ECHA Newsletter

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Editorial

No 6 - November/December 2009

Greetings from a sub-zero Helsinki!

This is our last newsletter of 2009. It's been a momentous year for me personally – moving with my family to live and work in Helsinki – and I know that it's been an important year for you too.

If last year was the year of pre-registration, then this year has been the year of the SIEF, when companies throughout Europe and beyond began to get to grips with the notion of SIEFs and started trying to make them work. And we know that hasn't been easy. The idea of sharing information on substances - their hazards, managing their risks and using them safely – is popular and understood. Reducing the need for animal testing and company costs are both also very worthy aims. But the practicalities of doing that with potentially thousands of companies in a SIEF have been challenging. We all owe a vote of thanks to the thousands of companies who have stepped forward and been willing to take responsibility as Lead Registrant for their substance's SIEF. We have been trying to support you where we can – with activities for example for Lead Registrants (workshops, webinars and an online discussion platform) and more translations for small firms. We've had positive feedback on all those initiatives so please take the time to look at what we're now providing online.

It's been an intense year of working with our stakeholders too. We held two Stakeholder Days in Helsinki – in May and December – they attracted over 1200 participants in person or via webstream. You can still see the video online if you missed out.

And a major activity of the year has been planning for 2010. This will be the most challenging year yet for ECHA and for many of you. Two legal deadlines loom at the end of next year – the first registration deadline and the deadline for notifying the classification and labelling of substances. These come within a month of one another, either side of Christmas.

Just as you are gearing up to meet your obligations under the REACH and CLP Regulations, so too are we gearing up to meet our obligations to you. As part of that planning process, we have been building scenarios of the potential workload throughout 2010 (centred around the timing and volume of the submitted dossiers) and working through our resource requirements to manage the load. We've also been stress testing our IT systems and procuring a back up to REACH-IT that can receive dossiers in the event of system failure. Of course, no preparations are ever foolproof, but we've learned a great deal from our first major deadline of pre-registration and we're putting those lessons into practice.

Finally, I take great pleasure in wishing you a very merry Christmas and a happy New Year. And of course I wish us all the greatest of success in 2010.

Lindsay Jackson

From *the Executive Office*

From the ECHA Management Board

Access to REACH-IT

The Management Board of ECHA has reached agreement on the conditions for providing access to REACH-IT for Member State Competent Authorities. The matter was discussed between ECHA, the Commission and EU Member States because of the fine balance that needed to be struck between vital security aspects and transparency.

The final agreement ensures that the industry data which ECHA makes available over secure connections to Member States Competent Authorities is well protected. ECHA will provide limited access to the authorities so that they only have access to information that they need in order to be able to fulfil their obligations under the REACH and CLP Regulations.

The connection to REACH-IT is important for the EU Member States for example in the context of scientific substance evaluation. Access to registration dossiers is also crucial for the efficient enforcement of the REACH and CLP Regulations in the Member States.

Board of Appeal

First appeal received

On 16 September ECHA's Board of Appeal received its first appeal, opposing an ECHA decision to reject a registration submitted by the appellant. A summary of the appeal is available in the Appeal section of ECHA's website.

In this particular case, the Executive Director of ECHA concluded, after consultation with the Chairman of the Board of Appeal, that the appellant's case was admissible and well-founded. The Executive Director therefore decided to rectify the contested decision, a possibility which is provided for in the REACH Regulation. The concluding decision of the Board of Appeal of the case is also published on the ECHA website.

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

Geert Dancet at the European Parliament´s Environment Committee

On 3 November, the European Parliament Committee on the Environment, Public Health and Food Safety welcomed ECHA's Executive Director, Geert Dancet, for an annual exchange of views. The occasion allowed the Committee an opportunity to hear from Mr Dancet on developments within the Agency over the past year, and to consider the challenges that lie ahead as the first registration deadline under REACH nears, shortly followed by the deadline for industry to notify ECHA of the Classification and Labelling (C&L) of their hazardous substances.

Of the issues raised by MEPs, much attention was paid to how ECHA is alleviating the impact of REACH on small and medium-sized enterprises (SMEs) – particularly given the complexity of the Regulation, and the current economic climate.

Mr Dancet acknowledged the demands industry is facing to meet its legislative obligations, and explained that by consulting regularly with them, ECHA is striving to ensure its guidance, support services (such as the Helpdesk) and IT tools, are accessible and best suited to the needs of companies – particularly SMEs.

He pointed also to the importance of industry data-sharing requirements – key to the successful implementation of REACH, and vital to avoiding unnecessary animal testing and costs, and to enabling SMEs to fulfil their chemicals management obligations. The Committee heard that while ECHA holds no formal role in the Substance Information Exchange Fora (SIEF) process, it has been proactively working to provide special services for lead registrants and to increase support to SMEs, by providing training to national helpdesks, for example. A dedicated campaign was launched by the Agency in 2009 to encourage the formation of SIEFs and foster data sharing, and a corresponding C&L campaign will begin at the next Stakeholders Day, he explained.

Reviewing the successful progress made by the Agency since its establishment, Mr Dancet noted the risk management work that had already begun – e.g. the publication and initial updating of the Candidate List of substances of very high concern and the submission of a first recommendation to the Commission for priority substances for authorisation. Work on the dissemination of information on chemicals to the public is also progressing. However, both he and the Committee pointed to the demands that will be placed on the Agency in the coming year.

Navigating the uncertainties that remain about the volume of industry registrations to be received during 2010 will require flexibility in the management of the Agency's resources, and may imply increases in resource needs – particularly human – emphasised Mr Dancet. He acknowledged the impact that an unprecedented number of registrations could have upon priority-setting, and the limitations of even the most comprehensive (administrative) risk management plans. Nevertheless, the Committee were assured of the work being done by the Agency to prepare for and anticipate these challenges, and MEPs reiterated the willingness of the Committee to provide the Agency with the best assistance that it could.

During the exchange, Mr Dancet thanked the Committee for its continued support, and invited a Committee delegation to visit the Agency in the new year. He also took the opportunity to extend a welcome to the newly proposed Parliamentary representatives on the ECHA Management Board, Mr Guido Sacconi and Mr Hartmut Nassauer, who are expected to join the Board shortly.

