oriented research and development notifications (PPORD) and classification and labelling notifications (C&L). Inquiries and C&L notification dossiers do not undergo a TCC under Article 20 of REACH and are therefore not included in the processing statistics.