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Newsletter

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Second REACH registration deadline a success

At the end of May, we together achieved another key milestone on the REACH journey towards safer use of chemicals in Europe.

The second REACH registration deadline on 31 May saw 9 084 registration dossiers submitted by 3 215 companies covering almost 3 000 chemicals manufactured or imported in the EU at quantities between 100 and 1 000 tonnes per year. This represents a major effort on the part of European industry and I would like to personally extend my congratulations to those registrants who successfully submitted their dossiers.

The results of the deadline are readily available on ECHA's website.

One fifth of the registrations submitted were from micro, small or medium sized companies; this is in line with what we had been expecting for these medium-tonnage substances.

A significantly higher proportion and number of SMEs is expected to register smaller volume chemicals for the 2018 deadline. ECHA is, thus, keen to improve its support to SMEs who will, in any case, have to take the lead. That is why we will consult all SMEs who have registered for the 2013 deadline in the autumn.

We already have a strong track record of supporting SMEs: providing a host of information on our website in all the EU languages and supporting the work of the

national helpdesks that are providing help to SMEs. But we will and can all do more. We also need to recognise that SMEs not only figure as registrants, but even more prominently as duty-holding formulators and article producers.

I would like to encourage larger, experienced companies to take on a substantial role in supporting smaller industry players. For example, larger companies can offer advice to mentor those inexperienced in REACH who will have to register for the third deadline in 2018. They could also offer access to registration data at reduced costs within a SIEF. ECHA will be working with the European Commission and European industry associations in elaborating suggestions to this end.

While the registration deadline is rightly seen as a successful step towards making Europe a safer and healthier place, our journey should not stop here.

The Agency's work will continue as we look to further improve the efficiency and effectiveness of our work. At the end of May, we opened a consultation requesting comments on our draft Multi-annual Work Programme (MAWP) for 2014-2018.

The key drivers of the MAWP are focused by our strategic objectives to improve the quality of information on chemicals and how to use them safely, using this information intelligently to select substances of concern that warrant regulatory intervention, and undertaking our work with underpinning good regulatory science to address scientific challenges. We also have to be effective in implementing the new Biocides and PIC tasks while maintaining the standards we have achieved with REACH and CLP.

We are, therefore, looking for your comments on the MAWP because your voice and opinions are integral to our success. You can help us to deliver to your needs and we welcome your comments.

The deadline for submitting your comments is on 15 July.

Geert Dancet
Executive Director

"At the end of May, we together achieved another key milestone on the REACH journey towards safer use of chemicals in Europe."

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REACH 2013 results

Nearly 3 000 more substances registered by industry

TEXT BY HANNA-KAISA TORKKELI

By the second REACH registration of 31 May, 3 215 companies submitted 9 084 registration dossiers for 2 923 substances to ECHA.

Overall, the registration process worked well: industry responded actively to the 2013 registration deadline, ECHA teams were ready to receive dossiers and the IT systems performed smoothly. However, a number of lead registrants registered only during the final days, causing unnecessary pressure to some member registrants to submit their dossiers on time.

"REACH is a journey that takes place over the years up until 2020. In that context, we just achieved a major milestone, which brings in the second category of existing substances and takes us a big step closer to having a robust chemicals database for all the main chemicals in Europe. It also shows that, in principle, industry has now reviewed the hazards and uses of their chemicals produced from 100 to 1 000 tonnes a year, and confirmed that the registered uses are safe," says *Kevin Pollard*, ECHA's Head of Unit for Dossier Submission and Dissemination.

The number of dossiers and substances submitted was very close to ECHA's estimations, which were based on the information provided voluntarily by lead registrants of the substance information exchange forums (SIEFs) and on surveys carried out with industry organisations.

"We received the expected number of registration dossiers. At the substance level, we did not receive registrations for all of those substances that industry had informed us about during the surveys, but this was partly compensated by submissions for other substances, of which industry had not given us a prior indication. Overall, the number of substances registered was close to our expectations. Some concerns were raised about those substances, which had been intended to be registered by industry but were not, but so far there has been no sign from the market that any essential substances would have 'disappeared'. We will keep our ears open during the summer, but according to the first reactions from industry the differences between the intentions and the reality are due to shifts in the market and are not a concern."