The new CLP Regulation – challenges and opportunities

The new EU Regulation on the Classification, Labelling and Packaging of substances and mixtures brings new obligations for suppliers of chemicals. From 1 December 2010, all chemical substances on the EU market must be classified and labelled according to the new system. In many cases, ECHA needs to be notified of the classification and labelling of the substance. Suppliers can propose harmonised classification and labelling for a particular substance and request the right to use another chemical name for substances in mixtures.

The CLP Regulation (EC) No 1272/2008 entered into force on 20 January 2009 and introduces the UN Globally Harmonised System (GHS) into the legislative framework of the European Union.

From 1 December 2010, all suppliers placing chemical substances on the market have to classify and label their substances in accordance with the new criteria. From 1 June 2015 this also applies to mixtures (preparations) produced from the substances. The classification according to the Dangerous Substance Directive (DSD) continues until 1 June 2015.

As under the previous legislation, industry has to use the classification harmonised at EU level whenever available; however now only for those hazard classes covered by the entry in the list of harmonised classifications.

Obligation to notify ECHA

By 3 January 2011, manufacturers and importers of chemical substances placed on the market on 1 December 2010, have to notify the classification and labelling to ECHA. This applies to all substances, which need to be registered under REACH, and to all other substances meeting the classification criteria, irrespective of the volume manufactured or imported.

ECHA will establish a classification and labelling inventory which will be accessible over the internet. This will include the notified classifications as well as classifications included in the registration dossiers submitted under REACH and the classifications that are harmonised at EU level.

Suppliers can propose harmonisation

Unlike the previous legislation, it is now possible for suppliers to submit proposals for harmonised classification; however, only for substances and hazard classes for which the classification has not already been harmonised.

The harmonisation of classifications has become more transparent and all proposals will now be published so that all parties concerned can provide their comments on the proposals.

Harmonisation under CLP focuses on the hazardous properties of substances that are of highest concern. However, classifications for other effects can also be harmonised, if it is justified. The classifications for all hazards need to be harmonised for active substances of plant protection products and biocidal products.

Alternative names for substances

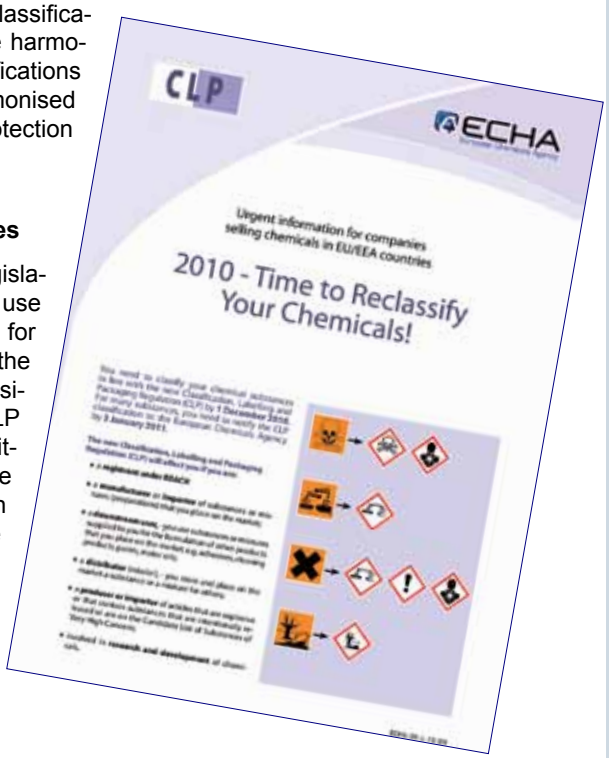
Finally, as under the current legislation, suppliers can request the use of an alternative chemical name for substances in mixtures placed on the market. When the mixture is classified in accordance with the new CLP criteria, the request shall be submitted to ECHA and, if accepted, the alternative name can be used in all EU Member States. When the mixture is still classified in accordance with the Dangerous Preparations Directive, the requests have to be sent to the national competent authorities.

A priority issue in 2010

Although the new CLP Regulation provides challenges for the European industry, it also brings opportunities. The major challenges pertain to the requirements to classify substances in accordance with the new criteria from 1 December 2010 and to notify the new classifications to ECHA by 3 January 2011.

Thus, classification and labelling of chemical substances is a priority issue for industry in 2010.

The new CLP leaflet is available on ECHA's website:
http://echa.europa.eu/publications_en.asp



Important CLP deadlines

1 December 2010	Substances must be classified and labelled according to the CLP criteria
3 January 2011	Substances which are hazardous or subject to registration and are placed on the market (Date of marketing) on 1 December 2010 must be notified
Ongoing	Substances which are hazardous or subject to registration and are placed on the market after 1 December 2010 must be notified within one month
1 June 2015	Mixtures placed on the market must be classified and labelled according to the CLP criteria

News from *ECHA*

CLP deadlines in 2010 and 2011

Manufacturers and importers have to classify their substances in line with the new CLP criteria from 1 December 2010 and notify the classifications to the Classification & Labelling Inventory in ECHA by 3 January 2011. Petteri Mäkelä from ECHA Communications thinks that many small companies may still be unaware of their obligations.

Large companies which need to register chemical substances under REACH are aware of their obligations to classify and label. However, small companies and sectors which have traditionally not been impacted by chemicals legislation may not know about them. “Big companies are already very active, but many smaller companies which manufacture or import substances in low tonnages are not yet aware that they have to prepare for CLP even though they are not subject to REACH”, says Petteri Mäkelä, Communications Officer at ECHA.

Photo by Esko Jämsä

Petteri Mäkelä

ECHA, the EU Member States and industry associations are responding to this lack of awareness with a wide range of activities. “All Member States and ECHA have put websites dedicated to CLP in place. National helpdesks in all EU Member States offer their support if a company needs clarification on its obligations”, Petteri Mäkelä explains. “Actually, we are witnessing an increasing interest in the CLP Regulation. Recent statistics have revealed that many questions posed to the national helpdesks concern the notification deadline, labelling obligations and how to prepare Safety Data Sheets using the CLP classifications.”

