ECHA Newsletter

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In this issue page

Editorial

Greetings from a cold and sunny Helsinki, where the snow is still deep, but the days are lengthening and filling us with the expectation of spring!

As well as looking forward to spring, we're very much looking forward to the challenge of the year ahead. As you have heard, we have been planning for the demands of 2010 for some time now, recruiting permanent and temporary staff, upgrading REACH-IT and streamlining procedures to try to make sure that we can meet our obligations to you. Of course nothing is foolproof, but we're confident that our planning gives us the best possible chance of acquitting our responsibilities professionally.

We know also of the preparatory work that is going on in companies throughout Europe to meet the coming REACH and CLP deadlines – within one month of each other. This year will be just as challenging for you as it is for us and we wish you the best of success. The goal for all of us is a higher level of protection for man and the environment while keeping industry competitive – worthwhile aims by anyone's standards.

I would like to draw your attention to one further priority for this year in ECHA – to improve the way in which we communicate with you. We need your help to do it.

I want to know what kinds of things you want to hear about, how often and by what means. We can only try to meet your needs and wishes if you tell us what they are. So I urge you to participate in our survey – it should only take a few minutes of your time. I hope that the subsequent improvements will make you feel that it was ten minutes well spent.

I wish you a joyful spring and a successful start to 2010.

Lindsay Jackson

ECHA|Newsletter

Have your say in our Readers´ Survey.
Click on the link and let us know what you think

➔ **http://echa.europa.eu/newslettersurvey/**

From the ECHA Management Board

New Members of the Management Board

The Council of the European Union has appointed Mr Helmut de Vos, Belgium, member of the Management Board of the European Chemicals Agency in place of Mr Marc Leemans. The Council appointed Mr Arwyn Davies, United Kingdom member of ECHA´s Management Board in place of Mr John Roberts. Both new members were nominated for a period which runs until 31 May 2011.

Budget, planning and cooperation

The Management Board met on 17 and 18 December 2009 for its 15th meeting since June 2007. Besides adopting the Agency's budget for 2010 – which totals circa €85 million and includes the costs of the required additional staff members – the Board received a report from the Executive Director on ECHA's planning for 2010.

This year is crucial for the REACH implementation with the first registration deadline for high-volume and most hazardous substances. In addition, millions of Classification and Labelling notifications are expected to be submitted to ECHA; ECHA's planning is based on a detailed analysis of the uncertainties related to the number of registration dossiers and classification notifications companies will submit to ECHA and includes mitigating measures and risk management scenarios in order to ensure the success of ECHA's mission.

The Management Board also adopted, subject to the agreement of the Commission, rules of procedure to cooperate with the European Food Safety Authority (EFSA) when giving opinions in the food safety context. It also received reports on ECHA's planning for evaluation and the Agency's work on nanomaterials.

Work Programme 2010 translated

ECHA´s Work Programme for 2010 is available in 22 languages, and the translated versions of the Work Programme Summary will also be published soon.

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

From *the Executive Office*

ECHA 2009 review and outlook

2009 saw ECHA focus on consolidating the foundations for the next steps in the implementation of REACH, and specifically, for the first registration deadline in November 2010. Agency capacity increased – with a growth in personnel from 219 to 321, accompanied by targeted training to enhance and sustain science-based activities – and internal regulations were improved: through the introduction of a new quality management system and initial development of a new document management system, to name but a few. The organisational structure was also adapted to optimise delivery of the Agency's core tasks, leading, for example, to the creation of new units dedicated to Evaluation and Legal Affairs.

The Agency also stepped up efforts to assist industry in meeting its obligations prior to the 2010 deadline – providing advice on data-sharing; supporting the creation of Substance Identity Exchange Fora; and providing a special service for Lead Registrants. With continuing improvements made to scientific IT tools, ECHA established initial access to REACH-IT for Member State Competent Authorities, and also launched web pages to make information on chemical substances publicly available.

Likewise, the Agency Committees progressed steadily in their tasks in 2009, identifying further substances to be placed on the Candidate List of substances of very high concern; adopting opinions, for the first time, on the authorisation of such substances, and on harmonised classification and labelling; and reaching agreement on the first REACH testing decision.

The functioning of these and other ECHA bodies, such as the governing Management Board, was boosted by the completion of a new Conference Centre, which officially opened in April 2009 – part of the renovation work on the Agency's premises which continued throughout the year, to meet the needs of a rapidly growing organisation.

2010 now brings many challenges for industry, stakeholders, and ECHA alike, and extensive contingency planning by the Agency in 2009 will ensure it is ready and well-prepared to meet a high volume of registrations. Guaranteeing the operation of the Agency is vital for the success of this demanding year, and this will be bolstered by a temporary subsidy, agreed to by the European Parliament in December, to cover the expected shortfall in fees due to the registration deadline falling late in 2010. Nevertheless, with the Agency now at cruising speed after its initial start up phase, its technical capacity and scientific expertise will continue to grow to serve its critical role in this first registration year.

Head of Unit appointed for the new Registration and Dossier Submission Unit

Mr Kevin Pollard has been appointed as the Head of Unit for the new Registration and Dossier Submission Unit. Mr Pollard is from Edinburgh, Scotland and has been working in ECHA since August 2007. He became registration leader in early 2008 after initially working on a range of REACH implementation issues in the context of the 'start-up' action plans and has been involved in all aspects of the registration process at ECHA.

Before joining ECHA Mr Pollard spent one year working at the European Chemicals Bureau at the DG JRC in Ispra, also on REACH implementation. Prior to that, he was working for around 8 years at the UK's Department for Environment, Food and Rural Affairs in the field of chemical exposure assessment.