ECHA will contact those lead registrants who originally intended to register substances for the deadline but after all did not, and ask for their reasons. "It is of course voluntary for leads to share this information. The main source of feedback for us is the downstream users and different industry sectors and whether they express their concern for a key substance no longer being on the market. But as I said, so far there is no sign of that," Mr Pollard says.

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"We are one step closer to having a database of all the main chemicals in Europe," says Kevin Pollard.

SUPPORT PROVIDED TO COMPANIES

The Agency started to provide support to REACH 2013 registrants right after the first deadline in 2010. It has held three stakeholders' days, two lead registrant workshops, broadcast a series of webinars and offered IT trainings.

In the last weeks before the deadline, ECHA helped 510 companies having technical difficulties with their submission by proactively calling them and sorting

out the problems. In addition, a few companies experiencing problems in SIEF management were helped.

"The main issues close to the deadline were passing the business rules step in REACH-IT and problems with file format. The 'business rules' is an automated check that confirms whether the information in the dossier is consistent. For example, if a company making an initial submission creates the dossier as an update, the system won't let it be processed. The file format has to do with making sure that the dossier is the right kind of IUCLID dossier," Mr Pollard explains.

The ECHA Helpdesk dealt with 425 questions related to REACH 2013 registrations in May. Of these, 62% had to do with REACH-IT blocked accounts.

In addition, ECHA has updated and created new IT tools, revamped the Helpdesk contact forms, and published new and updated guidance documents, fact sheets, practical guides and illustrative examples.

FOCUS ON QUALITY

At this stage, it is too early to say whether the quality of dossiers has improved for this second deadline.

"We will know more about quality of data once the dossiers are passed on to evaluation. We have taken actions in the past years to help companies prepare good quality dossiers, the most recent development being the Dossier Quality Assistant tool launched in February," Kevin Pollard points out.

ECHA has gained experience on dossier quality since 2010 and is now well prepared to tackle potential quality issues in the REACH 2013 dossiers.

It will carry out database screening on the registered dossiers in order to examine quality, including further targeted screenings on intermediate use and substance identity. ECHA will also continue to verify the SME status of those registrants claiming to be small, medium or micro companies.

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Director of Registration, Ms Christel Musset, and Executive Director Geert Dancet presented the results of the second registration deadline at a press conference in Brussels.

REACH 2018

The last REACH registration deadline is on 31 May 2018 for phase-in substances manufactured in the European Union or imported in quantities of one tonne or more per year. The last deadline is expected to be quite different from the two previous ones, with many more registrations prepared by small SIEFs or individual registrants, and concerning many more SMEs than before. "This final deadline is expected to generate the highest number of registrations and there will also probably be far more inexperienced registrants. In this respect, the advice provided by the national REACH and CLP helpdesks becomes even more important as they will be the first line helpers for companies in their own languages," says Kevin Pollard.

The major challenge related to the last registration deadline will be reaching out to the smaller companies. To this aim, ECHA intends to establish a roadmap for 2015-2018, in collaboration with stakeholders to adapt and streamline procedures, IT tools and support to the registrants.

"Although the European Commission's REACH Review concluded that the implementation of REACH is proving to be a success, it also recommended that work be done to see if sharing of data can be improved. Dialogue will be needed to gather feedback from industry in an attempt to identify potential changes either to the data sharing process or to the pre-SIEF in REACH-IT. At the same time, consideration will be given to SMEs and whether there is a possibility to simplify the process for them," Mr Pollard highlights.

Another area of improvement is the technical dossier submission system. "Our aim is to upgrade the system to make the submission of member dossiers technically more straightforward," he concludes.

Further information:

REACH 2013 results
http://echa.europa.eu/reach-2013

Information for registrants
http://echa.europa.eu/reach-2013/information-for-registrants

Information for downstream users:
http://echa.europa.eu/reach-2013/information-for-downstream-users

MAIN FIGURES FROM REACH 2013 REGISTRATION DEADLINE:

Data as of 3 June 2013

	Registered	In process	Total
SUBSTANCES	2 344	579	**2 923**
	Completed	**Pending**	**Total**
REGISTRATIONS	6 100	2 984	**9 084**

NEXT STEPS FOR REGISTRANTS

The most important advice to registrants is: Follow up on your registration. Your dossier is your responsibility. You need to keep it up-to-date.

