World of biocides brought up to date

Safer biocidal products, less animal testing and equal treatment of active substance suppliers are some of the changes that the new Biocidal Products Regulation will bring in the future.

Steering the work to make the new biocides regulation a success

What role will the European Commission play under the new Biocidal Products Regulation? ECHA Newsletter spoke with Mr Pierre Choraine, the Biocides Team Leader in the Commission, to find out.

Setting up national biocides helpdesks

The Biocidal Products Regulation requires Member States to provide advice on responsibilities and obligations. Find out how they are doing.

Working together for better communication on the safe use of chemicals

ECHA and its stakeholders have signed up to improving chemical safety reports and safety data sheets. This is a long term collaborative effort.

Getting ready for the Biocidal Products Regulation

This summer at ECHA has been filled with preparations for the new Biocidal Products Regulation, which will apply from 1 September 2013. We have been working with this date in mind since the regulation entered into force on 17 July 2012, but the pace has intensified during the last couple of months.

Of course, we have learnt lessons from doing similar tasks under the REACH Regulation. We have been able to take advantage of the synergies with REACH and CLP processes, which we hope will make the use of the tools and support easier for our stakeholders. We still have some work to do before the first applications can be received, but I am confident that we will be ready in time so that the companies can apply.

The key to success is cooperation between the applicants, ECHA, Member States and the European Commission, who all have an important role in the implementation of the regulation. We at ECHA are responsible for setting up a submission system for the applications; publishing and maintaining the list of companies who have submitted a successful dossier; and supporting the work of the Biocidal Products Committee, who will deliver opinions on active substance approvals and renewals as well as Union authorisations. Due to the regulation’s strict deadlines, good cooperation is needed to ensure that a high level of protection for humans and the environment is efficiently achieved.
From a technical point of view, the new regulation brings biocides up to date with, for instance, the introduction of an online submission system. The latest version of IUCLID (5.5) was released in April and since then, applicants have been able to organise their biocides data and prepare their dossiers in the required format.

We are currently finalising the development of the Register for Biocidal Products (R4BP 3) that will be a central hub for all biocides applications. It will be used by the applicants to submit their dossiers and then to communicate with the authorities. Authorities will also use it to organise their work and interact with each other and the applicants. R4BP 3 will be up and running on 1 September 2013 and ready to receive your dossiers.

To ensure an efficient and smooth application process we have prepared as much support as possible, especially keeping in mind the needs of small and medium-sized enterprises. In addition to written support through submission manuals and scientific guidance, ECHA’s Helpdesk is ready to answer your questions related to the approval of active substances; Union authorisation; and inclusion in the list of approved active substances. Many of the Member States have their own helpdesks for biocides questions in their national languages and there is also an active helpdesk network providing support to those national authorities who are just starting their helpdesk activities.

On our website, you can always find the latest information related to the upcoming activities and webinars. I encourage you to use the support you can find there and to give us feedback so that we can better help you meet your obligations.

Implementing a new regulation in a short period of time has been both challenging and exciting. The number of ECHA staff working on the implementation is growing all the time and we estimate having close to 100 staff involved in biocides activities by the end of this year. However, with all this taken into consideration, this is a joint venture and we can only make the Biocidal Products Regulation a success together with you.
Biocides Stakeholders’ Day

Raising awareness on the new Biocidal Products Regulation

TEXT BY HANNA-KAISA TORKKELI

ECHAs first Biocides Stakeholders’ Day, held on 25 June, aimed to ensure that companies are aware of their roles under the Biocidal Products Regulation (BPR), the available tools and assistance provided to help them meet their obligations.

During the day, speakers from ECHA explained the new processes, such as data sharing, technical equivalence and obligations for suppliers under the BPR, and informed stakeholders on guidance and IT tools that will be available by the entry into operation on 1 September 2013.

ECHA also presented the review programme of active substances and the practical implications of Union authorisation. Guest speakers from the European Commission, the Member States and industry explained their roles under the new regulation and brought their perspectives into the discussion.

Nearly 300 people from the EU Member States, Turkey, India, China, Canada and the USA came to Helsinki to follow the programme and to network. Additionally, 1 300 viewers watched the event online.

If you missed the event, the presentations and the video recording are still available on ECHAs website: http://echa.europa.eu/view-article/-/journal_content/2a841ed1-7761-479d-91a8-3e439a11ebbb

WEB PAGES UPDATED AND GUIDANCE PUBLISHED

The biocides web section on ECHAs website has been updated and the first biocides guidance documents and submission manuals have been published. The ECHA Helpdesk is ready to support industry by answering enquiries related to biocides.


Nearly 300 people from the EU Member States, Turkey, India, China, Canada and the USA came to Helsinki for ECHAs first Biocides Stakeholders’ Day.
World of biocides brought up to date

INTERVIEW BY PÄIVI JOKINIEMI

Safer biocidal products, less animal testing and equal treatment of the active substance suppliers are some of the changes that the new Biocidal Products Regulation introduces. The application date, 1 September 2013, is the first of many important milestones of the regulation.

"The new Biocidal Products Regulation brings the world of biocides up to date and brings it into line with the regulations for chemicals," says Hugues Kenigswald, the Head of Biocides Unit in ECHA.

As an example of important changes, he mentions mandatory data sharing, a principle familiar from the REACH Regulation. The goal of this principle is to reduce the amount of testing on vertebrate animals by avoiding the duplication of studies. Another important element in the new regulation is the exclusion and substitution criteria for the most hazardous active substances, which in turn will lead to safer biocidal products.

With these and other changes, the regulation intends to cover the limitations of the Biocidal Products Directive, which was the predecessor of the Biocidal Products Regulation.

One of the advantages of the regulation, according to Mr. Kenigswald, is the fact that the regulation is directly applicable across the EU, which will make the biocides market more harmonised.

"For the applicant, one of the most concrete changes is the shift to a completely online submission system," says Hugues Kenigswald.

COOPERATION BETWEEN MANY PLAYERS

The new approval and authorisation processes under the regulation involve input and cooperation from many actors. The applicants of course have the key role, as they will provide all the required information to the authorities and possibly take action in different phases during the process.

ECHA is involved in most of the processes, for example by validating the incoming applications, developing the online tools and maintaining the list of active substance suppliers as well as supporting the work of the Biocidal Products Committee.

The Member State competent authorities play a significant part under the regulation. "The Member States will be responsible for evaluating the applications for approval of active substances or Union authorisation of biocidal products. They will either act in the role of an evaluating competent authority or present their view when the evaluation report prepared by one Member State is assessed by the others," explains Mr Kenigswald.

Each Member State can nominate one member to the Biocidal Products Committee.

To ensure that the applicant is able to estimate the required processing time of their application, the regulation gives strict deadlines for each step of the process.

'BE ON THE LIST OR OUT OF THE MARKET'

The regulation also aims to increase the equal treatment of the different active substance suppliers with the obligation that every company on the market must contribute to the costs of the application.

"If you are not on the list of approved active substance suppliers by 1 September 2015 you are out of market," Mr Kenigswald emphasises. This is good news for the companies who have until now taken the economic burden alone for getting an active substance approved while other companies may have been marketing the same substance in Europe without having made any contribution.