Important deadlines

- 30 November 2010: 1st REACH registration deadline
- 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

The chemical industry in the EU Economy

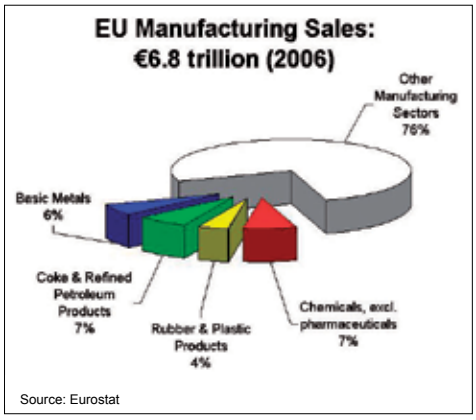
REACH processes, registration in particular, impact the chemical industry and other related sectors of the European economy. In order to identify key stakeholder groups and to better understand the importance of the chemical industry, ECHA has completed an initial study of key economic statistics using the latest EU-wide data. The highlights of this study are given below.

The chemical industry[1] is an important contributor to the economy of the European Union. With a workforce of 1.3 million employed in over 29,000 enterprises, it is one of the largest industrial sectors and an important source of direct and indirect employment in all EU Member States. In 2006, the industry generated close to €120 billion value-added. This represented 7% of the total manufacturing value-added at factor cost*.

European chemical products are internationally competitive. Exports of Member States represent 44% of world trade in chemicals (WTO 2007). The industry is one of the few EU manufacturing sectors which has maintained a positive trade balance every year between 1999 and 2008. Over the same period the value of the extra-EU27 exports of the chemical industry grew by close to 7%, reaching €112 billion.

The chemical industry sells over €500 billion worth of diverse products, from commodities to tailor-made, speciality products. Examples include basic chemicals, industrial gases, dyes and pigments, fertilizers and nitrogen, plastics and synthetic rubber in primary forms, explosives, soaps, detergents, glues, etc. As the product diversity suggests, the chemical industry is linked to essentially all sectors of the economy. In fact the industry is so intertwined with the petrochemical sector[2] and the rubber and plastic sector[3] that they are often combined in economic review publications.

"Therefore, it was very important for us to define what we mean by "chemical industry" and to arrive to the most appropriate definition in the context of REACH." said Matti Vainio, Team-leader of Socio-economic assessment. "In addition to the chemicals, petrochemicals and rubber and plastic, we added basic metals[4] to the definition, as many of the companies will have to register their substances to comply with REACH. We know that there are other sectors that are impacted by REACH but those will be considered at a later stage."



The four sectors combined – chemical, coke and refined petroleum, rubber and plastic, and basic metals – represent more than 24% of total manufacturing sales. (See chart) In 2006, the four industries employed over 2.5 million people in 112,000 enterprises. The industries accounted for 19% of total manufacturing value-added for 2006.

In 2008, the combined extra-EU exports for the four industries were valued at more than €280 billion, which represented close to 22% of total European exports. The exports grew at a fast pace – on average by approximately 11% annually between 1999 and 2008, which was higher than the average for all sectors of the European economy.

ECHA will continue to monitor the economic performance of these and other industries through regular economic scans and through discussions with stakeholders. The Socio-economic assessment team can be reached at **sea@echa.europa.eu**.

Sources: Eurostat Structural Business Statistics 2006, Eurostat External Trade 2008, and World Trade Organisation 2007

[1] as defined by NACE 24: Manufacture of chemicals and chemical products, excluding pharmaceuticals (NACE 244)
[2] as defined by NACE 231: Manufacture of coke oven products and NACE 232: Manufacture of refined petroleum products
[3] as defined by NACE 25: Manufacture of rubber and plastic products
[4] as defined by NACE 27: Manufacture of basic metals

* Value added at factor cost is the gross income from operating activities after adjusting for operating subsidies and indirect taxes

Evaluation Progress Report 2009

By the end of February each year the European Chemicals Agency (ECHA) provides a progress report on evaluation. This report is required by Article 54 of the REACH Regulation (EC) No 1907/2006. The purpose of the report is to describe the progress made by ECHA in its evaluation tasks and in particular to provide recommendations to potential registrants in order for them to improve the quality of future registrations.

The first report was published for the year 2008, covering the first six months of activities in ECHA after the REACH Regulation came into force. At that time, there were only a small number of complete registration dossiers which ECHA could have evaluated. In 2009 more experience has been gained and this is explained in the 2009 progress report.

The report will be published on the ECHA website **http://echa.eu/publications_en.asp** under Reports. The report will be published by the end of February in English and translations to other community languages will follow later.

Information on safe use of chemicals for all

On its website, ECHA publishes hazard and safe-use information on chemical substances that have been registered. Over time, this growing database will permit citizens to make well informed decisions about the use of chemicals or articles containing chemicals that they purchase. The information was provided by companies who manufacture or import the substances. It will be updated each time additional information is received by ECHA.

In the ECHA CHEM section of our website, you can find information on substances which companies manufacture or import in the EU: their hazardous properties, their classification and labelling and how to use them safely.

The information in this web-portal comes from registration dossiers which have been assigned a registration number. The assignment of a registration number only indicates that the dossier is complete but does not guarantee that the information contained therein is compliant with REACH. The quality of data can be challenged in the evaluation processes of REACH.

The amount of information provided can be different for individual substances – for example, the higher the production volume of the substance, the more information the companies need to provide. It is possible that some information is not included because companies have claimed confidentiality. That information may become available at a later stage after ECHA has decided whether these claims are justified.

The number of substances in the database will increase considerably over time as more registrations are received by ECHA. Reproduction or further distribution of the information is subject to copyright laws and may require the permission of the owner of that information.

Potential registrants are reminded that pursuant to Article 10 of the REACH Regulation, robust study summaries and study summaries disseminated in this portal may only be used for the purpose of registration, where the potential registrant is in legitimate possession of the full study report or has permission to refer to the full study report.

Candidate List updated

On 13 January 2010, the European Chemicals Agency added 14[1] chemical substances to the Candidate List of Substances of Very High Concern (SVHC) for authorisation. Companies manufacturing or importing these substances need to check their potential obligations that result from the listing.

The substances which ECHA added to the Candidate List are provided on ECHA´s website. Decisions on whether the substances need to be subject to authorisation will be taken later.