Member States have produced information leaflets and brochures dealing with the CLP obligations. This material is available in the national languages. ECHA has published on its website an introductory guidance document on CLP in 22 EU languages, a guidance document on the application of the CLP criteria, a general leaflet and a first package of Frequently Asked Questions.

Further material is under preparation, including a brochure explaining how to notify a classification to ECHA. “We have to spread the message in many ways to reach SMEs”, Petteri Mäkelä says, “and the Member States and industry associations are key in that regard. Lots of conferences, workshops and seminars on CLP are organised in the Member States. Also ECHA´s recent Stakeholders’ Day in early December was devoted to CLP issues.”

ECHA thinks that the notifications to the Classification & Labelling Inventory may arrive in waves. The ECHA IT team is currently implementing new features in the REACH-IT system. These will facilitate for example the submission of several notifications at the same time and the submission of notifications by a group of manufacturers or importers.

It is difficult to estimate how many notifications will arrive in ECHA. Petteri Mäkelä has tried to get more clarity on this: “We have received estimates from industry which amount to 500,000 to 1 million notifications for one sector only. Overall, we expect to receive several million notifications, most of them in November and December 2010.”

What about contingency planning to manage this challenge? Petteri Mäkelä says. “Indeed, December 2010 is only twelve months away. We are hoping that industry will start with their notifications already in the spring or summer 2010 and will not send them at the last minute. Nevertheless, our helpdesk and IT team have started to plan also for such a last minute scenario.”

**Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, OJ L353, 31.12.2008*

ECHA at your service – in your native language!

Since 1 June 2007, when ECHA started its activities, more than 170 documents have been translated from English into 21 other official EU languages. We translate guidance, fact sheets, webpages, IT manuals, information leaflets, work programmes and annual reports. The translations are intended for wide audiences across the EU and can be found on ECHA’s website in the following languages:

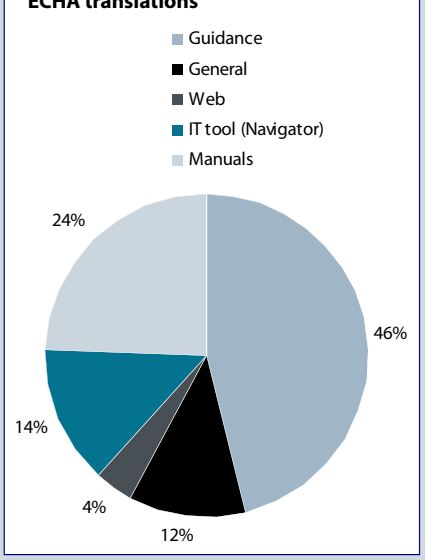
Bulgarian, Czech, Danish, Dutch, Estonian, English, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovene, Spanish, Swedish

In 2010, as in the recent past, priority will be given to guidance documents, webpages and administrative documents that have a wide audience. Highly scientific or technical documents, as well as urgent time-bound publications, will continue to be published in English.

The greatest challenge in the translation process is to ensure the correct and consistent use of terminology in all 22 languages. To improve the quality and consistency, ECHA is working with the Member State Competent Authorities who are validating the translations for us. ECHA has also launched a project to develop a multilingual REACH terminology database in cooperation with The Translation Centre for the Bodies of the European Union (CdT). Initially, the database will cover REACH-related terminology in 22 EU languages. In the long term, the database may also include CLP terminology and possibly cover even more languages, too. The first version of the platform is expected to be published in late 2010 and it will be publically available for all to use.

ECHA’s documents are translated by CdT which is located in Luxembourg and provides translation services to all EU agencies. ECHA is the second largest client of CdT.

ECHA translations



New mandate on biocidal products proposed for ECHA from 2013

ECHA's mandate may be extended to include biocidal products. The European Commission's recent proposal for a new Regulation on Biocidal Products[1] foresees a role for ECHA in the evaluation and re-assessment of active substances and in a new centralised authorisation process. The proposed procedures have similarities to REACH.

The new Biocides Regulation proposed by the European Commission in June 2009 aims to tackle problems that were encountered when implementing the present EU rules on biocides (Directive 98/8/EC). The scope of the new regulation is wider and includes both biocidal products and materials treated with them, such as textiles and furniture.

The proposed Regulation has similarities with REACH. It foresees for instance information requirements with possibilities for waiving, a data sharing mechanism and exclusion criteria for substances with certain properties of high concern.

New tasks, new Committee

According to the proposal, ECHA would coordinate the evaluation of new and existing active substances and re-assess the already approved active substances. The current two-step authorisation scheme for active substances and for products would mainly stay the same. A new centralised authorisation scheme would apply for products containing new active substances and for so called low-risk products. ECHA should play a key role in this centralised authorisation process. All other products would be authorised through national schemes.

A new Biocidal Products Committee would be established in ECHA, and it would be composed of members nominated by the Member States and appointed by ECHA's Management Board. The Committee would issue scientific opinions on active substances and on products that require Community authorisation, to be used by the European Commission in its decision making.

The ECHA Secretariat would provide scientific and technical support, guidance and advice for the implementation of the new rules. It should maintain databases, manage the applications and coordinate their scientific assessment by Member State Competent Authorities.

The necessary additional staff for ECHA would be funded partly by fees and partly by a subsidy from the Community budget. The negotiations on the proposal have started in the Council and in the European Parliament. The foreseen entry into force of the new rules is in January 2013.

[1] Commission proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products. COM(2009) 267 final

Biocides are active substances

Biocidal products are chemicals that are used against harmful organisms like bacteria or pests to prevent them from causing damage to human health and to different products and materials.

There are many different types of biocidal products. Consumers use them in households, for instance insecticides and disinfectants, and industrial and professional users may use biocidal products like wood preservatives or antifouling paints in the workplace.

Biocidal products contain active substances that may, due to their properties and uses, also pose a risk to human health or the environment. To prevent these risks, biocidal products need to have an authorisation which aims at ensuring the safety of the products that are on the market.