NEW WAYS TO AUTHORISE PRODUCTS

After 1 September 2013, a biocidal product can only be sold in the EU after its active substance has been approved and the product itself has been authorised. "For companies interested in more than one national market, the new regulation provides alternatives to the existing process of national authorisation followed by individual national mutual recognitions," says Mr Kenigswald.
Union authorisation opens the whole EU market in one go. On the other hand, for companies only interested in a limited number of national markets, the mutual recognition in parallel gives the possibility to start the authorisation process in all chosen Member States at the same time.

Mr Kenigswald also mentions another new possibility for product authorisation, which supports one of the main goals of the regulation: ensuring a high level of protection for human health and the environment.

“To encourage the applicants to use only the safest active substances in their products, the regulation introduces a simplified authorisation that is faster and requires less supporting data”.

**MILESTONES**

1 September 2013
Biocidal Products Regulation enters into operation and the first list of approved suppliers is published

1 September 2013
Union authorisation is available for all products containing a new active substance, as well as for product-types 1, 3, 4, 5, 18 and 19

1 September 2015
All active substance suppliers must be on the list of approved suppliers in order to stay on the market

1 January 2017
Union authorisation available for product-types 2, 6 and 13

1 January 2020
Union authorisation available for remaining product-types 7, 8, 9, 10, 11, 12, 16 and 22


**New online tools for biocides applications**

**TEXT BY PÄIVI JOKINIEMI**

Companies will be using three IT-tools to prepare and submit their biocides applications once the Biocidal Products Regulation enters into operation.

The main IT tools prepared by ECHA to support submissions under the Biocidal Products Regulation are IUCLID 5.5 (International Uniform Chemical Information Database) and R4BP 3 (Register for Biocidal Products).

**IUCLID 5** is a software application used to store information on chemicals and prepare a dossier containing data required by regulatory authorities. The latest version 5.5, released in April 2013, includes new functions to manage biocide-specific information and two new dossier types, namely active substance applications and biocidal product authorisations. IUCLID can be downloaded free of charge from the IUCLID website and installed onto the applicant’s own computer.

**R4BP 3** is a central hub used for all communications between the actors of the new regulation: the applicants, ECHA, the Member States and the European Commission. The biocides dossiers created in IUCLID will be submitted to the authorities using R4BP 3.

Applicants will also use R4BP 3 to follow up on their applications, read their messages and to reply to requests they receive from the authorities.

Additionally, the applicants need to use **REACH-IT**, which is the submission tool used for REACH and CLP, to create their user accounts for R4BP.

If you do not yet have access to REACH-IT, you need to create a new user account to be able to log in to R4BP. More information on how to do this is can be found in the Industry User Manual – Part 2: Sign-up and account management available on ECHA’s website. If you already have a REACH-IT account for your legal entity, you can use your existing credentials to log in to R4BP.

R4BP will be available on ECHA’s website on 1 September, when the Biocidal Products Regulation enters into operation.

**Further information:**

IUCLID 5.5

R4BP 3

Industry User Manual – Part 2: Sign-up and account management
Steering the work to make the new biocides regulation a success

INTERVIEW BY PÄIVI JOKINIEMI AND HANNA-KAISA TORKKELI

What is the role of the European Commission under the new Biocidal Products Regulation? ECHA Newsletter spoke with Mr Pierre Choraine, the Biocides Team Leader in the Commission, to find out more about the upcoming changes, improvements and challenges brought by the regulation.

The role of the European Commission will not change radically when the Biocidal Products Regulation enters into operation. Some of the most important tasks of the Commission, according to Mr Choraine, are to guarantee the successful implementation of the regulation and to anticipate and respond to the concerns of industry.

The Commission also has an important role to play in encouraging discussion and debate around the regulation. “Our role in the meetings with the Member States is to promote new ideas and to steer the debate until the discussion comes to a conclusion that could be supported by the majority of the Member States.” The role of the Commission’s Joint Research Centre, which managed the former Biocidal Products Directive, is taken over by ECHA.

In more practical terms, the Commission is involved in the ECHA Management Board and will continue to chair meetings with the competent authorities where the implementation of the regulation is discussed. “We will provide support to the coordination group, which is responsible for making sure that the mutual recognition of authorisation between Member States is working as smoothly as possible. We also participate as an observer in the meetings of the Biocidal Products Committee to ensure that the opinions that come out from the Committee can be directly processed in the Commission without a need to re-discuss with the Member States,” he explains.

In the context of the review programme and active substance approval, Mr Choraine reminds that it is a task of the Commission to provide ECHA with the necessary budget and resources to carry out its tasks. “The review programme should be completed by 2024, which means that ECHA will have to adopt around 50 opinions per year on the active substances under assessment. Once these substances have been approved, within two years, the products containing them have to be authorised. This means that companies that choose Union authorisation or mutual recognition need to submit applications for product authorisation to ECHA.”

The Commission will be monitoring the implementation of the regulation and take action if needed. “The regulation has given the Commission the power to adopt implementing rules and that is what we will do if any changes are needed.”

CHALLENGES AHEAD

As with much other European legislation, small and medium-sized companies also need special attention when the biocides regulation becomes operational. “We understand that this is a very complex piece of legislation and therefore it is important that companies, especially SMEs, know what they are expected to do and what rules they need to follow.” According to Mr Choraine, SMEs need support in accessing data to make sure that they are not forced to accept unfavourable agreements.

The sustainable use of the biocidal products is an issue that the Commission hopes to address in the coming years.
“We are thinking of ideas and tools on how to provide incentives for products that have the best profiles for the environment and human health. One of the ideas is to enable products with better profiles to be recognised in the market, for example, by giving them a specific eco-label,” he says.

Another challenge Mr Choraine refers to are treated articles and the new requirements that the Biocidal Products Regulation introduces for articles that have been treated with a biocidal product. “Many companies are not yet aware of the obligations they are facing and, therefore, it is critical to spread the information and educate industry on these new requirements.”

**BENEFITS OF THE NEW REGULATION**

The new regulation lays down clear timelines for the different processes and actors which Mr Choraine sees as a positive development.

“With set timelines, we can guarantee that the active substance approvals and product authorisations are processed in a given timeframe and, consequently, that safer products will be placed on the market faster than before.”

Union authorisation, which is one of the new ways of getting biocidal products authorised, is another good development worth flagging. “Once the Commission has granted the Union authorisation, the company is allowed to place their product on the entire EU market the next day. In terms of harmonisation of the internal market, this is the best thing we can offer,” he says and continues, “this will be especially interesting for companies who are marketing for a large number of countries or for the entire EU market”.

Companies who have taken their responsibilities seriously under the Biocidal Products Directive, will benefit from the introduction of Article 95 that responds to industry’s concerns about sharing of costs.

“The BPR will provide a level playing field because all substance suppliers have to contribute to the costs that have been incurred by companies in bringing an active substance to the review programme,” Mr Choraine explains.

**LEARNING FROM OTHER LEGISLATION**

The REACH Regulation has been said to be a forerunner in the world of chemicals legislation. The Biocidal Products Regulation may not quite fill the boots of REACH when it comes to having global impact, but the regulation certainly addresses many issues that have not been taken into consideration before.

“We are covering the nanoforms of active substances, have introduced the concept of exclusion and substitution, we will assess substances that have endocrine disruptive properties, and we have some new provisions on treated articles. We are at the forefront of what has been done and we have looked at the best practice from other legislation when developing this legislation,” Mr Choraine concludes.

**FROM OUR STAKEHOLDERS:**

“Support for small enterprises is crucial”

Katriina Sairinen, Regulatory Affairs Specialist at the Finnish healthcare company Algol Pharma, has been closely following the regulatory developments on biocides during the past years.