Companies may have legal obligations resulting from the inclusion of substances in the List. These obligations can apply to the listed substances on their own as well as in mixtures and in articles. A short summary of the obligations is also available on ECHA´s website.

[1] Acrylamide (EC No 201-173-7 and CAS No 79-06-1) was also identified as a Substance of Very High Concern by ECHA's Member State Committee. However, pursuant to an Order of the President of the General Court of the European Union, the inclusion of acrylamide in the Candidate List of substances for eventual inclusion in Annex XIV of REACH is suspended until the President of the General Court has made its order terminating the proceedings for interim relief in Case T-1/10 R.

Candidate List: **http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp**

More about obligations: **http://echa.europa.eu/chem_data/authorisation_process/candidate_list_obligations_en.asp**

IUCLID 5.2 is now available

A new version of IUCLID is available on the IUCLID website. Registrants can already install IUCLID 5.2 to be ready to submit dossiers in the new REACH-IT version which will be released early March 2010. IUCLID 5.0/5.1 must still be used in order to submit dossiers with the current version of REACH-IT until early March.

The new version of IUCLID includes several updates of the OECD Harmonised Templates used to report information from studies on chemicals. The latest revisions of the Globally Harmonised System of Classification and Labelling and of its European implementation (the CLP Regulation) have also been integrated. Sections 3.2, 3.5 and 3.6 of IUCLID have been overhauled for reporting information on uses. Endpoint summaries, where experts can store the outcome of their hazard assessment per endpoint, have also been extended in order to optimise the use of IUCLID with chemical assessment tools.

In addition, several other functionalities have been enhanced in IUCLID 5.2.

Installation of IUCLID 5.2 and submission to REACH-IT

IUCLID 5.0/5.1 must continue to be used for the preparation of dossiers that will be submitted *before* the switch to a new REACH-IT version in early March 2010.

IUCLID 5.0/5.1 data can be imported into IUCLID 5.2 – but not the reverse! – and IUCLID 5.2 must be used for the preparation of dossiers for submission *after* the switch to the new REACH-IT version (see ECHA's news alert published on 04/02/2010).

For more information, installation manuals are included in the installation packages of the distributed and standalone versions of IUCLID 5.2 that can be obtained from the IUCLID website.

Update of existing plugins for IUCLID 5.2

As previously announced on the IUCLID website (cf. news alert of 25/11/2009), different plug-ins available for IUCLID 5.0 or 5.1 will have to be updated for IUCLID 5.2. These updated plug-ins will be made available over the coming month in the following order:

- Technical Completeness Check plugin
- Chemical Safety Report plugin
- Query Tool plugin

For additional details on IUCLID 5.2, please go to **http://iuclid.echa.europa.eu/**

ECHA *introduces...TCC Tool*

The Technical Completeness Check plug-in is now available

One of the duties of ECHA is to undertake a completeness check of every registration and PPORD notification to ascertain that all the elements required by the regulation for each kind of dossier have been provided. These requirements vary from one type of dossier to another. Because a IUCLID 5 dossier contains around 10,000 different fields, verifying that a dossier is complete is a complex task. Last December, ECHA released an IT tool to enable companies to check the completeness of their registration dossiers or PPORD notifications themselves, before submitting them to the Agency.

Critical to companies' registration strategy will be the use of the Technical Completeness Tool, which gives a greater degree of confidence to companies of successfully passing the technical completeness check. The new software tool is a IUCLID plug-in that works with IUCLID 5.0/5.1[1] and simulates the technical completeness check carried out by ECHA (to the largest extent possible) for all the different types of registration dossiers that may need to be submitted to ECHA.

In addition, the Technical Completeness Check (TCC) plug-in also simulates certain business rules checks carried out on dossiers submitted to ECHA. Therefore, checking a registration dossier with the TCC plug-in before submitting it to ECHA, helps to make the registration process easier and faster, since the chances of failing the business rules check or the TCC are much lower. At the current time, not all of the business rules can be replicated in the TCC plug-in, because some of them rely also on information held in the REACH-IT database rather than in IUCLID, so the TCC doesn't offer a guarantee of succes.

Getting the TCC plug-in

The TCC plug-in can be downloaded free of charge from the IUCLID webpage: **http://iuclid.echa.europa.eu**. Like all the other IUCLID plug-ins, it is necessary to have a IUCLID user account in order to be able to download it.

The current release of the TCC plug-in is 5.1.10. The TCC plug-in can be found in the "Download" section. Detailed step-by-step instructions on how to install the TCC plug-in on your IUCLID 5 installation are provided in the IUCLID 5 TCC plug-in manual available in the downloaded ZIP file.

Using the TCC plug-in

The TCC plug-in allows the checking of substance datasets or dossiers within your local or network IUCLID 5 installation. This means that the user does not need to create a dossier and export it before simulating the TCC, but can find the missing information in the substance dataset and complete it easily, since it is possible to edit substance datasets (unlike dossiers, which are read-only).

Once a substance dataset or a dossier is run through the TCC plug-in, this tool displays a report indicating which sections are not complete and information about how to complete them.

Limitations

The TCC plug-in simulates the TCC carried out by ECHA to the largest extent possible. However, the outcome of both the TCC and the business rules check depends not only on the information inside the dossier, but also on certain parameters set in REACH IT. Thus, not all the possible scenarios in which a dossier may be found incomplete or found to fail the business rules can be perfectly simulated. In addition, the completeness check performed by ECHA will include expert involvement and could potentially lead to different conclusions from those indicated by the plug-in. Accordingly, the responsibility remains with the company to ensure that their submission fulfils all relevant legal requirements.