Right after submission:

- If your dossier fails the technical completeness check (TCC) undertaken by ECHA, you will receive a letter in your REACH-IT account. The letter will include instructions on how to proceed, including a timeframe to resubmit your dossier (usually four months). Should your registration fail the TCC for a second time, it will be rejected. If you have any doubt about how to address the result of the TCC, contact the ECHA Helpdesk.

- Remember that your registration will only be considered complete, if the registration fee is paid within the deadline indicated in your invoice. Make sure that your accounting department has received the relevant invoices and has made arrangements to pay them on time. Non-payment of the fee will result in the rejection of the registration.

Once you have completed your registration:

- Registration is not the end, it's only the beginning. If you were in a rush to prepare your dossiers, have a look at our advice and tools for maximising quality of information and proactively review and correct any deficiencies you are aware of. ECHA will be carrying out targeted IT screening on the dossiers and if deficiencies are found, the dossier may be prioritised for compliance check under evaluation.

- Update your dossier as soon as possible when you receive new data and reasoning.

- ECHA's quality advice and tools

  Dossier Quality Assistant
  http://iuclid.echa.europa.eu/index.php?fuseaction=home.news&type=public&id=62

  Webinars
  http://echa.europa.eu/support/training-material/webinars

  Evaluation reports
  http://echa.europa.eu/evaluation

  Chemical safety report illustrative examples
  http://echa.europa.eu/support/practical-examples-of-chemical-safety-reports

FROM OUR STAKEHOLDERS:

***Erwin Annys*, European Chemical Industy Council, CEFIC**

The chemical industry has met the second registration deadline in time, as it did for the first. The second phase was in a certain way more difficult than the first registration deadline. In 2010, registration was the only issue. This time, companies have had to simultaneously handle the new registrations, the updates of previous registrations, as well as the results of dossier and substance evaluation, the development of the Candidate List and, in some cases, even the first applications for authorisation. The total impact of REACH on companies becomes more and more clear.

Until now, the number of small and medium-sized enterprises registering has been rather limited, as expected. For the next deadline, however, we expect SMEs to register many more substances, and in many cases they may be the only company registering the substance, placing the full responsibility very much on their own shoulders. The number of substances to be registered is also expected to be seriously higher than the combined number of substances for 2010 and 2013. Despite the fact that the information requirements are less, the total workload will seemingly be much higher and will be done by less experienced companies.

The European Commission in their review, ECHA in their communications and industry associations are all stressing on the need to help SMEs for 2018. As the chemical industry, we believe that a close collaboration on how to get the required information with less burden for companies will be beneficial not only for SMEs but for all companies confronted with the REACH obligations.

http://www.cefic.org

***Inneke Claes*, European Association of Metals, Eurometaux**

The non-ferrous metals companies continue to ensure REACH compliance and have stepped up their efforts and resources to submit their dossiers in time for the 2013 registration deadline. No major problems were reported, the IT-system put in place by ECHA is robust, and companies appreciated the considerable amount of assistance provided by ECHA over the past few weeks leading up to the registration deadline.

At the same time, the non-ferrous metals companies are continuing to update their existing registration dossiers and to implement the other challenging parts of REACH and the CLP Regulation such as authorisation, restriction and (harmonised) classification. All these activities will help to make better information on metals and metal compounds, their uses and risk management measures more readily available.

In addition, industry urges ECHA and the Member States to ensure the correct implementation and enforcement of REACH in order to avoid free riders.

http://www.eurometaux.org

***Sylvie Lemoine*, international Association for Soaps, Detergents and Maintenance Products, A.I.S.E**

We hope this second phase of REACH is a success, despite the recent concerns expressed by ECHA in relation to delays in substances due to be registered in 2013 actually being registered on time. So far, in our membership, we have not heard of essential chemicals that have not been registered.

We remain concerned with the quality of data communicated in the supply chain and the ability of downstream users to meet their legal duties. In this respect, we hope that the coverage of uses and the quality of extended safety data sheets will improve after the lessons learnt from 2010, although we acknowledge a lot remains to be done in terms of standardisation and harmonisation of exposure scenarios.

We are also increasingly concerned about the impact of substance evaluation decisions on downstream users, in particular when they have not been contacted in the evaluation process. In some cases, downstream users may have useful information to provide (e.g. risk information) to avoid decisions being based on limited and unrealistic criteria or assumptions.