“As the legislation changes, everyone has to learn - both authorities and companies. The challenge for SMEs is, of course, the question of resources,” she says.

“In our case, we only have one person to follow the regulatory developments on several sectors, which requires specific knowledge. Therefore, the role of national biocides helpdesks is crucial, especially for small enterprises. They help companies to understand why certain measures are taken.

Further support from both national authorities and ECHA, such as through stakeholder events, guidance documents and informative websites, is also very welcome. So far, the recognition process has gone smoothly for us.”

Algol Pharma is an international healthcare company providing regulatory services to other companies as well as importing and distributing pharmaceuticals, food supplements, medical devices and cosmetics. Among its clients are companies producing biocidal products, and Algol Pharma is importing two insect repellents to Finland.

The company has already applied for mutual recognition for two biocidal products in Finland.
Experienced with biocides regulations

INTERVIEW BY HANNA-KAISA TORKKELI

Ilona den Hartog, Registration Officer at AkzoNobel Surface Chemistry AB, says her company has been following the development of the BPR very closely since they are an active member in the European Biocidal Product Formulators (EBPF) working group under CEFIC.

“The challenge has been to predict the consequences for us as a producer of active substances and consequently for our customers. Our active substances were already on the market many years before the Biocidal Products Directive (predecessor of BPR) was implemented and we had to follow the procedure for existing substances,” Ms den Hartog says.

Her company also had to ‘register’ biocides before the directive. “This was for countries where national registration schemes existed, such as the Netherlands, Sweden, Finland and Belgium,” she clarifies.

Ms den Hartog is glad that the new regulation introduces obligations for alternative suppliers. “Under the BPD, producers that did not make investments in biocides dossiers could still remain on the market until the decision on Annex I inclusion was taken. We are happy that the BPR finally brings an end to this - in our opinion - very unfair situation.”

As for ECHA, Ms den Hartog hopes that the Agency can improve the efficiency of the evaluation process and produce clear and workable guidance documents. “We also hope that the Member States will become more open for communication with industry in trying to solve open issues together. There should be a combined interest and effort both from industry and the authorities to make sure that biocides are used safely.”

BACKING SMEs

In the past months, debate on providing more support for SMEs and potentially reducing their financial burden has been intense. AkzoNobel agrees that SMEs need special attention. “Large industries have different investment possibilities compared to small companies and their marketed volumes of biocidal products are normally higher,” Ms den Hartog points out.

However, compliance with the regulation may also pose a financial challenge for the bigger players. “Large companies usually market a bigger variety of different biocidal products, which in turn leads to an increase in the costs. As a consequence, the number of different biocidal products could well decrease in the future.”

In addition, the costs for getting authorisation for a biocidal product will come on top of the investments already made by the active substance producers. “Those companies are carrying a heavy financial burden, which is often increased by REACH registration costs,” she concludes.

AkzoNobel Surface Chemistry AB is the world’s leading supplier of specialty surfactants. The company produces four active substances, which are all under evaluation in the review programme of the Biocidal Products Directive.

Simplification would benefit SMEs

INTERVIEW BY HANNA-KAISA TORKKELI

Consultant Piet Blancquaert, is helping companies to comply with the new regulation. He is concerned for SMEs who are struggling with the complexity of biocides legislation.

“There are companies that don’t know what a biocidal product authorisation is, as some of the EU Member States currently do not have a national authorisation scheme. Many of the companies cannot justify an authorisation cost of a couple of hundred thousand euros for one or a few Member States where they have their products on the market. If they can, they need to make a joint effort and go to several Member States,” he says.

The BPR aims to increase transparency on the different processes and offers industry clear, fixed timelines for active substance approvals and product authorisations. In addition, the online submission system will ease the submission of applications.

However, the biocides world is complex and explaining to people who are not used to working in a regulatory framework but who now need to comply with the law is not easy. “It is like going from zero to 10 000 for them. Biocides guidance documents are hundreds of pages long, IUCLID takes time and effort to master and you also need to learn about REACH to understand the interlinks between the regulations. I feel there is a mismatch of market and costs.”

Dr Blancquaert says that simplification of procedures would benefit SMEs. “Access to data is also very important. On the one hand, companies should be treated equally, and on the other, SMEs need cost relief. This is very challenging.”
Setting up national biocides helpdesks

The new Biocidal Products Regulation requires that the Member State competent authorities provide advice to all interested parties about their responsibilities and obligations under the regulation. To this end, many competent authorities are establishing a national helpdesk, which ECHA will support. ECHA Newsletter interviewed helpdesk representatives from Finland, the Netherlands and Slovenia to learn how these countries are building up their service to the biocides industry.

Creating a common understanding

INTERVIEW BY PÄIVI JOKINEMI

The Finnish Safety and Chemicals Agency, Tukes, is aiming to have the necessary support ready when the Biocidal Products Regulation enters into operation.

Mr Hannu Mattila, planner of biocides activities, tells that the biocides group in Tukes has been working hard to create a common understanding on the regulation and the tasks it brings to them. “The regular meetings that the biocides group started to have already last year are an example of our preparations. In each meeting, one person was responsible for presenting a certain part of the Biocidal Products Regulation to the rest of the group and after that the topic was discussed together,” he says.

As the National competent authority in Finland, Tukes is responsible for implementing and enforcing the regulation as well as organising the helpdesk services. “We started the preparations for the biocides helpdesk already over a year ago,” Mr Mattila says.

Tukes has been responsible for the national REACH and CLP helpdesk in Finland and therefore has experience with helpdesk work. Providing support for companies on questions related to biocides is not a new task either, since they have already been supporting companies under the Biocidal Products Directive. However, some improvements compared with the service provided today will be made.

“When the regulation enters into operation, the biocides helpdesk will get its own telephone number, which will be dedicated only to questions related to biocides. We will also launch a webform which will be used for biocides questions. With the help of this new system, we can better coordinate our answers and monitor that all the questions are answered within a set timeframe.”

Tukes’ REACH and CLP helpdesk website is currently under construction and will be updated to include information about the biocides helpdesk services. New information related to the Biocidal Products Regulation will also be added.

“To keep our customers up-to-date on the latest news, we also publish an electronic newsletter about biocides four times a year both in Finnish and English. This way the customers can keep themselves informed even if they do not visit our website regularly,” Mr Mattila adds.

Along with the regulation, the cooperation with ECHA has become more frequent. “We are participating in different committees and working groups organised by ECHA. Among other things, we have recently been part of a working group who contributed to the categorisation of biocides questions and answers for the HelpEx tool that will be used by the national biocides helpdesks,” Mr Mattila explains.

http://www.tukes.fi/en/
Expanding the sphere

INTERVIEW BY HANNA-KAISA TÖRKKELI

The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) has had a biocides helpdesk already for the national scheme and the biocides directive.

“Now, we are modifying our system so that it comes into connection with ECHA’s helpdesk. We will no longer be communicating only to Dutch companies who are interested in authorising their biocides in the Netherlands, but exchanging and sharing information with other countries through the IT platform HelpEx, which aims to coordinate and harmonise helpdesk responses throughout the different national helpdesks,” says Jan Willem Andriessen from the Ctgb.