ECHA welcomes the proposed new role on biocides

Jukka Malm, ECHA's Director for Assessment, greets the plan to entrust ECHA with new tasks in the Biocides Regulation.

"The new proposed tasks are consistent and compatible with our current tasks under REACH and the CLP Regulation. Our present scientific work and these new tasks are quite similar, and also the procedures have much in common", Jukka Malm says.

He adds that the experiences gained from REACH and CLP implementation could be useful for the new tasks. "This experience should be taken into account when the biocides tasks are planned. This would ensure synergies in the practical implementation of the new rules."

Jukka Malm underlines that it is necessary to start with practical preparations well before the entry into force of the new rules. "ECHA is of the opinion that we should already now start the preparatory work to ensure efficient implementation from the very beginning. This was done with REACH through the so called RIP projects and proved to be extremely helpful for all actors."

However, Jukka Malm underlines that ECHA needs additional resources for the proposed new tasks: "For ECHA it is extremely important to have appropriate additional resources for any new tasks. The current and already foreseen future resources will be fully needed for implementing REACH and CLP."

Photo by Esko Jämsä

Jukka Malm finds that the proposed tasks correspond well to ECHA's current mandate and competences, but more resources and early preparations would be necessary.

ECHA *introduces...Webinars*

Webinars - interactive online guidance for lead registrants

Since October 2009, ECHA has been organising online guidance events for focussing mainly on Lead Registrants. These webinars are available for all on ECHA´s website after each event. The first experiences have been very positive.

ECHA webinars are interactive online events that provide industry with guidance on the registration of chemical substances. The participants follow the presentations over the internet and can submit questions during the webcast. The term "Webinar" refers to a "web seminar". Webinars are an effective means of communication between a group of presenters and a large audience. An ECHA webinar can host up to 1000 participants. No travelling is required, and participants can follow the event from anywhere, as long as they have access to a computer with an internet connection.

Although ECHA´s webinar campaign focuses on Lead Registrants, the information is also useful for any company preparing a registration dossier. Therefore, the webinars are recorded and published on ECHA´s website shortly after the event.

The first Lead Registrant webinar "General Principles of Dossier Preparation and Submission" was attended by over 300 participants from 31 countries. Two further webinars focussing on information requirements were also held at the end of 2009. Additional webinars are scheduled for the first half of 2010. A more detailed timetable and content from previously held webinars can be found in the events section of the ECHA website at: **http://www.echa.europa.eu/news/webinars_en.asp**.

The overall feedback has been very positive. ECHA will use it in the planning of future webinars with the aim of making the events as relevant as possible for the needs of industry.

Good technical quality

The demand for online meetings and conferences is increasing and the technologies have developed significantly in the past years. While we are used to sending text via email and other text based messaging tools, or audio via VoIP software, online conferencing tools provide the facilities for all of these options and more. The webinar platform used by ECHA is capable of transmitting audio, video and PowerPoint presentations over the internet and the presenter's desktop can be shared with the audience. This enables for instance live software demonstrations using tools such as IUCLID 5.

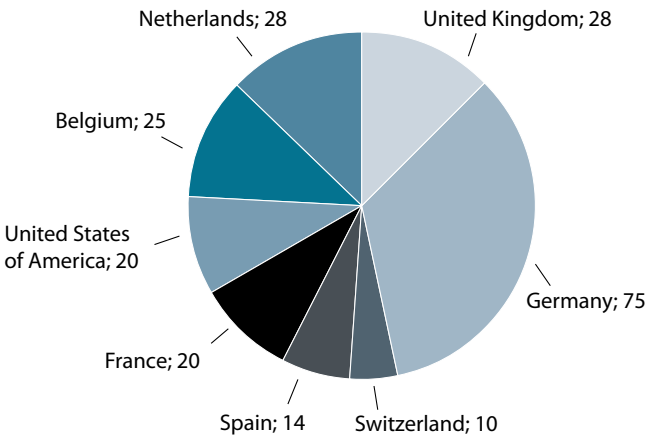
With the webinar platform, there are issues that need to be taken into account. As the software streams large amounts of data over the internet, bandwidth restrictions and computer hardware may affect the overall quality of the webinar for individual participants.

However, according to the feedback of the first webinar, only 5–10% of the attendees experienced difficulties with sound or picture quality. The recordings of the events are always of good quality.

ECHA is looking forward to your active participation in the next Lead Registrant webinars!

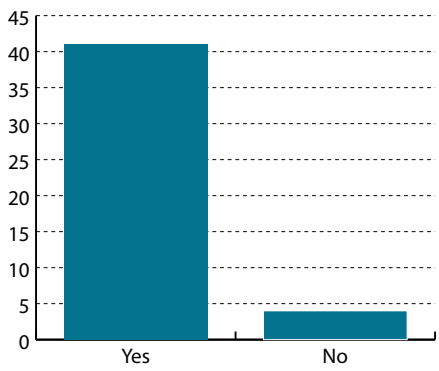
ECHA staff provides answers to industry questions during the webinar

Top Countries (Number of participants)



Overview of the top participating countries during the first Lead Registrant webinar

Has this webinar helped you to better fulfil the role of Lead Registrant? (Number of participants)



Feedback from the participant survey of the first Lead Registrant webinar

Interview: *Alain Lefebvre*

Managing challenges

Alain Lefebvre, Head of the Executive Office in ECHA has a careful eye on 2010 and the next registration deadline.

The Head of the Executive Office and his staff assist Executive Director Geert Dancet and the Management Board in all management tasks, from strategic, organisational questions and day-to-day management, to preparing the agency for unforeseen events.

Currently, ECHA and its partners from industry are working for next year's registration of chemicals. It is a major challenge, as no one knows exactly how many registration dossiers will be submitted to ECHA by the deadline which is on 30 November 2010. However, ECHA must be capable of receiving all registration dossiers and doing the follow-up work as required by REACH.