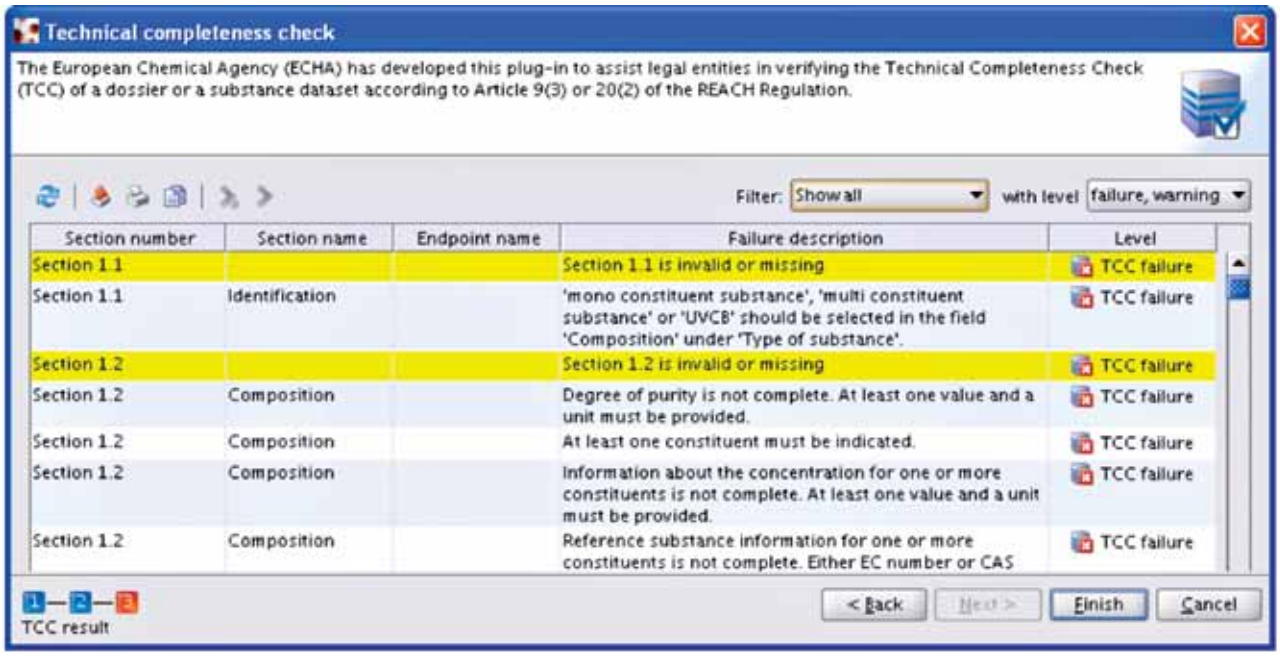
Nevertheless, use of the TCC plug-in is highly recommended in order to ensure that companies minimise the possibility of receiving a completeness check failure during the registration process.

Further information:

Guidance on registration available at **http://guidance.echa.europa.eu/guidance_en.htm**
Data Submission Manual 5 (How to complete a technical dossier for registrations and PPORD notifications) and *Data Submission Manual 8 (Business rules validation)* available at **http://echa.europa.eu/help/help_docs_en.asp**.

TCC plug-in: **http://echa.europa.eu/reachit/registration-it_en.asp**

[1] A TCC plug-in adapted to the new IUCLID 5.2 will be released in the months to come.



Interview: *Jack de Bruijn*

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Jack de Bruijn – Involved with REACH from the very beginning

Risk management – choose the best option!

Jack de Bruijn, Head of ECHA's Risk Management Unit, leads on the effective implementation of the two risk management processes under REACH: restriction and authorisation. He stresses that the key to successful management of these processes is a good analysis of the best option for each chemical.

Mr de Bruijn got involved with REACH from the very beginning. After completing his studies in chemistry and PhD in computational toxicology at the University of Utrecht, The Netherlands, Mr de Bruijn joined the Dutch Ministry of the Environment and dealt with national and international chemicals policy development.

"Then after about ten years, I had the opportunity to join the European Chemical Bureau in Ispra, Italy. There, we soon got very involved in discussions on REACH, providing scientific and technical advice to the Commission," explains Mr de Bruijn.

As the European Chemicals Agency (ECHA) was established in Helsinki to implement REACH, Mr de Bruijn convinced his family to leave Italy for the cold North. "It was not an easy task," he says.

"Working in ECHA is a great opportunity for implementing the ideas that we had when developing the draft legislation, trying to learn from the past as well as avoid making the same mistakes. That is the big challenge and also the great privilege to see ten years of discussion, interaction and negotiation now finally being really implemented."

Crucial choice

Mr de Bruijn explains that there are several options for managing the risks of hazardous chemicals. The correct choice of the measure is important, and authorities which submit proposals should carefully analyse which is the best risk management option. Mr de Bruijn stresses that once the authorities decide to send a substance into the restriction or authorisation process, it has consequences and may also limit the choices later on.

"As regards the Candidate List of Substances of Very High Concern, I would like to refer to a useful discussion we had in January 2009 in a workshop between the Member States, the Commission and us about what the Candidate List is actually for. We focussed on why a substance should or should not be on the Candidate List, and not so much on whether this list should be long or not" Mr de Bruijn explains.

"There can be various reasons for adding a substance to the Candidate list, the most obvious one being that you want to identify the substance as a substance of very high concern (SVHC) to prioritise it further in the authorisation process. Once it goes there, then the whole machinery starts and industry has to send in applications. If they do not, then after a certain deadline, the sunset day, they cannot use the substance any more."

"Another reason to put a substance on the Candidate List is the link with REACH Articles 33 and 7. These articles contain specific requirements for manufacturers to provide information to people buying products if they contain substances of very high concern. "For PBTs[1] and vPvBs[2], identification as a substance of very high concern is practically the only way of getting their PBT status formally recognised. There is no other mechanism at present. Whereas for CMRs[3] there is the normal harmonised classification system which identifies them, and that is what normally is done before they enter the list of substances of very high concern," underlines Mr de Bruijn.

"We agreed with the Member States that the most relevant aspect is to know whether you have the right substances on the list and whether the Candidate List is the best way to address concerns on these substances. This question is not easy to answer."

ECHA has worked on a framework to support the authorities in identifying the best risk management option. The target is that before a dossier is sent in, an exchange of views between the Member States, the Commission and ECHA will take place on the reasons and arguments for selecting a certain route.