In general, we share the concerns of other parties regarding the complexity and heavy burden for SMEs, at all levels.

We hope that ECHA will, in the coming years, continue to provide active support to downstream users to help them fulfil their duties, create smoother work processes, and implement the new biocides regulation effectively and in full transparency.

http://www.aise.eu

***Uta Jensen-Korte*, European Association of Chemical Distributors, Fecc**

Fecc have received a number of enquiries both prior to and following the May 2013 registration deadline that indicates the preparation to meet the obligations was extremely difficult. While we know that our members were busy with the preparation of dossiers as well as their other REACH obligations (2010 dossiers update, authorisation, evaluation) they were often hampered by forces outside their control.

There were a number of examples of lead registrants registering very close to or on 31 May, which resulted in severe anxiety within the substance information exchange forums (SIEFs). Some joint registrants had to register after the deadline because the lead registrant would not release their token until they had received confirmation of their registration.

Some non-EU companies announced very late that they were not going to register, which caused difficulties especially as, in some cases, stock was already on the sea travelling to Europe and was due to land after the deadline.

A number of consortia within SIEFs were requesting unreasonable fees for letters of access very close to the deadline. They had no chance to look for alternative options and either had to pay or withdraw.

After the 2010 registration deadline, there was a constant stream of IUCLID and guidance updates. In itself each change may not have caused a specific issue, but it slowed down the whole process for 2013. With regard to IUCLID, the lead registrants from 2010 had to update their dossiers after the July 2012 update before they could issue anything to anyone. This slowed the whole process down and meant that a number of organisations were delayed in starting registrations for 2013 because the lead registrant was 'playing it safe' and not doing a lot of work until the amendments had stopped.

The same concern was raised regarding guidance. For instance, after the 2010 deadline there were issues for UVCB* substances regarding a few registration dossiers, raised by ECHA. This caused issues, lemon oil being one, where the whole registration process had to be reformatted even though the guidance was still ambiguous.

Even though a prohibition on amending guidance six months before any deadline is always in place following the 2010 experiences, this still meant that a number of guidance documents were changed in 2011 and 2012, meaning that SIEFs had to review their work to ensure that it met all the new guidance, which caused an extra amount of work and further delays.

All of these issues above meant that a number of Fecc members, who were fully resourced and ready to go, could not actually do anything whilst the SIEF and the lead registrants were ensuring that their dossiers would work in the system. This resulted in a number of sleepless nights worrying whether they were going to be able to be compliant with the regulations.

To illustrate the level of resource necessary to comply, one company (that we are aware of) had two members of staff working their contracted 140 hour month to handle a number of lead and joint registration dossiers. They both also had to work an additional 100 hours overtime for 3.5 months (January to April) to meet the deadline. They could not find any 'top up' experienced resources available to help them cope with the peak demand of the 2013 deadline.

It is important that industry now focuses on the 2018 deadline which will be a real challenge in terms of number and size of companies involved – mostly SMEs, as the deadline requires the registration of substances produced or imported in lower volumes. This will mean that data generation and data access costs will become a major issue which could lead to potential disruption in the supply chain.

In the coming years, ECHA and industry need to work together to develop supportive mechanisms and simpler (IT) tools for SMEs to register their substances.

Not only does the administrative burden need to be reduced, but simplifications and the overall costs of registration for low volume substances need to be considered.

Raising awareness among the smaller companies to remind them about their duties will be a challenge, especially reaching those which are not members of any trade association.

* Unknown or Variable compositions, Complex reaction products and Biological materials

http://www.fecc.org

Fourth meeting of the Exchange Network on Exposure Scenarios

From an exchange platform to providing practical solutions

INTERVIEW BY HANNA-KAISA TORKKELI

The fourth meeting of the Exchange Network on Exposure Scenarios (ENES) in May was built around the Chemical Safety Report/Exposure Scenario (CSR/ES) Roadmap, which was presented for the first time to a wider stakeholder group. The aim of the roadmap is to set out clear actions for improving the quality of information in the chemical safety reports and the extended safety data sheets, both of which are built around the exposure scenario.