"We may receive more dossiers than expected. We have seen it with the pre-registrations, and we need to be ready for it", Alain Lefebvre explains. " That is why we created a task force in ECHA which has looked at different scenarios and worked out solutions for each of them. And we are taking measures to be sure that our IT system, REACH-IT, will be available in all cases for the registration of chemicals in the European Union."

ECHA is permanently working with its stakeholders to be able to estimate more precisely the number of registrations in 2010, and a very detailed monitoring system is prepared to follow the evolutions of next year's registration process, in order to implement corrective measures when necessary.

Alain Lefebvre is used to dealing with challenges from unexpected events, as he has worked previously with the European Centre for Disease Prevention and Control (ECDC).

"In ECHA we can plan things, even if we have to make some guesses about the volume of the work, but at least we know what work we need to do. ECDC was dealing with epidemics, which are generally more difficult to predict. I have learnt to be prepared for the unexpected." Alain Lefebvre explains.

Quality helps

"REACH defines many of our tasks very precisely. What we have to do is written in what is probably the biggest regulation for an EU Agency. So we mainly have to implement the regulation. We have much less room for manoeuvre than the other Agencies to define what we do, but we have a lot more work in making sure that we are doing what is in the Regulation," the Head of Executive Office says.

"Our quality policy is the main tool for ensuring this. It also guarantees to stakeholders that we have a transparent way of working and treating all our "customers" equally", Alain Lefebvre reminds.

ECHA uses working instructions and internal procedures which guarantee compliance with REACH, together with other tools, and they also help the new staff, currently arriving twice each month, to learn their jobs quickly and to work efficiently.

Security is all in the mind

Alain Lefebvre also is in charge of security and information management, and in ECHA these two areas are closely interlinked. With registration, ECHA will have to manage an enormous amount of information on chemicals, unique in the world, and this information has to be organised and used efficiently. "We are in charge of information on chemicals from industry, and we need to publish part of it, and to protect another part which is confidential. Therefore, we have to have excellent management of this information, and a high level of security", he stresses.

"Security is also a state of mind, not only having heavy doors. Therefore, we make sure that everyone in ECHA is aware of its importance."

Tango against stress

The everyday work of Alain Lefebvre takes place in a very international environment, and he is regularly in contact with the EU Institutions and Agencies, the Member States and national Competent Authorities dealing with REACH.

Alain Lefebvre is French, from Provence. "Initially, I worked in the French administration as a IT engineer and statistician, then as a senior civil servant for the Ministry of Health and Social Affairs. During the last ten years I have worked for the European Council, in the French Permanent Representation in Brussels and in the European Centre for Diseases Prevention and Control in Stockholm, in the Executive Office."

"I had a double motivation to come to ECHA, because my wife is from Finland, and also because public health, which is one of the main objective of REACH, is very important for me," Alain Lefebvre says.

"ECHA is a nice place to work, probably because it is a young Agency and we have to build it. People are motivated and contacts are easy inside ECHA. It strikes to me that quite many people are very happy to be in Finland."

Alain Lefebvre reveals his recipe for work-life-balance: Tango in a traditional Finnish dancing environment. "*Lavatanssit* is the best place to relax when you have worked hard during the week. And then I do cross country skiing and every winter I spend one week in Lapland skiing."

Alain Lefebvre and a task force prepare ECHA for the busy year 2010.

Stakeholders

Third Stakeholders' Day focused on classification and labelling

Over 600 stakeholders took part in ECHA's Stakeholders' Day on 7 December. Around 250 participants and journalists from all over the world came to Helsinki for the event, and over 400 more followed via web stream.

The main focus of the event this time was the Classification, Labelling and Packaging of chemicals (CLP). At the event, ECHA also launched its CLP web pages in 22 languages. Two other topics were also covered: REACH enforcement and the registration process. The participants also had a chance to discuss current issues directly with ECHA staff.

The Stakeholders' Day was web streamed live across the world. The web stream recording and the presentations are still available on the ECHA website. The next Stakeholders' Day will take place on 19 May 2010, back to back with the Helsinki Chemicals Forum.

Further Information

Web stream recording, presentations and the agenda:
http://echa.europa.eu/news/events/3rd_stakeholders_day_en.asp

New CLP web pages
http://echa.europa.eu/clp_en.asp

Photos by Esko Jämsä

Classification and labelling of chemicals was the main topic at the Third Stakeholders' Day. The panellists of the morning session from left: Sandrine Lefevre Brevart (ECHA), Finn Pedersen (ECHA), Jukka Malm (Chair, ECHA), Geert Dancet (ECHA), Thomas Holtmann (BusinessEurope) and Phil Todd (Syngenta Ltd).

ECHA's Third Stakeholders' Day gathered around 250 stakeholders in Helsinki.

Introducing ECHA's stakeholders

ECHA's Stakeholder Days bring together diverse stakeholder groups such as representatives of EU and non-EU manufacturers, representatives of industry associations, importers, downstream users, REACH and CLP consultation companies and the press. For many, the main reason to attend these events is the chance to meet colleagues dealing with the same regulatory challenges and to meet ECHA's staff.

The editor of Chemical Watch, Ms Mamta Patel, thinks that Stakeholders' Days are important opportunities to meet ECHA staff and to hear their perspective on how things are going. In her opinion, however, ECHA could still improve by being more transparent: "I think it would be good for more people to know the staff at ECHA and the high level of expertise involved, to understand better the reasoning behind decisions. There is a lot of miscommunication going on about what ECHA is trying to do. Certainly it would help if there was more transparency in terms of meeting the people behind ECHA", she says. Ms Patel says that the main challenge of REACH is maintaining confidence in the implementation. "Of course there are lots of issues that only industry can resolve. But people are also still looking more to ECHA and the Commission to give guidance and reassurance that things will go well. I would like to hear more about the contingency planning for the critical year ahead and of both bodies acknowledging the difficult issues and providing all possible help."