A lot on the agenda

ECHA and the EU Member States and EEA/EFTA countries have agreed that the Candidate List will be updated twice per year.

On 1 June 2009, ECHA sent the Commission its first recommendation for substances that should be added in Annex XIV of REACH (List of substances subject to authorisation) and not to be used without prior authorisation. The Commission is developing the Annex XIV proposal but has not come up with it as of yet.

"In theory, the day after the Annex XIV is published, we could receive an application for authorisation," says Mr de Bruijn. "And then the whole opinion making process starts. We have responsibility to make the information available on our website, and also to request further information for instance on alternatives for those substances. And of course we then have to manage the opinion-making process for the RAC and SEAC in a very short timeline with the aim of providing the Commission with the best possible support for their final decision-making."

The restrictions process has also started. Annex XVII, which lists all restrictions agreed in the past, was updated and published again in a new version. ECHA is expecting proposals for new restrictions from the Member States in the first half of 2010.

"In addition, our unit is working on a restriction dossier on mercury in blood pressure measuring devices which was requested by the Commission. It is basically a revision of an already existing restriction in Annex XVII. We are looking at whether there is a need for further restrictions on the use of mercury devices such as blood-pressure meters. In addition, the Commission has asked us to look whether there is a need to review the current restrictions on phthalates, taking into account all new scientific information. We have collected all the new information and are evaluating it. And that we will communicate to the Commission very soon and decide on the next steps," says Mr de Bruijn.

A key element of REACH

The Risk Management Unit also provides work on developing exposure scenarios. Mr de Bruijn considers them to be one of the key new elements of REACH and very important for industry in risk management and communicating to the downstream users proper advice on how their substances can be handled safely. "I believe particularly that if we get the exposure scenario concept working well in the companies, and there is appropriate communication down the supply chain to all the relevant people using chemicals, *that* is the area where we will ultimately see the greatest impact of REACH."

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[1] PBT=persistent, bioaccumulative, toxic,

[2] vPvB=very persistent, very bioaccumulative,

[3] CMR=carcinogenic, mutagenic, toxic for reproduction

Classification and labelling under CLP

The ECHA Newsletter is publishing articles on the practical implementation of classification and labelling under CLP, with regard to the 1 December 2010 deadline. If you would like to share with us your experiences with the CLP, please contact **newsletter@echa.europa.eu**.

Phil Todd is an expert on European classification and labelling issues in Syngenta, one of the world´s largest agrobusiness companies. The company supplies crop protection products, seeds and seed treatments throughout the world and has manufacturing sites in Europe, North America, South America and Asia. It also imports into all regions, including Europe. Mr Todd was interviewed in December on the occasion of ECHA´s Stakeholders´ Day where he was a speaker.

How far are you with CLP classification and labelling?

The total amount of substances and mixtures that we have to reclassify lies in the region of several hundreds. We are coming towards the end of our planning phase. We have spent this year working on identifying what needs to be done by when and have created an implementation organisation. Next year we will concentrate on making system changes to handle the new labelling data, re-labelling our substances and preparing for the classification and labelling inventory. In addition, we will work on communicating the new requirements to those affected together with suitable training. We have already started to prepare the classification of our substances and mixtures and have made substantial progress.

Do you encounter specific problems in relation to classification and labelling according to CLP?

Having worked with GHS for a number of years prior to CLP, the technical aspects of reclassification are fairly straightforward. What is more difficult is to explain the new text and pictograms to the people who have to use the classifications.

Will your company notify substances before the first deadline, 3 January 2011?

At the moment it is too early to say. There are still too many uncertainties about the practical process to be able to make a clear judgement about how we are going to address this issue. For example, the tools to notify are still not available but I understand that they should be available during early 2010. Our plan for notification currently assumes the use of the bulk upload facility. However the technical specifications for the file format and the working processes relating to bulk uploads are not available from ECHA yet. This means that the add-on to our classification database is not yet available from our software supplier and therefore we cannot plan with any certainty for when we could implement the tool or indeed, whether the tool will be as useful to us as we hope it will be.

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Phil Todd spoke about classification and labelling at the Stakeholders´ Day in December.

Are there other topics in relation to classification and labelling relevant for your company?

For crop protection companies in general, one of the issues that needs to be resolved is the interaction between CLP and regulation 1107/2009, the new Regulation on Plant Protection Products. The issue is that the CLP labelling elements are a small part of the label for a crop protection product. Under regulation 1107/2009, the label has to be submitted to and approved by the national regulator for plant protection products. On the other hand, the CLP regulation clearly states that classification is the responsibility of the supplier. The requirements of CLP and the Plant Protection Products Regulation can be achieved by an understanding amongst both companies and regulators that the label approval process under the Plant Protection Products Regulation does not include the CLP labelling elements and that these remain the responsibility of the company.

What would you ask of ECHA if you had one wish?

My main wish would be for ECHA to make rapid progress towards resolving the outstanding implementation issues for which it has responsibility. For example, companies need clarity on many aspects of the operation of the C&L inventory in order to plan how they will notify to it. Additionally, the process by which the Risk Assessment Committee comes to a classification opinion is still not completely clear. We acknowledge that progress has been made in the past few months but would need further clarity. It is important to industry that the classification opinion is credible and to achieve this, it must be the result of a process that is open, transparent and based on sound science.

What is your general impression of the implementation of CLP in your business sector? Are there specific problems?

The initial internet consultation suggested that the transition period for substances would be in the order of 3-4 years. In reality, this has turned out to be less than two years. Considering that many of the one-off changes also have to be made during this period, hindsight is already indicating that a transition period in line with the original suggestion would have been more realistic. It will be challenging to meet the 2010 deadlines.

In the Crop Protection sector, we do need to resolve the issue of the interaction between CLP and the Plant Protection Products Regulation. Not only does this have direct impact on the detailed timetable for reclassifying our mixtures, it is also critical for ensuring that the aims of CLP are realised i.e. one product has the same classification in all countries in Europe. I suspect that many readers will be surprised to know that, under the current Dangerous Preparations and Plant Protection Products directives, one product may not have the same classification in all countries in which it is sold despite the suppliers desire to have only one classification.