"It is not enough that the information in the chemical safety reports and exposure scenarios is legally correct – it also has to be useful for the registrants, downstream users and authorities. The information that downstream users get through the extended safety data sheets is of variable quality in terms of amount of detail, conflicting or even absent information. A cross-stakeholder coordination group has developed the CSR/ES Roadmap to address these quality concerns so that those who use chemicals have the right information available, in the right level of detail and in a consistent and familiar format. The ultimate goal is that this information is used effectively to ensure that these chemicals are used safely" says ECHA's *Andrew Murray*.

The roadmap was well received by the participants and they expressed their commitment to work on the actions identified in the document. Altogether, the roadmap has five broad areas of actions, which will be taken forward either by ECHA or by industry associations, and in certain specific cases Member States. All other stakeholders are invited to contribute.

"One of the main actions is to improve the understanding of the elements of chemical safety reports and exposure scenarios, and raising awareness of their purpose. Our idea is to have specific workshops to talk through what the essential information requirements are and what benefits they bring," Dr Murray explains.

ECHA will also take the lead on developing and improving IT tools related to supporting chemical safety assessments, another area of action of the roadmap. This work is already on-going for Chesar and IUCLID at ECHA. Within industry work on tools they have to communicate exposure scenarios in an electronic format down the supply chain (such as the ESCom) proceeds.

The Downstream Users of Chemicals Coordination Group (DUCC) has agreed to take the lead on mixtures, addressing the concerns of formulators of mixtures and the end users.

"We are looking to help formulators to better understand how to take the information from the substance safety data sheets and process it so that it is suitable for a mixture. As for those who use mixtures, they need to get the right level of information in a format which is both fit for their use and understandable," Dr Murray says.

Through the roadmap, the ENES is bringing stakeholders together to manage issues related to chemical safety assessment. "

We are constantly looking for more sectors under this umbrella, so that they could all contribute and make use of the outcomes. We would like to create a genuine cross-stakeholder group where the solutions that people have worked through can be presented and assessed on whether they are workable and can be used," Andrew Murray says.

The fourth meeting of the Exchange Network on Exposure Scenarios (ENES) in May was built around the Chemical Safety report/Exposure Scenario Roadmap, which was presented for the first time to a wider stakeholder group.

The CSR/ES Roadmap will be published during summer. To accompany it, ECHA will publish a specific web page with the aim of keeping stakeholders up-to-date with the various actions under the roadmap. The roadmap actions will be rolling until 2016 with actions in place for the last REACH registration deadline of 2018.

DEVELOPMENT ON SCEDS

The ENES4 dedicated a session to specific consumer exposure determinants (SCEDs). The SCEDs are helping companies to refine the inputs for exposure estimation for consumers, so that people have a more accurate estimation of impact and how to control it. Industry has been working on developing SCEDs for the past 18 months and the current status of development was presented to ENES4 participants.

The Member State competent authorities play an important role in developing SCEDs, since they monitor and enforce the legislation and will have an eye on how the registrants have carried out their assessment. "This is an area where there needs to be further dialogue between industry and competent authorities. We are now starting to set up working meetings to have that exchange," Dr Murray says.

ECHA will follow the development of SCEDs closely and ultimately make the import of SCED data possible in its own assessment tool Chesar.

ENES5 TO CONCENTRATE ON MIXTURES

The next meeting of ENES will be held in late autumn and the main topic will relate to mixtures. "Formulators are conscious that after the REACH 2013 registration deadline, they will start receiving a lot of information on substances through the extended safety data sheets, which they then have to take into account when preparing safety data sheets (or risk management advice) for mixtures. At the ENES4 meeting, participants identified the top priorities regarding mixtures. The stakeholders intend to work together to resolve them and potentially present workable solutions at the autumn meeting," Dr Murray concludes.

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Through the CSR/ES Roadmap, the ENES is bringing stakeholders together to manage issues related to chemical safety assessment.

Further information:

Programme, summaries and presentations
http://echa.europa.eu/view-article/-/journal_content/title//fourth-meeting-of-the-echa-stakeholder-exchange-network-on-exposure-scenarios

What is ENES?
http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

Moving forward with exposure scenarios, Newsletter 6/2012
http://newsletter.echa.europa.eu/home/-/newsletter/entry/6_12-enes3

ENES discusses good practice in deriving and communicating exposure scenarios, Newsletter 4/2012
http://newsletter.echa.europa.eu/home/-/newsletter/entry/4_12-enes

Setting scientific principles for sediment risk assessment

INTERVIEW BY HANNA-KAISA TORKKELI

How to use science for regulatory purposes was one of the key questions tackled at ECHA's first topical scientific workshop, which covered sediment risk assessment. The workshop brought together over 100 experts from around the world to set the scientific principles for assessing risks to the sediment compartment in all regulatory contexts.