Ms Sylvie Lemoine, who works in A.I.S.E., an international industry association, thought it was important to have a classification and labelling focus at the event since there has not been enough awareness raising on the topic in the past: "The CLP regulation comes quite late compared to REACH – and on top of REACH. It has an impact on companies who think that under REACH they have some time to rest, but they cannot rest under CLP." Her current challenges are related to downstream user duties. "As an association we focus on the downstream user and are much glued to the consumer area. We want to be sure the substances we need to meet consumer product needs are registered on time for all relevant uses. We are concerned about consumers' acceptance of chemicals, and REACH is a mechanism to help them gain confidence in chemicals. However, its implementation and the regulatory process in general are extremely complex and challenging, largely because REACH is innovative in many respects", she says. From ECHA Ms Lemoine wants pragmatic help and monitoring of the situation. She also hopes that ECHA does not change the guidance and the IT tools in 2010: "We need a predictable, stable baseline to do the actual work", she stresses.

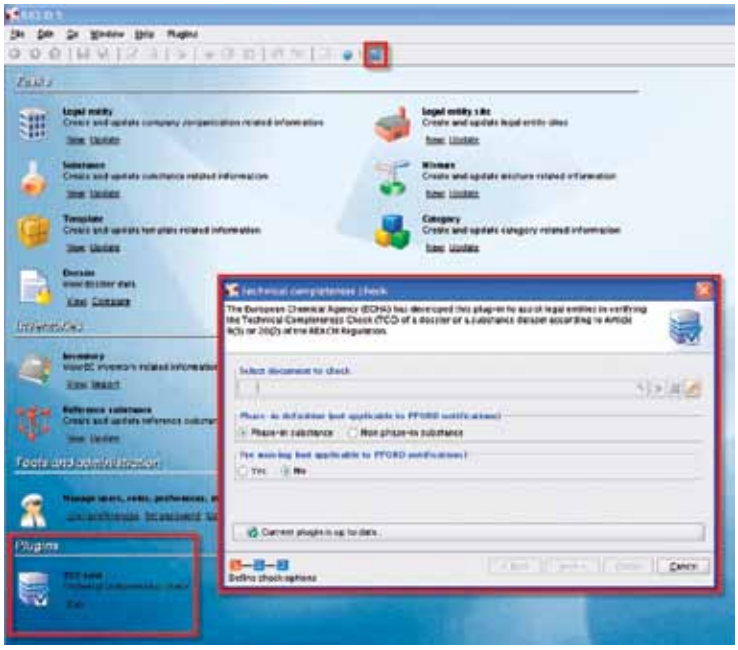
ECHA welcomes all feedback

At the Stakeholders' event ECHA collected feedback which will be communicated at a later stage.

ECHA invites all stakeholders to send additional feedback on ECHA events or communications to: **info@echa.europa.eu**

Tool for Technical Completeness Checking available

The Technical Completeness Check tool is available on ECHA´s web site from December. This plug-in will allow registrants and notifiers to check by themselves the completeness of their substance datasets and dossiers before submitting them to ECHA.



The TCC tool can be downloaded from the IUCLID website from December.

According to REACH, registration dossiers and PPORD notifications are subject to a completeness check (Article 20(2)). This completeness check includes two components: the technical completeness check (to check if all the elements required by the Regulation have been provided) and the financial completeness check (the payment of the fee if relevant).

Concerning the Technical Completeness Check (TCC), the main guidance tools available until now have been the Data Submission Manual 5 (**http://echa.europa.eu/reachit/registration-it_en.asp**) and a TCC IT tool for PPORD (**http://iuclid.echa.europa.eu/index.php?fuseaction=home.pporde**).

In addition to these tools, a IUCLID5 plug-in enables registrants/notifiers to check by themselves the completeness of their substance datasets/dossiers before submitting them to ECHA.

The software is downloadable from the IUCLID website (**http://iuclid.echa.europa.eu/**).

IUCLID 5.2 will be released early 2010

Since the publication of the first IUCLID 5 in June 2007, user requirements, change requests and improvement needs have been constantly collected, particularly by the IUCLID Helpdesk. These have been assessed and discussed by the OECD IUCLID User Group Expert Panel.

The main modifications, corrections and enhancements that will be available in IUCLID 5.2 are:

- Correction and enhancement of OECD Harmonised templates
- Update of Section 2.1 in order to take into account the latest revisions of the GHS and to incorporate the new European CLP Regulation
- Modification to Section 3.2 that will allow to provide more detailed information on tonnages
- Revision of Sections 3.5 and 3.6 for the reporting of uses
- Modification of some endpoint summaries to allow the storage of parameters chosen by experts to be used to perform chemical assessments

Other modifications will include specific enhancement linked to the EU REACH Regulation (e.g. creation of inquiry dossiers, modification of REACH related dossier templates).

To upgrade to the new version, the data will have to be migrated from the previous versions. In IUCLID 5.2, this migration will be transparent to the user and will happen automatically during import.

IUCLID 5.2 will be backward compatible, i.e. all IUCLID 5 files will be able to be used in the latest version. However once the migration process has been performed, IUCLID 5.2 files will not be able to be processed with previous IUCLID 5 versions.

The release of IUCLID 5.2 and the new versions of CSR, Query Tool and the TCC plugins, is planned for February 2010.

REACH-IT and helpdesk availability at year end

REACH-IT will be shut down completely from 18 December 19:00 EET and will re-open on 4 January. It has been closed for submissions already from 14 December 13:00 EET. ECHA will use the year end break for a major upgrading of the REACH-IT submission system.

ECHA will migrate to a new version of the REACH-IT software at the end of this year and closed the submissions from 14 December 13:00 EET in order to be able to process all previously submitted dossiers (business rule check, invoicing and technical completeness check) before performing the migration.

The new version is an essential part of the ongoing programme to enhance the performance of the software to sustain the extraordinary volume of registrations expected in 2010. The changes will also 'pave the way' for further releases of REACH-IT during Q1 2010 which will provide new industry functionalities, including the 'Legal entity change' module and C&L bulk notification submission module.

REACH-IT continues to be available until 18 December for companies to sign-up, search, view and retrieve information on pre-registrations and registrations and to claim the registration numbers for "new" substances they notified before 1 June 2008 under the previous legislation.

By lunchtime of 4 January 2010, REACH-IT will re-open and be available for submissions 24 hours a day during the working week – from 8.00 Monday until 19.00 Friday EET.