At present, the Dutch helpdesk has three staff covering questions for both biocides and plant protection products. “We are expecting a lot of questions on treated articles, and on which legislation to apply. People are already used to the national scheme, but are now asking what the new biocides regulation will mean for their business, their authorisations and applications. Certainly, new opportunities, such as Union authorisation, will raise questions.”

The Dutch biocides helpdesk is separate from the REACH and CLP helpdesks, but the two have a good collaboration. “We are cooperating together in the HelpNet work. Overall, our perspective is different due to the differing natures of the two legislations. REACH and CLP obligations apply to most established chemicals manufacturers whereas biocidal products are not allowed on the market until they have been authorised. We need to take this different approach into account,” Mr Andriessen says.

95% of the Dutch biocides market consists of SMEs. For them, informing about the changes is important. “The BPR is not designed for SMEs, and it will be a challenge to keep SMEs on board,” Mr Andriessen predicts.

To support the companies, the Ctgb not only replies to questions through the helpdesk but also issues bi-monthly newsletters on biocides. A website update is expected by the end of the year to reflect the changes in the regulation. According to Mr Andriessen, they are ready for 1 September. “Good cooperation between ECHA and the authorities is required. We need to keep the lines short, so that we are able to call or email each other when necessary,” he concludes.

http://www.ctgb.nl/

Individual assistance

INTERVIEW BY HANNA-KAISA TÖRKKELI

Ms Marta Pavlič-Čuk from the Chemicals Office of the Republic of Slovenia (CORS) says that her office is now preparing for the new biocides regulation. The Slovenian authority has, since 1998, provided assistance to companies under the national notification scheme. “We help companies via email and phone. In specific cases, when the issue is complex or the company representatives wish to show us their documentation, we invite them to visit us,” Ms Pavlič-Čuk says.

The helpdesk has regular contacts with the national chamber of commerce. “Generally, once a year, we hold a workshop for our stakeholders. We have one coming in October this year. These workshops are especially targeted at producers and distributors,” she says. For general information needs, the authority e.g. maintains a website, produces leaflets, holds press conferences and conducts research.

Ms Pavlič-Čuk says that the regulation is demanding for small companies. “In Slovenia, we have a lot of distributors that are SMEs. Sometimes, the small players are not fully aware of their obligations and might face exclusion from the market if they fail to fulfil their duties.”

She expects that companies will send in a lot of questions regarding the status of their application after 1 September. “The classification according to the CLP regulation that kicks in in 2015 will also create questions,” she concludes.

http://www.uk.gov.si
REACH Review Workshop

Call for creative ideas to overcome REACH challenges

TEXT BY HANNA-KAISA TÖRKKELI

“Only by listening to the opinions of our stakeholders are we able to understand better and only by understanding, will we be able to regulate better,” said Antonio Tajani, the Vice President of the European Commission in his opening at the Technical Workshop on the Review of REACH held in Brussels on 27 June. The aim was to listen to the views of SMEs, which deal with the challenges of the regulation every day, and find practical solutions. ECHA Newsletter reports back on some of the views presented at the workshop.

NOT A NICHE ISSUE

Allen Creedy, the Chair of the Federation of Small Businesses Environment, Energy and Water Committee in the UK, gave an overview of the challenges that the small and micro non-chemical businesses face, when striving for REACH compliance. “It is right that potentially dangerous chemicals are regulated and controlled. Small businesses have the duty to protect human health and the environment, it is only right that we play our role. But, unlike large businesses, many of us cannot afford the administrative time and cost that so often comes with these 'one size fits all' regulations which unfortunately REACH is,” he said.

He also pointed out that now, after the 2013 registration deadline, REACH is very much a small business issue. “Unfortunately, the complexity of the regulation is stopping SMEs from creating jobs and generating wealth.”

Mr Creedy listed a few simple things that could help small companies. Firstly, he said, there is a need to increase awareness. “According to a survey in the United Kingdom, 50% of the small companies are not aware of REACH. We are not getting across to small and micro business. We need to now have a concerted effort to raise awareness of SME responsibilities and information on where they can turn to get help.”

Another point that he made is that SMEs need simple and tailored guidance. “The guidance needs to give SMEs confidence that they are complying with the regulation.”

In addition, the functioning in substance information exchange forums is a concern. “We would like to see official and concrete guidance on fair cost sharing,” he stated.

Lastly, Mr Creedy called for an effective monitoring system to provide understanding of the impact of REACH on SME competitiveness.

MORE SUPPORT IN LOCAL LANGUAGES

Ms Barbala Otto from a Hungarian SME Agroterm lists language barriers, the complexity of IT tools, safety data sheets and the costs of registration as the main challenges her company faces with REACH compliance.

Language barriers, in various REACH communications from the ECHA website and IT tools for substance information exchange forums, might create legal uncertainties, as taking a decision based on insufficient understanding is difficult. “I am the only one in the company who speaks English and I am neither a toxicologist, chemical engineer nor lawyer, so for me to understand the regulation itself or the guidance documents is very difficult,” Ms Otto said.

As a suggestion for overcoming the language barriers, Ms Otto asked for national authorities to provide more practical training in national languages.
The challenge with safety data sheets comes when the supplier does not provide all the information required by law. “Why should we be responsible for our supplier’s non-compliance? Downstream users are not able to provide the information that the authorities are asking for,” she said.

She would like to see a European-wide safety data sheet centre, where all the safety data sheets would be collected. “Suppliers should be made to upload their data sheets into the system, including translations, and the users could then download them.”

The cost of registration is another hurdle, according to Ms Otto. But the issue is not so much the registration fee, but more the costs of letters of access and consortium membership.

“We are not sure what the administrative cost of the letters of access covers, as this is not very transparent. As a member of a consortium, I am also granted ownership of the data. However, if I buy a letter of access for the same amount of money, I do not own the data. In most of the cases, this does not seem fair,” she said.

Ms Otto would like ECHA to be more involved in SIEF activities. She would like ECHA to lay down certain rules concerning the ownership of data and define what transparent, fair and non-discriminative cost sharing means.

“We would also love to have a proportionate distribution of fees based on the production volume, an opportunity to pay in installments as well as potentially to get some subsidy from the national government or the EU.”

She also suggests creating an EU fund to provide resources for SMEs to pay for legal services and experts to help them comply with the provisions of the regulation in their own language.

Further information:

The presentations and recordings of all 17 speakers of the conference as well as discussion sessions are available on the European Commission’s website: http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm

Read more about ECHA’s activities concerning SMEs in upcoming newsletter issues.

Board of Appeal members’ term in office prolonged

ECHA’s Management Board has prolonged the term of office of ECHA’s Board of Appeal chair Ms Mercedes Ortuño and four alternate members for five more years.

The mandates of the following alternate members have been prolonged:

- Barry Doherty, alternate and additional legally qualified member
- Rafael Antonio López Parada, alternate and additional legally qualified member
- Marc Pallemaerts, alternate and additional legally qualified member
- Henricus Spaas, alternate and additional legally qualified member

The alternate members of the Board of Appeal, though not employees of ECHA, form an integral part of the work of the Board of Appeal. They are called upon to ensure that appeals can be processed at a satisfactory rate and to deal with cases in the absence of the members.

Guest column | Violaine Verougstraete

Reflections on the review of REACH

Five years ago, Eurometaux and its members embraced the principles of the REACH legislation, committing to provide the required efforts to make it a transparent and efficient chemicals management tool. While inorganics account for less than 10% of the number of substances on the EU market, their volumes and daily use by society is much larger, accounting for more than 50%. These aspects, as well as the hazard profiles of a number of metals, justify why the sector tries to appropriately address both the generic requirements and the specificities of inorganics.