"There have been significant developments in science concerning sediment risk assessment, which are not reflected in the current guidance," says ECHA's *Jose Tarazona*, the workshop Chair. He says that the workshop conclusions provide a good basis for reviewing the current guidance.

"Our aim was to set basic principles that could be applied in all regulatory contexts. After all, the science is the same for predictive risk assessment conducted for example for substances under REACH, and for retrospective site-specific assessments conducted on contaminated areas, for example under the Water Framework Directive. Depending on a specific regulation, the tools and methods may vary, but should be based on shared scientific grounds."

The two-day workshop included general plenary sessions with case studies and topical breakout group sessions, where the participants discussed specific recommendations on how to use scientific knowledge for regulatory purposes.

"There were, for example, recommendations on when to trigger the risk assessment for the sediment compartment, what should be the basic principles and how to use the equilibrium partitioning method* for screening purposes. The participants also gave their ideas for covering the exposure assessment, predicting the concentration levels expected in the environment and reaching the sediment organisms, and elaborated on the tools that are available for describing and predicting the effects," says Dr Tarazona.

Workshop chair Jose Tarazona was pleased with the outcome of the meeting.

Another conclusion from the workshop was that the risks for sediment should be considered as part of the aquatic assessment and should not be restricted to invertebrates. "The current guidance focuses only on sediment invertebrates. Obviously, the invertebrates are very relevant but there

The conclusions of the sediment workshop provide a good basis for reviewing the current guidance concerning sediment risk assessment.

are other taxonomic groups and ecological functions that need to be considered as well," Dr Tarazona points out.

This conclusion might mean that simply updating the guidance is not enough - a new conceptual model needs to be developed to make sure that the risks are covered for all relevant substances.

NEXT STEPS

The impact of the workshop outcome is quite extensive, according to Jose Tarazona. The workshop proceedings will be published by the end of 2013 on ECHA's website following an extensive consultation with all participants and the workshop's international Scientific Committee.

"The proceedings will serve as a basis for reviewing and potentially updating the guidance for REACH and biocides. In addition, participants from the European Food Safety Authority (EFSA), the European Commission and the US Environmental Protection Agency have told us that they will use the workshop outcome for updating their guidance on sediment assessment under the Plant Protection Products Regulation, the Water Framework Directive, and the US sediment assessment framework. The OECD will consider using the workshop outcome and the ECHA guidance update as a starting point for further harmonisation of sediment risk assessment at the OECD level."

The success of the workshop and the valuable network created have already made Dr Tarazona consider a similar event for addressing terrestrial and soil risk assessment.

"That would be a typical follow up because many of the elements for sediment risk assessment are also applicable for terrestrial risk assessment. But we would need to see."

*The equilibrium partitioning method (EqP-method) can be used for adapting the REACH information requirements on soil and sediment testing. To derive screening environmental quality standards for soil or sediment, it uses aquatic toxicity data and a soil/water or sediment/water partitioning coefficient.

Further information:

Workshop programme, presentations, list of participants, background material and case studies
http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-on-risk-assessment-for-the-sediment-compartme-1

FROM THE PARTICIPANTS:

Dr Chris Schlekat from the Nickel Producers Environmental Research Association (NiPERA) is one of the scientific committee members, who prepared the outline for the content of the workshop.

"The workshop managed to bring together the right experts to address the very complex issues within regulatory science. Many of the concerns that we have with respect to technical challenges have been discussed and I believe that those discussions can help the nickel industry to incorporate very complicated data into our REACH dossiers," he says.

Dr Schlekat presented to the workshop an approach the nickel industry has taken to solve the technical and scientific challenges for providing generic exposure scenarios for the sediment compartment under REACH. "The appropriateness of the approach we took was discussed in the breakout groups. My initial assessment is that the participants supported most of our decisions."

He thinks that the workshop outcome reflects the state of science from a global perspective. "The workshop proceedings will eventually set the base for developing regulatory guidance for sediment risk assessment."