4th Stakeholders´ Day in May

ECHA´s fourth Stakeholders' Day will be held on 19 May 2010 in the Helsinki Exhibition and Convention Centre (Messukeskus). The event will be followed by the 2010 Helsinki Chemical Forum on 20 and 21 May 2010.

The busy years of risk assessment starting

At the end of January, ECHA's Committee for Risk Assessment (RAC) reached its opinion concerning the harmonised classification and labelling of three chemical substances in the EU and in Norway, Iceland and Liechtenstein. In RAC´s opinion, *Di-tert-butyl peroxide – DTBP* which is currently classified at EU level for certain physico-chemical hazards, should be also classified as a mutagen. The classification of the other substances is currently not harmonised at EU level. In RAC´s opinion, *Trixylyl phosphate* should have a harmonised classification as toxic for reproduction, and *Indium phosphide* should be classified as carcinogenic, toxic for reproduction and for repeated dose toxicity through prolonged or repeated inhalation.

RAC also appointed rapporteurs for the opinion it will give on restrictions that ECHA is preparing for mercury in measuring devices. RAC´s decision on the risk of boric acid and other boron compounds in photographic applications was postponed, as new information to be provided by industry should be assessed by the Committee.

Consumer risk assessment not easy

RAC´s opinion on borates is a special task. The European Commission asked ECHA for an opinion, and the Executive Director of ECHA gave RAC the mandate. Borates are used in photographic applications by consumers, but they are classified as toxic for reproduction in a category which should not be used by consumers.

"Some applications use concentrations above the limits that should be provided for consumers," says Jose Tarazona, Chair of the RAC. "The Commission has initially estimated that this specific use could remain, if it is demonstrated that there is no risk for those consumers. There is very little information on exposure to borates under those particular conditions. So the Committee is working on the exposure scenario and will also review relevant toxicological information to identify if there is a possibility of adverse effects to consumers using those products."

The Chair of RAC adds that the assessment of risk for consumers is particularly challenging. "In industrial facilities, there are regular measurements and even bio-monitoring and surveillance studies. You can have a much clearer idea of conditions of exposure for the workers, but for consumers exposure may depend on behaviour – and becomes a real challenge! But, it is clear that it is absolutely essential to protect consumers as well!"

Busy years ahead

RAC has prepared for its work intensively since the start of ECHA´s activities. Mr. Tarazona assumes that with its 40, potentially up to 60 members, it is the largest risk assessment committee in Europe. The expertise covers a wide range of fields related to human health and environmental risk assessment and management. External experts can be invited if necessary.

Harmonised classification and labelling, restriction proposals and applications for authorisation will keep the Committee busy in the years to come, and the Committee needs to adopt opinions at a fast pace, while maintaining top scientific quality.

"Most REACH and CLP processes involve risk assessment for human health and environment and hazard identification for classification and labelling. There is a huge amount of work ahead of us. RAC is already evaluating dozens of classification proposals, and according to the registry of intentions, the first proposals for restrictions will arrive soon, opening new challenges. The Committee should indicate the appropriateness of the proposed management measures in reducing the risk and work in close cooperation with the Committee for Socio-Economic Analysis," says Mr. Tarazona.

The risk assessment tasks of RAC include identification and characterisation of hazards and evaluation of exposure.

"As regards harmonised classification and labelling, we are mostly involved in the harmonised classification criteria for carcinogenicity, mutagenicity, toxicity for reproduction and respiratory sensitisation. The proposals can request harmonised classification also for other endpoints. For active substances in pesticides and biocides, a full harmonised classification covering all the endpoints is requested," Mr. Tarazona adds.

For its opinions on harmonised classification and labelling, for instance, the Committee is reviewing all the information in the proposal, and a public consultation is organised to ensure that RAC receives all information from industry, NGOs and the scientific community on further studies available. "The experience shows that the consultation is a very relevant part of the process," says Mr. Tarazona.

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"The main challenge for RAC will be to adopt opinions of top scientific quality and at a fast pace" says Jose Tarazona, Chair of RAC.

The Committee evaluates the information considering the weight of evidence and applying the criteria in the legislation. Then it agrees on its opinion concerning the classification category and the proper labelling. The RAC opinion is just one step in the process, it is the European Commission who makes the final decision on classification.

Expert in risk assessment methodology

Jose Tarazona is Spanish, originally from Barbastro in Aragon. He is a veterinarian, and has a PhD in veterinary toxicology. Later he worked also in the field of ecotoxicology. Since the 1990s, Mr. Tarazona has concentrated on the scientific development of a methodology for assessing the environmental risks of chemicals. He has participated in the work of many EU Scientific Committees serving as vice-chair of CSTEE and SCHER, and in activities of the OECD, the UN Stockholm Convention as a member of the Persistent Organic Pollutants Review Committee, and has been an expert for several panels in different EU Agencies.

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HelpNet is a vital part of REACH and CLP implementation.

HelpNet provides harmonised answers to REACH and CLP questions

HelpNet, the common network of national REACH and CLP helpdesks was established in October 2009. The objective of the network is to promote consistent, harmonised answers and the best possible advice to companies seeking to fulfil their obligations under the REACH and CLP (Classification, Labelling and Packaging) Regulations. The HelpNet is strongly committed to contributing to the overall success of REACH and CLP implementation.

The Regulations stipulate that Member States shall establish national helpdesks for advising companies on their responsibilities and obligations. These national REACH and CLP helpdesks of the 27 EU Member States, Norway, Iceland and ECHA form the HelpNet Steering Group. The European Commission is an associated member. The HelpNet Steering Group has also observers from EU-wide helpdesks operated by industry stakeholders as well as observers representing EU candidate countries.

The HelpNet Steering Group meets on a regular basis to discuss issues of common interest, future activities and the functioning and organisation of the helpdesks and of the network. As of October 2009, the Steering Group replaced REHCORN, which was operational as the steering body of the network of REACH helpdesks since April 2007.