In the context of the REACH Review, Eurometaux has conducted an evaluation* of the functioning, benefits and impacts on the sector and identified recommendations to ensure that the regulation remains true to its second objective: “maintaining a competitive industry within the European Union”.

REACH has changed the landscape of chemicals management regulation in the EU and beyond. The systematic approach to screening hazards and risks, the identification of risk management measures and their communication through exposure scenarios are unprecedented, and have contributed positively to a more integrated management of chemicals within the EU. REACH has provided a structured way to stimulate further data generation and fill data gaps, and metals consortia have invested significant efforts to ensure the quality of their assessments. It has also given significant impetus to the development of approaches designed to improve the relevance of risk assessment and management practices for inorganics.

The financial and human resources involved in registration activities have been substantial: on average 10 million euros, 10 FTE/year for one metal and its salts. The high attention paid to metals under authorisation came somewhat as a surprise as many metals identified as substances of very high concern were selected for CMR properties, whilst already covered by other legislation.

Our evaluation concluded that, five years on, registration and communication have contributed to an increased understanding of the properties of substances through the supply chain. On the other hand, our experience shows that the efforts and benefits or impacts are not in balance for the authorisation and restriction sections of REACH.

We did not identify the need for a major overhaul of the REACH legislation, and we support the conclusion of the European Commission that guidance updates and REACH/ECHA Committees - with a stable framework - could handle the issues and refinements needed at this stage. The metals sector would, however, contribute the following generic recommendations:

- Sufficient time should be allocated to debating and agreeing appropriate methodologies in order to widen the relevance and applicability of ECHA and Member States’ opinions and decisions and ensure that approaches are non-discriminatory for any sector.
- Legislators should put more emphasis on using the REACH methodologies data sets in other EU and national policy areas. Such streamlining would also fit with the objectives of the Commission’s proposal for the ‘Living well, within the limits of our planet’ Environmental Action Plan.
- The Strategic Approach to International Chemicals Management (SAICM) drives chemicals management globally and REACH is definitely one of the fore runners in this area. Differences in systems cannot be allowed to lead to ‘chemicals management shopping’. The active participation of ECHA in international chemicals management forums, and agreements on datasets that can be used in other jurisdictions will leverage chemicals management and eliminate potential trade barriers caused by differences in systems.
- To ensure that appropriate efforts are spent in areas with benefits for society, the sector urges to proceed with the 2020 roadmap initiative with an emphasis on early and transparent risk management option exercises for chemicals for which specific uses require risk management.

Violaine Verougstraete
Environmental, Health and Safety (EHS) Director, Eurometaux

Eurometaux is a European association servicing and representing the European non-ferrous metals industry. The association is one of ECHA’s Accredited Stakeholder Organisations.

*The evaluation paper can be found on the REACH metals gateway http://www.reachmetals.eu
Working towards the REACH dossier evaluation goal

TEXT BY TIJUBRÄUTIGAM

ECHA is combining a targeted, concern based approach with full compliance checks to improve the quality of information and ultimately the safety of chemicals.

By the end of 2013, ECHA aims to have carried out compliance checks on at least 5% of the 19 772 registration dossiers from the 2010 deadline. By 1 July, it has evaluated a total of 671 dossiers, from which over half have had quality shortcomings. ECHA has sent draft or final decisions on 373 of those dossiers to companies asking them to update their information.

To ensure the quality of registration dossiers, the Agency uses a combined approach.

In a full compliance check, the whole dossier is evaluated. Concern-based checks look at specific parts of the dossier that matter most for the safe use of chemicals. Combining the two types of check means that non-compliant dossiers are very likely to be picked up.

In using the targeted approach, ECHA automatically screens every single registration dossier. One focus is on endpoints that matter for human health and the environment with an emphasis placed on the persistent, bioaccumulative and toxic (PBT) or carcinogenic, mutagenic or toxic to reproduction (CMR) status of a substance. Substance identity and chemical safety report related issues are also targeted.

Individual dossiers that were submitted outside a joint submission and dossiers with obvious shortcomings (e.g., an inconsistent chemical safety report) will also be automatically considered for compliance check. Besides improving efficiency, the aim of the approach is to treat all companies equally, ensuring that the most important areas for the safe use of chemicals are tackled.

**UPDATE YOUR DOSSIERS**

Under the targeted approach, as each endpoint is checked separately, one company can receive more than one draft decision about its dossier. If a registrant receives a draft decision related to a specific concern, it should not assume that the rest of the dossier is compliant.

Therefore, every draft decision should be seen by companies as a wakeup call to look at the entire dossier. Further decisions could follow for different endpoints within the same dossier. If a registrant receives more than one draft decision, it would make sense to revise its registration strategy or the data generation strategy of the substance information exchange forum (SIEF). Even better is to proactively update the dossier based on the recommendations provided by ECHA in its annual report on evaluation.

The work on compliance checks will not stop after 5% of the 2010 dossiers have been evaluated by the end of 2013. Dossier evaluation will continue in future years to improve the quality of registration dossiers and thus the safety of chemicals in Europe.

Further information: http://echa.europa.eu/evaluation
ECHA is now inviting interested parties to provide information on safer alternative substances or technologies that could be used instead of DEHP for the use defined in the application. “In the application, the company applying for authorisation has to assess potential alternatives. The public consultation aims to ensure that the assessment has been done properly and that all relevant information on alternatives is gathered,” says Richard Dubourg from ECHA’s Risk Management Implementation Unit.

Getting the most from the consultation

When preparing their applications, applicants need to find the right balance between the information they claim confidential and the information they agree to be published.

The information which is made publicly available should be clear and detailed enough to allow a meaningful consultation. By doing so, applicants can avoid having to respond to comments which are not relevant to their application.

How does the consultation work?

During the consultation, anyone can provide information on alternative substances or technologies for the uses of the substance included in the application. “Those most interested will be other companies or organisations representing industry or civil society since they are most likely to have information relevant to an application,” Mr Dubourg says, and adds, “But in principle anyone can contribute.”

The information on alternatives should include the identity of the alternative substance and/or the description of the technology. For a substance, its properties and classification should be included. Information related to the technical and economic feasibility, availability and risks to human health and the environment is also very valuable. “Most important is that the information is relevant to the applicant’s situation. It should relate to an alternative, which the applicant could actually use instead of the Annex XIV substance for which they are applying for authorisation.”

All non-confidential information provided by interested third parties will be published on ECHA’s website on a regular basis. If the applicant wishes to provide responses, they will also be published on ECHA’s website.

All the information submitted will then be considered by the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC). “The Committees will evaluate the information submitted in terms of its relevance, quality, clarity and completeness. It is really important that the information is detailed and complete enough to allow proper evaluation by the Committees,” says Richard Dubourg.

The final opinions of the two committees will be sent to the European Commission. Based on these opinions, the European Commission will decide whether to grant the applicant an authorisation for the use requested or not.

Authorisation for a limited time

The decision to authorise the use of a substance of very high concern (SVHC) will be based on solid risk assessment and socio-economic analysis. If a company using a substance listed on the Authorisation List has a good case for continuing to use it after the sunset date and the circumstances of its use meet the requirements laid down in REACH, there is in principle, no reason why an application should not be granted. “Companies should not be afraid of applying for an authorisation if they believe they have a case. However, they have to take the process seriously. The decision to apply for authorisation rather than to replace the Annex XIV substances should be a core business decision,” says Mr Dubourg.