ECHA will close its offices and the Helpdesk from 24 December until 4 January.

15 new substances for the Candidate List and a testing proposal

ECHA´s Member State Committee identified 15 new chemical substances for the Candidate List of substances of very high concern at its meeting 2–4 December 2009 in Helsinki. The Candidate List will formally be updated in January 2010. The Member State Committee also agreed unanimously on a testing proposal from ECHA which was submitted under the REACH regulation.

The Member State Committee agreed unanimously that 15 new substances of very high concern (SVHC) should be put on the Candidate List. Six of these substances were identified in a written procedure and eight at a Committee meeting in Helsinki 2–4 December. One substance, lead chromate, will be included in the Candidate List without involvement of the Member State Committee, because ECHA received no comments on its hazardous properties in the preceding public consultation.

ECHA will include the 15 substances in the Candidate List in January 2010. The substances are listed on ECHA´s website. Decisions on the need to subject these substances to authorisation will be taken later.

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Anna-Liisa Sundquist.

Agreement on ECHA´s first testing proposal

The Member State Committee also agreed unanimously on a testing proposal from ECHA which was submitted under the REACH regulation. This is the first time that the Committee has discussed such a proposal. They agreed that the registrant should have to carry out tests for

- Viscosity
- Aquatic toxicity (Daphnia magna long term toxicity)
- Repeated dose toxicity and
- Reproductive toxicity.

The Committee discussed thoroughly the registrant's proposal to use read-across from another substance, instead of testing the repeated dose toxicity and reproductive toxicity. All members of the Committee agreed, after an exchange of views on the basis of scientific arguments and the requirements of the REACH Regulation, that the tests are necessary. The conclusion of this discussion was that the registrant had not provided enough justification for the read across and that the hazards of the registered substance could therefore not be concluded on that basis.

ECHA will make the final decision in accordance with the Committee's unanimous agreement and the decision will be addressed to the registrant.

http://echa.europa.eu/news/press_en.asp#press20091207

Important substances

"Quite important substances", Anna-Liisa Sundquist, Chair of the Member State Committee, says about the new substances of very high concern (SVHCs) for the Candidate List. "There are dye stuffs, one phthalate, one aromatic nitro compound – used for instance as starting material for explosives – and one flame retardant. The identified PBT (persistant, bioaccumulative and toxic) substances are coal tar derivatives: one coal tar pitch and anthracene oil derivatives. The two refractory ceramic fibres are classified as carcinogens. These fibres used for industrial purposes are often substitutes for asbestos. To include them in the candidate list puts pressure to find safer alternatives for them.", Anna-Liisa Sundquist explains.

The first testing proposal caused a lot of discussion in the Committee, "The first case is always some kind of a precedent. The discussion was very good, and finally the Committee managed to find unanimous agreement. It was not easy, but there was clearly a will to find agreement on this issue", the Chair says.

She adds that the Committee has developed a very successful way of working together, respecting others' views and developing a common understanding on that basis.

In 2010, the Committee will continue with the identification of SVHCs; the next deadline for proposals is in February. The Chair expects also an increasing number of draft decisions on testing proposals and compliance checks to be on the agenda next year.

REACH-EN-FORCE 1 found good compliance

The preliminary results of REACH-EN-FORCE1, the first project coordinated by the Forum, indicates that the level of compliance is, in general, good. By the end of November, the 28 participating countries had made over 850 inspections. The operational phase of the project will be concluded at the end of this year and the factual report will be published in the first quarter of 2010. The REACH-EN-FORCE1 enforces the core principle of REACH: no data, no market.

The preparations of the second Forum project will start immediately and will focus on the REACH compliance of downstream users, especially formulators.

In 2009, the Forum adopted a number of important documents which aim to contribute to the harmonisation of REACH enforcement. Most recent of the documents, the minimum criteria for REACH inspections, gives guidance for the effective organisation, planning, implementation and carrying out of REACH inspection activities. In 2009 work started to establish efficient working procedures for the control of REACH by the customs authorities.

This year the Forum met in three plenary sessions, all of them having an open session for stakeholders. There are also seven Forum Working Groups, which met in total 11 times.

Richard Bishop, the Forum member from United Kingdom was elected at the plenary meeting in December. The first Forum Chair, Ulrike Kowalski, resigned in November to take up a post in ECHA.

The Forum will hold two plenary meetings in 2010, tentatively scheduled for 18–20 May and 12–14 October.

ECHA CALENDER

December 2009
17–18 *Management Board*

January 2010
25–29 *Risk Assessment Committee (RAC-9)*
26–28 *Risk Communication Network (RCN-3)*

February 2010
2–3 *REACH and CLP Competent Authorities (CARACAL) meeting, Brussels*
15–16 *Member State Committee (MSC-11)*

March 2010
4–5 *Management Board*
9–11 *Socio-economic Analysis Committee (SEAC-6)*
15–19 *RAC-10*

Presented dated are tentative

Submission statistics – what they reveal

In order to better understand what the submission statistics mean we need to look at the submission process and try to understand what it means when a dossier is not accepted for processing or when it fails the Technical Completeness Check (TCC).

After a company submits their dossier, REACH-IT has to make sure that it is indeed a valid dossier that can be processed further down the line. This is done automatically by REACH-IT in Step A (with some manual tasks for ECHA staff). Unfortunately we frequently come across dossiers that are not in the correct format, that are not correctly filled in or simply there is a mismatch in the information provided. In these cases the dossier is '*not accepted for processing*' and the company will have to correct the inconsistencies and resubmit the dossier. Because Step A is almost entirely automatic a company can resubmit their dossier as many times as they need within a short timeframe. Because the submission has not yet been confirmed as accepted, there are no legal or financial consequences. The column *'Total submitted'* in Table 1, indicates the total volume of submissions to ECHA while the column *'Accepted for processing'* indicates the number of dossers which successfully passed step A and where the relevant regulatory processes were initiated.