Harmonisation of answers given to industry across EU and EEA/EFTA countries is the key task of the network. HelpNet puts a lot of effort into proposing and agreeing on questions and answers to be published as Frequently Asked Question (FAQ) on the ECHA website. Complicated questions are discussed among the national helpdesks through a secure web based discussion platform called the HelpNet Exchange.

The helpdesks have a very challenging task in supporting the actors of REACH and CLP and they strive to provide high quality answers within a reasonable timeframe. However, it is not always possible to provide tailor made answers fitting a specific case. Companies have the duty to take responsibility to determine their obligations. The most important task of helpdesks is therefore to lead companies to find answers to their questions in the various guidance documents, manuals and other information available.

Most of the national REACH helpdesks have now been operational for almost three years. They have established common practices in running the helpdesk activities and are experienced in providing answers of high quality. Having the CLP helpdesks join the network is an asset which will further enhance the competence of the network on new chemical legislation in the EU.

HelpNet REACH training: 28–29 April 2010

Third meeting of the Risk Communication Network

The Risk Communication Network met on 26 and 27 January 2010 for the first joint meeting of representatives nominated by REACH Competent Authorities and CLP Competent Authorities. Stakeholder observers also participated.

The meeting was held in the ECHA conference centre and was followed on 28 January by a Project Expert Group meeting on the draft Risk Communications Guidance document.

There was a high degree of participation and interest: 30 Members attended the meeting in addition to the European Commission and observers from the European Food Safety Authority (EFSA) and the European Agency for Safety and Health at Work (EU-OSHA).

The main aims of the meeting were to:

- Provide Member States Competent Authorities with a general understanding of the preparations for a Eurobarometer Survey on the perception of chemicals and labels by European citizens and the future steps in the project. The RCN members were also asked to contribute to the Eurobarometer Survey informing ECHA of their needs and their past experiences and future plans in this field;
- Consult the Member States on the study that ECHA will conduct on communication to the general public on the safe use of substances and mixtures and on the potential need for additional information on labels. (CLP Regulation, Article 34.1). They were asked to provide comments on ECHA's overall approach in preparing the communication study;
- Consult participants on the first draft of the Risk Communication Guidance. RCN Members provided comments on the scope of the guidance and on individual sections of the draft guidance document. ECHA will take RCN input and that of the PEG meeting into account in further Guidance development.

On the draft Risk Communication Guidance the RCN members provided their comments in advance of the meeting. They expressed a general appreciation on the quality of the first draft of the document. RCN members also appreciated that ECHA is "on the right track" in developing the communication study.

Statistics

1. DOSSIER SUBMISSION BY YEAR

The tables below provide the number of dossiers submitted per dossier type. Indicated with the numbers 1 to 5. The column 'Accepted for processing' indicates the number of dossiers which are accepted for processing and where the relevant regulatory processes were initiated. The TCC represents the dossiers that passed the technical completeness check. Complete refers to the number of dossiers that reached the end of the submission process and that received a reference number.

1.1 Year 2009

Dossier Type desc	Accepted for processing	TCC Passed	Complete
1. Inquiry	1034		
2. Registration of on-site isolated intermediates	110	85	84
3. Registration of transported isolated intermediates	284	195	194
4. Registration	362	215	212
5. PPORD	226	215	211
Sum:	**2016**	**710**	**701**

note: inquiries do not undergo a TCC, so the number of complete inquiry dossiers equals the numbers of dossiers Accepted for processing.

1.2 Year 2010 till 16/02/2010

Dossier Type desc	Accepted for processing	TCC Passed	Complete
1. Inquiry	155		
2. Registration of on-site isolated intermediates	31	28	11
3. Registration of transported isolated intermediates	72	59	31
4. Registration	132	118	84
5. PPORD	31	31	16
Sum:	**421**	**236**	**142**

note: inquiries do not undergo a TCC, and the number of complete inquiry dossiers equals the numbers of dossiers Accepted for processing.

2. REGISTRATIONS BY TONNAGE BAND

The below tables provide the number of registration dossiers submitted per dossier type. The column 'Accepted for processing' indicates the number of dossiers which are accepted for processing and where the relevant regulatory processes were initiated. The TCC represents the dossiers that passed the technical completeness check. Complete refers to the number of dossiers that reached the end of the submission process and that received a reference number.

2.1 Year 2009

Registration type	Tonnage	Accepted for processing	TCC Passed	Complete
Registration of on-site isolated intermediates	1to10	13	10	10
	Over10	98	76	75
Registration	100 to 1000	28	16	16
	10 to 100	49	29	29
	1 to 10	199	104	102
	Over 1000	86	66	65
Registration of transported isolated intermediates	10 to 1000	140	100	100
	1 to 10	116	78	77
	Over 1000	31	18	18
	Sum:	**760**	**497**	**492**

note: registration dossiers that combine the registration for e.g. an on-site isolated intermediate (OSII) and/or transported isolated intermediates (TOSII) were counted as separate registrations.

2.2 Year 2010 to 16/02/2010

Registration type	Tonnage	Accepted for processing	TCC Passed	Complete
Registration of on-site isolated intermediates	1 to 10	1	1	1
	Over 10	35	32	13
Registration	100 to 1000	14	13	10
	10 to 100	17	16	9
	1 to 10	57	47	37
	Over 1000	39	37	25
Registration of transported isolated intermediates	10 to 1000	33	28	16
	1 to 10	25	19	9
	Over 1000	22	20	11
	Sum:	**243**	**213**	**131**

note: registration dossiers that combine the registration for e.g. an on-site isolated intermediate (OSII) and/or transported isolated intermediates (TOSII) were counted as separate registrations.