The large investment that companies have to make in preparing an application; the involvement of third parties; the scrutiny provided by ECHA’s Committees; and the time-limited nature of the granted authorisations, all make it more likely that the use of Annex XIV substances occurs only where risks are properly controlled.

Further information:


Making use of derived no-effect levels generated under REACH

TEXT BY ROGER STAMM, IFA AND ANDREAS AHRENS, ECHA

The German Institute of Occupational Safety and Health of the German Social Accident Insurance (IFA) has published an online database of derived no-effect levels (DNELs) based on information retrieved from ECHA’s website. This database provides easy access to a collection of DNELs relevant to workplaces for people involved in occupational safety and health within companies, research institutions and authorities.

The DNEL database aims to support the assessment of risks associated with tasks that involve hazardous substances. DNELs are recommended exposure limits established by the manufacturer or importer. In combination with knowledge about exposure, DNELs can help in drawing conclusions about the risks to health and the protective measures that should be taken to ensure safe use.

Altogether, 18 different types of DNEL values are defined in the REACH Regulation. Two of these are of exceptional importance to occupational safety and health: systemic effects and local effects due to long-term or repeated exposure via inhalation.

These two DNEL types are now available for more than 1,200 substances in the new GESTIS DNEL database. The data has been taken from the registrations published by ECHA and from the safety data sheets of a number of manufacturers and the list is continually being expanded. If there are differing DNELs for the same substance, they are presented in parallel without further evaluation.

FREE ACCESS AND SEARCH POSSIBILITY

Members of the public can freely access the data either through an alphabetical list of substances or a search screen. Searches can be done by substance name, a range of identification numbers (CAS, EC, INDEX) and the chemical formula.

The substance data sheets are divided into sections for identification, formulae, DNELs and sources, together with a link to further substance data in the GESTIS substance database.

Besides the database, the DNEL portal also contains a simple list of substance names, CAS numbers and the workplace DNEL for long-term exposure through inhalation.

Through the list, the user can access the document output for individual substances containing synonyms, the European Commission number and structural formula and, where applicable, the German occupational exposure limit (AGW) as well as an indication of whether the substance is classified as carcinogenic. A query in the DNEL database for an individual substance also leads to this document output.

ECHA: VALUABLE USE OF REACH INFORMATION

The Agency welcomes the German initiative and also encourages other stakeholders to take advantage of the increased information on chemicals, which REACH has brought about. “This example illustrates how information generated under REACH can support safe use of chemicals in workplaces and how ECHA’s website can be used as a source of information,” says Christel Musset, Director of Registration.

Access the database at: www.dguv.de/ifa/gestis-dnel
Manufacturers and importers registering a substance under REACH in amounts of **10 tonnes or more per year** are obliged to carry out a chemical safety assessment, which, as a minimum requirement, includes the hazard assessment of the substance.

As a result of the hazard assessment, derived no-effect levels (DNELs) are established. These are **concentration levels** below which a substance does not adversely affect human health. Under REACH, the registrants are required to address exposure via oral, dermal and inhalation exposure, taking into account identified local and systemic effects.

The DNELs can be used as **reference values** for establishing protective measures to control exposure in workplaces.

The registrants are expected to submit the DNELs as part of their **technical dossier** so that automated processing by authorities is possible, including dissemination through ECHA’s website.

Together with the DNELs themselves some of the underlying assessment information is disseminated: the most sensitive endpoint, the route of exposure in the original study, the dose descriptor starting point (no observed adverse effect level), and the overall assessment factor and DNEL derivation method.

Registrants are also obliged to **include the DNELs in the safety data sheets** for their substances in order to make this information available to downstream users.

So far, occupational exposure thresholds have been established at Member State or Community level for only a limited number of substances in use.

Publishing the DNELs generated for REACH is expected to **fill some of the gaps in existing information** and to **promote harmonisation** in developing thresholds for human health exposure assessment.

ECHA guidance for deriving DNELs is available in the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.8.

The DNELs made public on ECHA’s website have not been systematically reviewed by authorities or third parties.

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**WHAT ARE DNELs AND WHAT ARE THEY USED FOR?**

**Ongoing consultations:**


**Upcoming:**

- ECHA announces final results of the REACH 2013 registration deadline: mid September 2013
- ECHA to perform compliance checks on at least 5% of the registration dossiers from the 2010 deadline: December 2013

**Event Calendar**

**September - October 2013**

- ECHA Management Board: 26-27 September
- Tentative dates:
  - Committee for Risk Assessment (RAC): 10-13 September
  - Committee for Socio-economic Analysis (SEAC): 11-13 September
  - Member State Committee (MSC): 23-27 September
  - Biocidal Products Committee (BPC): 9-10 October
  - Enforcement Forum: 28-30 October

Working together for better communication on the safe use of chemicals

TEXT BY LAURA WALIN

ECHA and its stakeholders have signed up to improving chemical safety reports and extended safety data sheets. More stakeholder organisations are invited to join in this long term collaborative effort.

In July, ECHA published a cross-stakeholder roadmap towards improving the quality of information in exposure scenarios, in both the REACH chemical safety reports and safety data sheets. These documents hold essential information on the conditions of safe use of chemicals, and are the main tools used to disseminate the information both in the supply chain and between the authorities.

While an innovative way to compile and communicate information on the safe use of chemicals, exposure scenarios are relatively new, and the mechanisms for generating and communicating them still have room for improvement.

This became obvious to ECHA in spring 2012 when it analysed the experience gained since the first registration deadline in 2010 and received feedback from industry and downstream users.

At the time, ECHA proposed to set up a cross-stakeholder group to develop a roadmap to address the known shortcomings in a coordinated way.

The same observations and need for action were echoed by the European Commission in their review of REACH, published in February 2013. The consequent roadmap with its actions is now responding to these calls.

CALLING FOR MORE STAKEHOLDERS TO JOIN IN

The roadmap is structured around five action areas with 21 individual actions. ECHA is taking the lead on eight actions, industry organisations on 12 and one action will be led by the German Federal Institute for Occupational Safety and Health (BAuA). Several Member State authorities and industry organisations have expressed their commitment to contribute to the work.

The Agency is now calling for more stakeholder organisations to join in. They can do that by signing a specific Roadmap Charter available on ECHA’s website, and by contacting the action leads with a view to contributing to the areas where they have expertise. This way their commitment to the roadmap actions is also visible to the public.

The action areas are the following:

» Action area 1
Increase understanding among stakeholders:

Achieving a common understanding among stakeholders on the purpose of the information in the chemical safety report and the exposure scenario.

» Action area 2
Improve information on how substances are used as an essential input to the chemical safety assessment:

Identification of the information that registrants need from downstream users so that they can assess their uses.

Chemical safety reports and safety data sheets hold essential information on the conditions of safe use of chemicals, and are the main tools used to disseminate this information both in the supply chain and between the authorities.
DUCC, the Downstream Users of Chemicals Coordination Group, representing the majority of formulator chemical sectors, welcomes the CSR/ES Roadmap and intends to actively contribute to its actual implementation.

Practical experience from the last three years at formulator level has shown that the quality, the format and the content of exposure scenarios received in extended safety data sheets for substances varies to such an extent that complying with downstream user duties under REACH is a tremendous challenge. This is all the more difficult because supply chains for raw materials are dynamic and complex.