When a dossier reaches Step B, it has been confirmed as being officially accepted and the relevant regulatory deadlines apply (for example the 21 day completeness check for registration dossiers). At this stage, registration dossiers first pass through an automatic 'Technical Completeness Check' and the dossier will be accepted if it contains all the required information. A registration number will then be given as soon as the fee (when required) has been received. If the dossier is missing required information, this is confirmed by ECHA staff and then an official request for further information is sent to the company, explaining why it failed and requesting that the company resubmits all the missing information (without additional registration costs) within a given deadline. The column '*TCC passed*" in Table 1, indicates the number of dossiers which successfully passed step B. The difference in numbers between this column and the '*Accepted for processing*' column represent the submissions that were missing required information and where the companies were asked to resubmit. It also includes a number of dossiers which are currently pending at TCC.

Going to the last step in our diagram, Step C, one can observe that there is not much of a difference between the number of dossiers that are '*TCC passed*' and the ones in the '*Complete*' column. The reason is that a dossier is not categorised as '*Complete*' until the company has paid the fee. Dossiers which are awaiting fee payment are the main source of differences between '*TCC passed*' and '*Complete*'. In conclusion, after a dossier completes Step C we will either see a registration number being issued or a rejection letter being sent (if the company did not pay or did not successfully re-submit any requested information). It is worth noting that in 2009, less than 15 rejection letters were sent, with the vast majority of registrations being successful.

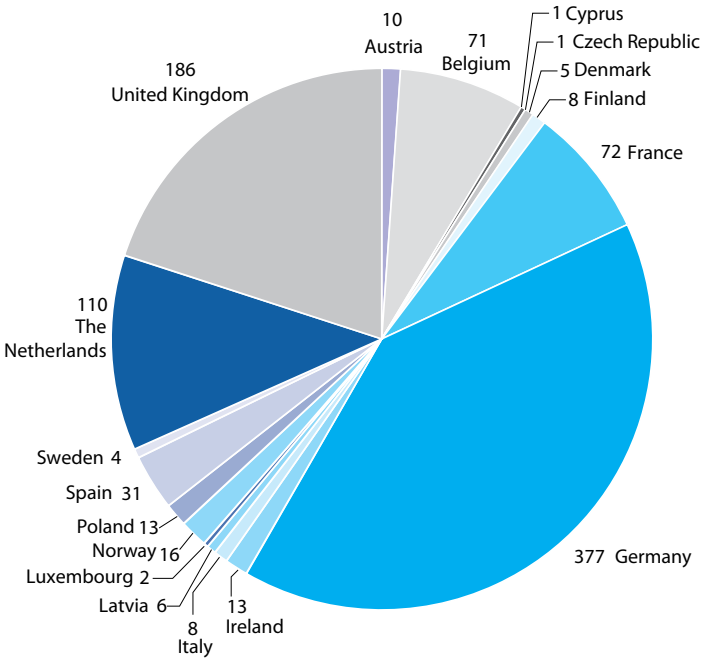
Table 1. Dossiers received by 11 December 2009

Dossier type	*Total submitted*	*Accepted for processing**	*TCC** passed*	*Complete*
Inquiry	*2282*	*1637*	*n.a.*	*1092*
Intermediates on-site	*224*	*129*	*86*	*79*
Intermediates transported	*687*	*337*	*230*	*227*
Registration dossiers	*1028*	*367*	*195*	*190*
PPORD notifications	*833*	*556*	*436*	*424*
Total	*5054*	*3026*	*947*	*2012*

** Accepted for processing: number of dossiers containing the necessary information for processing them, i.e. perform a completeness check. Examples of dossiers not accepted for processing are: dossiers without submission form, submission form not filled in correctly, information mismatch between the submission form and the IUCLID 5 dossier, company not signed up in REACH-IT, same dossier submitted twice, no substance information etc*

*** Technical Completeness Check*

Chart 1. Submitted registration dossiers by country in 2009 by 11 December (total 934)



Living in *Helsinki*

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The December market in the Esplanade Park brings light to the dark season.

Short daylight in Helsinki

Now, in the middle of December, Helsinki is veiled in a soft nocturnal light in the mornings and late afternoons. Especially on cloudy days, something of the cosmic darkness lies in the air, although it is actually light. As we move towards the winter solstice the experience is more intense. The winter solstice will take place on 21 December.

The time between sunrise and sunset is currently less than 6 hours in Helsinki - but in six months again, the city will have daylight during nearly 19 hours every day!

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Roberto Gilioli likes the special atmosphere of the dark season.

People may feel tired and a bit down during the dark time. This is often enhanced by the "darkness hormone" melatonin in us which makes us feel sleepy when it is getting dark. Light reduces the production of melatonin, and bright daylight lamps are also used against the midwinter tiredness. Some people feel also better if they do sports or get a lot of fresh air on walks.

Not affected by lack of light

Roberto Gilioli, an Italian chemical engineer working at the Communications Unit in ECHA, says he likes the dark period!

"Now it is like a never-ending dawn or a never-ending sunrise", Roberto characterises the special light of early December in Helsinki. "I can feel it of course, but it is not causing me any problems, because I am used to a reduction of light –a bit less than here – in autumn and in wintertime in my home region."

"I have lived for over 20 years in Lodi which is a small town 30 km south of Milan. It is situated in the middle of a plain that reaches from the Alps to the Apennines, and there are rivers and lakes. There, it is often quite foggy at this time of the year, and I really enjoy the fog. It gives me the feeling of comfort and safety", Roberto explains.

He was born in autumn and thinks that this may be one reason why he likes the season and finds it quite poetic with yellow leaves falling and grey fog covering the landscape like in a painting.

Roberto admits though that it is sometimes difficult to feel totally awake in Helsinki in December, because the onset of light is never really "completed". "But it was the same in my home region. However, I feel a bit funny because a lot of colleagues are suffering from the darkness and have daylight lamps to get more light, and I have no problem with the time of the year. Actually, in the summer I had more difficulties; I could not sleep well because it was too light!"

Roberto seems to be used to the lack of daylight also because of his life style: "Here I work as I did in Milan, arriving early in the office when it is dark and leaving late when it is dark again."

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The clock is ticking