3. ACCEPTED DOSSIERS FOR PROCESSING IN 2009 BY COUNTRY

	1.Inquiry	2. Registration of on-site isolated intermediates	3. Registration of transported isolated intermediates	4. Registration	5. PPORD	**Sum:**
Germany	320	64	79	156	92	711
United Kingdom	164	4	7	73	19	267
France	117	18	39	29	25	228
Spain	86	3	79	10	2	180
The Netherlands	94		7	39	7	147
Belgium	61		12	21	13	107
Italy	65	1	19	6	12	103
Ireland	27	5	15	11	21	79
Austria	8	10	3	2	13	36
Sweden	20			3	4	27
Czech Republic	11		6		3	20
Hungary	13		2		1	16
Poland	11			4	1	16
Finland	4		4	2	5	15
Denmark	8	3	2	1		14
Portugal	4		2	1	4	11
Norway	1	2	3	2	2	10
Malta	7		2			9
Luxembourg	6			1		7
Slovakia	2		3		2	7
Latvia	4					4
Cyprus				1		1
Slovenia	1					1
Sum:	**1034**	**110**	**284**	**362**	**226**	**2016**

4. ACCEPTED DOSSIERS FOR PROCESSING IN 2010 BY COUNTRY till 16/02/2010

	1. Inquiry	2. Registration of on-site isolated inter-mediates	3. Registration of transported isolated intermediates	4. Registra-tion	5. PPORD	**Sum:**
Germany	44	22	26	62	12	**166**
The Netherlands	19	1	2	18	5	**45**
United Kingdom	18		10	10		**38**
France	12	3	6	12	2	**35**
Belgium	9		11	6	5	**31**
Spain	10	1	7	8		**26**
Ireland	16		2		3	**21**
Italy	11	1	3	4	1	**20**
Sweden	6	1	3		1	**11**
Luxembourg	7			3		**10**
Austria	1		1	2	2	**6**
Finland	2	1	1			**4**
Cyprus				2		**2**
Denmark				2		**2**
Czech Republic				1		**1**
Hungary				1		**1**
Romania				1		**1**
Slovakia		1				**1**
Sum:	**155**	**31**	**72**	**132**	**31**	**421**

5. DOSSIER SUBMISSION BY MONTH

2.1 Submissions by Month

	Accepted for processing	Complete
2009.02	151	45
2009.03	192	69
2009.04	170	54
2009.05	203	59
2009.06	175	57
2009.07	210	54
2009.08	150	60
2009.09	178	67
2009.10	169	66
2009.11	154	63
2009.12	158	77
2010.01	262	116

Living in *Helsinki*

Realistic information and help in relocation promote well-being

”It was easy for the ECHA staff to move to Helsinki and to settle down, but it was more difficult for their families to get used to the new environment”. This was one of the results of a study that researchers from Helsinki University´s Department of Social Psychology conducted 2008 and 2009 among ECHA´s newly recruited staff.

The study consisted of two assessments online, before the move by staff members to Finland and half a year after their arrival. The study assessed the psychological, socio-psychological and organisational adaptation of the foreign professionals.

The aim of the researchers was to find out what makes migration and adaptation easier and factors which help to maintain the well-being of foreign professionals in Finland. The results indicate that it was very important for the recruited person to receive information on the future employer and on local conditions in advance.

The recruited employees had a positive attitude toward Finns, Finland and ECHA before their arrival, and these remained after the move but their well-being decreased after relocating, which is quite normal when moving to an unknown country and which is backed by previous research.

One factor of particular interest was the tendency of people seeing themselves as more ”European” having higher psychological well-being. Stronger orientation for preserving one’s own culture after relocation was related to lower levels of well-being, the study says.

The assistance provided by ECHA and the City of Helsinki in practical matters like finding housing facilities, day-care services, schools and job opportunities for spouses was very welcome. Even though the initial move and relocation caused more stress, employees who were accompanied by their families showed higher levels of job satisfaction than staff members who came alone.

The study recommends organisations to focus on pre-migration preparation for employees and their families. Support for the employees families is also noted as being very important.

Inga Jasinskaja-Lahti, Markus Laine (edit.): Founding the European Chemicals Agency: The perspectives of the employees and the authorities of the City of Helsinki, City of Helsinki Urban Facts research series 2009:7

http://blogs.helsinki.fi/interprof/2009/10/09/intro/

“Everybody talks about the weather, but nobody does anything about it” – Mark Twain. Winter 2010 in Helsinki: snow snow snow!

EVA Expat Forum asked foreign professionals about their life in Finland

How to make Finland a better place for foreign professionals and their families?

This was the question addressed at the first ever expatriate forum organised by the Finnish Business and Policy Forum (EVA) in mid January. The event brought together over 500 expatriates from 61 countries in a discussion to reflect the lives of foreign professionals, their challenges and difficulties of breaking into the Finnish social and professional networks.

The forum was opened by the chairman of Nokia and Shell, Jorma Ollila. He began with a clear message for the expatriate professionals:” We welcome all of you because we need you.” Finnish society truly needs foreign professionals to compete in the global market. The Foreign Minister of Finland, Alexander Stubb, seconded Mr. Ollila’s point and presented three proposals as to how this can be encouraged. First, he called for more English-speaking schools. Second, he wanted better conditions for the spouses and families. Finally, he encouraged foreign professionals to be more active and open in Finnish society, not to retreat into an “expat community”.

Over a dozen speakers from all over the world were invited to give their thoughts and opinions on living and working in Finland. The main challenges that emerged in the discussions were the feeling of isolation due to a distant location, cold winters, the language barrier and adjusting to a different culture.

ECHA’s Director of Cooperation, Andreas Herdina, explained to the audience about the difficulties of founding an EU institution in Helsinki. He said that bringing many foreigners to Helsinki to work at the Agency was a huge task. He thanked the Finnish Government and the City of Helsinki for their support.

John Simon, an American working for the Kone Corporation, spoke of the unused resource of foreign students. He said that Finnish schools need to import talented students and make a continuous effort to keep them here. “They help you think outside the box”, he said.

On the plus side, Finland was praised for being a safe and clean place to live; a country with high quality education and health care. Although more efforts should be made to help foreign professionals integrate and succeed in Finland, there are also many who have ‘made it’ by embracing the unique Finnish attribute: persistence. Iranian CEO of the Helsinki Times magazine, Alexis Kouros concluded: “If you are crazy enough to move to Finland you can do anything.”

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The clock is ticking