The ‘REACH Review’ project of the European Commission similarly concluded that supply chain communication mechanisms and risk management information via safety data sheets has to be improved.

We have five years ahead of us to come up with practical tools and recommendations for improvement. All actors, from industry and from authorities alike, need to work together if we want to achieve the roadmap objectives and, ultimately, safe use of chemicals through their life cycle.

We want REACH to support the European chemical industry and effectively deliver safety, not to create unnecessary administrative barriers, this more specific also for the SMEs.”

Sylvie Lemoine, DUCC

“While requiring registrants and downstream users to draw up chemical safety reports and exposure scenarios for safety data sheets, REACH has left it to the discretion of the actors to decide on the details of structure and format for the documents. ECHA guidance is not fully closing this gap in standardisation. That said, the CSR/ES Roadmap is an important high level commitment aiming at shaping all the ongoing efforts for creating best practice for chemical safety reports and exposure scenarios.

There are a number of roadmap activities for which the contribution of REACH enforcement authorities will be helpful. Eventually, the roadmap will help the enforcement authorities to make informed decisions based on the valid best practice related to exposure scenarios in safety data sheets. The Austrian REACH enforcement authorities will provide their experience to the roadmap actions.

Raising awareness of the roadmap to the national enforcement authorities and informing about the outcomes and their relevance for enforcement is important. Such information needs to be spread both at Member State as well as at ECHA Forum level.

Although REACH has many elements to promote the safe use of chemicals, it is the tools that support the creation and dissemination of safe use information that make the broad impact of REACH. Therefore, getting involved in the CSR/ES Roadmap is a key step for all REACH actors.

For industry organisations, any involvement will signal their endeavour to provide good quality information on safe use as required by REACH. For authorities, being involved is a recognition of the fact that best practice for chemical safety reports and exposure scenarios is still jointly to be achieved.”

Eugen Anwander, Austrian Enforcement Authority
What to do when receiving an extended safety data sheet?

TEXT BY DR STEFFEN PFEIFFER AND DR ROGER VAN DER LINDEN FROM BOREALIS

Handling extended safety data sheets (eSDS) as a downstream user is challenging. In addition to the existing obligation to follow the supplier’s advice in the main body of the safety data sheet, the downstream users now have to carefully check if their own uses are covered in the exposure scenarios received, and whether their conditions of use are equivalent to those specified in the exposure scenarios.

Our company, Borealis, is a leading provider of innovative solutions in the fields of polyolefins, base chemicals and fertilisers with headquarters in Vienna, Austria. We currently employ around 6200 people, operate in over 120 countries and have registered over 80 substances. As a large chemical company, we have many roles under REACH, including the role of downstream user.

As a downstream user, we have received almost 1000 safety data sheets in the last year at our operating locations in Europe. About 10% of these were extended safety data sheets, with exposure scenarios attached. These exposure scenarios are for the uses that the supplier has identified as relevant, and they describe the appropriate risk management measures for given operational conditions for each use.

THREE STEPS

How do we make sure that the supplier’s extended safety data sheets support our uses? Here are the three steps that we follow:

» Step 1: Verify that our own uses are covered in the supplier’s safety data sheet.

We compare the uses listed in the supplier’s safety data sheet with the uses in our plants. The exposure scenarios use standardised codes to describe the uses, for example as process category (PROC) and environmental release category (ERC). It has taken time, experience and training for our employees to become familiar with these codes and to be able to translate the uses of a chemical in our plant into this system.

» Step 2: Check if the operational conditions are respected.

We compare the operational conditions for the uses within the applicable exposure scenario(s) with the real conditions in our own plant or location.

» Step 3: Ensure that the risk management measures are implemented.

If the risk management measures that we implement are identical to those recommended in the extended safety data sheet, our own use can be considered as safe.

Otherwise, we need to look into it in more detail and decide what we should do. When possible, we check if the deviation can be compensated by another measure, a procedure called scaling. For example, if the duration of exposure is longer than in the supplier exposure scenario but the concentration is lower, scaling might show that the exposure level is the same or lower, and so our use is supported.

HOW WE CHECK EXPOSURE SCENARIOS

The exposure scenarios are checked by local staff in the various plants who have been trained in several workshops. We have developed an Excel tool which helps to check the exposure scenarios and which also documents this check at the same time.

We generate one document per substance, per location and per supplier. In this document, the “cover” worksheet details the substance, supplier, the safety data sheet, who performed the check and what the outcome was (Figure 1).

In the following worksheets, we fill in the data on uses and conditions of use from the extended safety data sheets and compare it with our own uses and conditions of use (Steps 1 and 2 above). As a location can contain several plants, the exposure scenario check is done at plant level for the worker exposure and at location level for the environmental part, as shown in Figure 2.

The tool automatically generates a “safe use” or a “no safe use” message.

The tool is easy to use and files can be shown to auditors or enforcement authorities to demonstrate
legal compliance and that downstream user obligations have been fulfilled.

**MAKING SURE RISK MANAGEMENT MEASURES ARE IMPLEMENTED**

We hold regular meetings at which we monitor the status of the exposure scenario check, to ensure we meet the six or 12 months legal deadline.

We also discuss any difficulties with the non-standardised exposure scenarios, and what to do if we get a “no safe use” message. If scaling is not applicable or does not result in safe use, we might contact our supplier to ask him to support our use.

We have established a technical support role to our procurement team, termed raw material owner, who is familiar with both REACH and our suppliers. This person undertakes technical communication with the suppliers and we have found it to be very effective.

Alternatively we may implement additional risk management measures, or create a downstream user chemical safety report to demonstrate safe use conditions.

We find that our approach is very suitable for a large company like Borealis with several locations and think it is also likely to be suitable for smaller or medium-sized companies.

**Further information:**
www.borealisgroup.com

Disclaimer: The views presented in this article do not represent the views of the European Chemicals Agency.

If you would like to contribute to the ECHA Newsletter by writing about your experience in fulfilling downstream user obligations, contact echanewsletter@echa.europa.eu.
Croatia joins the EU chemicals management framework

TEXT BY VEERA SAARI AND HANNA-KAISA TORKKELI

Croatia joined the European Union on 1 July 2013, taking the total number of EU Member States to 28. The REACH, CLP and biocides regulations now apply to companies established in Croatia.

This is the first time a new Member State joins the EU since the REACH Regulation has been operational. Therefore, specific deadlines not foreseen in the regulation have been introduced granting Croatian manufacturers, importers and producers of articles a special pre-registration period for their phase-in substances from 1 July 2013 until 1 January 2014.

Companies will then need to make full REACH registrations for substances manufactured or imported at levels over 100 tonnes together with those that are carcinogenic, mutagenic or toxic to reproduction or toxic and persistent in the environment by 1 July 2014.

From 1 July 2013, Croatian companies should also make a C&L notification to ECHA within one month of placing a substance on the market. In addition, companies need to notify the classification and labelling of their substance to ECHA from 1 August 2013 for the substances that were on the market on the date of accession.

ECHA Newsletter interviewed Ms Biserka Bastijančić-Kokić from the Croatian Ministry of Health and Ms Tatjana Benko and Mr Hrvoje Raukar from the national oil company INA-Industrija nafte, d.d., say that their company is already well acquainted with the REACH and CLP Regulations. “We foresee that REACH will put more demands on Croatian industry to protect human health and the environment and require companies to take more responsibility for their substances. This is a positive development.”

The main benefit of REACH, according to Biserka Bastijančić-Kokić, will be the improved communication in the supply chain. “We have been preparing since 2008,” says Biserka Bastijančić-Kokić, Head of the Department for Chemicals and Biocides at the Croatian Ministry of Health. Croatia has had a national plan for harmonising local legislation with the European, and has regularly published ordinances to update its legislation.

“We have also offered information on REACH and CLP on our website in Croatian and established REACH and CLP helpdesks already in 2008,” Ms Bastijančić-Kokić says. Close cooperation with the national Chamber of Economy has helped in reaching and informing the companies.

Since 2011, Croatian members have participated in the work of the ECHA Committees, Forum on Enforcement and Management Board, first as observers and, after 1 July, as full members. In addition, ECHA has, through the Instrument for Pre-Accession (IPA), organised study visits for Croatian officials to EU Member States and ECHA.

“The support from ECHA has been very helpful and appropriate. We have visited national authorities in Ireland, Lithuania, Slovenia, Austria and Germany in order to strengthen our capacity. Having material translated and published on ECHA’s website in Croatian before the date of accession was also very helpful. However, we definitely need further support from ECHA on REACH-IT, chemical inspection, Prior Informed Consent (PIC) procedures and on the new Biocidal Products Regulation.”

Ms Bastijančić-Kokić expects that implementing REACH will create the same challenges for Croatian companies as it has for companies in other EU Member States. “Large companies will manage well as we have already seen in our meetings with industry. They are aware of the main requirements of REACH and CLP. Reaching the small and medium enterprises will be a priority for us.” As a potential bottleneck, Ms Bastijančić-Kokić mentions the dossier creation in IUCLID 5. “We are also concerned about the tight deadline for the first CLP notifications.”

ALREADY ON THE REACH TRACK

Ms Tatjana Benko and Mr Hrvoje Raukar from the Croatian national oil company INA-Industrija nafte, d.d., say that their company is already well acquainted with the REACH and CLP Regulations. “In 2009, we signed an Only Representative contract with our biggest shareholder, Hungarian MOL Plc., to be able to register substances that we sold on the EU market by the first registration deadline of 2010. We are also a member of Concawe, the oil companies’ European association, through which we have received a lot of information and support for preparing our dossiers,” Mr Raukar and Ms Benko say.
The company will register the rest of its substances by September 2013. “Having already more than five years’ experience with REACH, we are very well prepared and will meet our target for dossier submissions.” On a national level, however, both Mr Raukar and Ms Benko expect that fulfilling the REACH and CLP obligations will be a ‘considerable challenge’.

The main issue faced by the oil company itself has to do with resources. “The pre-registration in 2008 and registration in 2010 required substantial human, organisational and financial resources. REACH has also initiated new, continuous activities, such as communication with suppliers and customers through the whole supply chain, and updating existing safety data sheets and registration dossiers”, Ms Benko and Mr Raukar point out.

As the main benefit of REACH and CLP, Mr Raukar and Ms Benko mention the harmonisation and simplification of chemicals legislation in the EU. “In the future, we expect to see competitive advantages and, overall, improved protection of human health and the environment. Better risk management for dangerous chemicals, especially with regard to worker protection, and a more efficient communication of chemical risks through the chemical safety reports are also important developments.”

Helsinki Chemicals Forum 2013
Debating chemicals policy
TEXT BY HANNA-KAISA TORKKELI

The 2020 goals and the sound international management of chemicals, chemicals in products, regulation of nanomaterials, listing of chemicals of concern, and combination effects were the topics discussed at the global Helsinki Chemicals Forum from 18 to 19 June 2013.

ECHA’s Executive Director Geert Dancet was one of the opening speakers of the event. He reflected that the Helsinki Chemicals Forum has become the key gathering of chemical professionals worldwide. “The debates address important issues for which we all need to design and provide an appropriate regulatory response. Although experts regularly gather for technical meetings that advance our knowledge on these crucial topics, it is the Helsinki Chemicals Forum which provides a platform for a policy debate that enjoys high visibility and, I hope, also impact,” he said.

Bjørn Hansen, Head of Unit at the European Commission’s DG Environment, spoke about the role of REACH, its successes and shortcomings as addressed in the review of REACH and introduced the Commission’s proposal for the new Environmental Action Programme (EAP) to 2020. “We want to work towards a nontoxic environment, which is supported by chemical knowledge bases,” he said of the strategic objectives of the new EAP.

GOALS OF 2020

The first panel discussion tackled the 2020 goals and the sound international management of chemicals.

Bjørn Hansen promoted REACH as the machinery to deliver for 2020 and contribute to the management of chemicals worldwide.
Kaj Madsen of UNEP pointed out that 2020 is a moving target as ‘with new knowledge, we find new issues to address.’ “Minimising the health and environmental effects of chemicals will keep us in business for the coming years,” he said.

All of the panellists thought that it was important to get the developing countries on board to manage their chemicals and also look beyond 2020 to make sure that the right things are in place to protect people and the environment from dangerous chemicals.

**EXPOSURE TO CHEMICALS IN PRODUCTS IS A COMMON CONCERN**

The second panel discussed whether the chemical safety regimes, which mostly concentrate on individual substances, pay enough attention to product safety. The panel concluded that exposure to chemicals in products is a shared concern and rightly part of chemical management schemes.

However, it is a complex area to manage and a systemic regulatory approach, which combines chemical legislation with sectoral product controls, is needed.

**REGULATION OF NANOMATERIALS EVOLVING**

The third panel focused on the regulation of nanomaterials. Dr Peter Kerns from the OECD said that OECD testing and assessment approaches are also suitable for nanomaterials, with appropriate adaptations taken into account.

The European Commission’s Otto Linher told the audience about the results of the Second Regulatory Review on Nanomaterials. “REACH sets the best possible framework for the risk management of nanomaterials. However, some detailed requirements are missing and the registration dossiers are unclear,” he said and continued: “Modifying the REACH Annexes is the fastest way to address the shortcomings.” The Commission will propose a revision of the REACH Annexes by the end of 2013.

While the regulatory strategies for nanomaterials are being developed, the work on gaining practical experience and confidence in assessing nanomaterials and for seeking technical convergence continues.

**LISTING CHEMICALS OF CONCERN IS A PRIORITY SETTING TOOL**

The fourth panel touched on the topic of listing chemicals of concern. The moderator, Andreas Herdina from ECHA, asked whether listing these chemicals makes sense and whether the harmonisation of the various national and international lists would be desirable or even possible.

The participants concluded that listing of chemicals of concern is an inevitable and a long-established aspect to chemical management systems. Nevertheless, the lists each have their specific purposes that should be communicated clearly and transparently to avoid misunderstandings of their purpose.

The panel also concluded that listing of chemicals is not an aim in itself, but a tool for priority setting for further assessment or risk management.

**FURTHER DEVELOPMENT NEEDED TO ADDRESS COMBINATION EFFECTS**

The need to address the cocktail effects of chemicals is widely acknowledged and there is active scientific work ongoing, according to the panellists of the last session looking at combination effects. However, the regulatory approaches need to be developed further.

To see all the presentations and video clips from the Forum, visit [http://helsinki CF.eu/](http://helsinki CF.eu/)

In 2014, the Forum will be held from 22 to 23 May in Helsinki.