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Another member of the scientific committee, *Dr Paul Sibley*, Associate Professor at the University of Guelph, congratulates ECHA for an excellent workshop. "It is very good to get experts together to discuss scientific topics. There are advances in different fields and when people network and share ideas, as a result you get a more synergistic perspective that is different from the prevailing sense that exists individually. This will advance the way that science is used in regulatory processes," he says.

Coming from North America, Dr Sibley is interested in seeing how the European regulators are making sure that their decisions are science based. "It is about striking a balance; recognising that science is critical for ensuring sound regulatory policy but at the same time not requiring so much detail that decision making becomes paralyzed."

Dr Sibley is looking forward to contributing to the workshop proceedings. In addition, some of the key issues might be published as scientific papers in peer reviewed publications. "I think that specifically those areas that were identified as knowledge gaps or areas of uncertainty at the workshop, could be flagged in some kind of a summary publication."

Understanding REACH

Restricting substances – how is it done?

TEXT BY PIA FALLSTRÖM MUJKIĆ

In 2010, France submitted to ECHA a proposal for restricting lead and its compounds in jewellery articles. In this case, exposure to children was the main concern.

If a chemical poses an unacceptable risk to human health and the environment and if there is a need to address the problem in all EU countries simultaneously, then an EU Member State or ECHA - at the request of the European Commission - can propose a restriction of that chemical. The restriction then limits or even bans the manufacturing, placing on the market or the use of the chemical.

In the case of lead and its compounds in jewellery, it was argued that children, especially those under 36 months, often put things including jewellery in their mouth. They could, therefore, be repeatedly exposed to lead from jewellery articles.

This repeated exposure could result in severe and irreversible neurobehavioural and neurodevelopmental effects. Children are particularly sensitive as their central nervous system is still under development and exposure to lead could, in fact, cause loss of intelligence.

This was considered as a European Union-wide unacceptable risk to human health and was therefore a basis for restricting lead in jewellery.

RESTRICTION PROCESS

The process of restricting a substance starts with the preparatory work and with **a notification**.

Either ECHA or an EU Member State firstly notifies that it intends to propose a restriction and then, within one year after the notification, the same country or the Agency submits the actual proposal.

ECHA then organises a **conformity checking** of the proposal. This is done by the two ECHA Committees: the Committee for Socio-economic Analysis (SEAC) and the Committee for Risk Assessment (RAC).

Once the proposal conforms to the requirements, it is published and a **public consultation** is organised.

The public consultation is open to anyone and those who normally comment the proposal are companies, trade unions, NGOs, individual citizens or public authorities. Comments are welcomed from all countries and the consultation lasts for six months.

When the commenting deadline is over, the Committees meet again and discuss **taking into account the comments** that they received from the public.

The Committee for Risk Assessment (RAC) then prepares its **final opinion** about the proposal.

The Committee for Socio-economic Analysis (SEAC) also discusses the proposal but writes first a **draft opinion.** The draft opinion is then opened up for **another public consultation**.
Once the public consultation of the SEAC draft opinion is finished, SEAC also prepares its **final opinion**. Once both opinions are ready, they are sent from ECHA to the **European Commission** in Brussels.

The European Commission starts **drafting new EU-law**. In practice, this means that the Commission prepares a draft amendment to Annex XVII of the REACH Regulation. This will be done within three months.

In a 'regulatory procedure with scrutiny' the **REACH Committee**, consisting of EU Member States representatives, looks at the restriction proposal and the opinions and provides its own opinion on the proposal. This procedure is overseen by the Commission in the REACH Committee meetings.

If the opinion on the draft amendment to Annex XVII is favourable for the restriction, the Commission sends the draft amendment to the **European Parliament and the Council** and if they do not oppose it, it is formally adopted by the European Commission and becomes **EU-law.** Annex XVII contains the list of restrictions and the new restriction is added to the list.

The restriction **comes into force** at the same time in all EU Member States and the substance cannot be used, manufactured or imported freely anymore in the European Union.

It takes approximately four years for a restriction to have an effect from the date when ECHA or a Member State started to work on it.

France started its work on the lead in jewellery restriction in 2009. The proposal gained support and, in 2012, the the ban of using lead and its compounds in jewellery articles was added to the Annex XVII list of restrictions with certain exemptions. The ban will be in effect from 9 October 2013.

Thanks to this restriction, children in the EU are less exposed to lead at young age.

Restricting chemicals - How is it done?

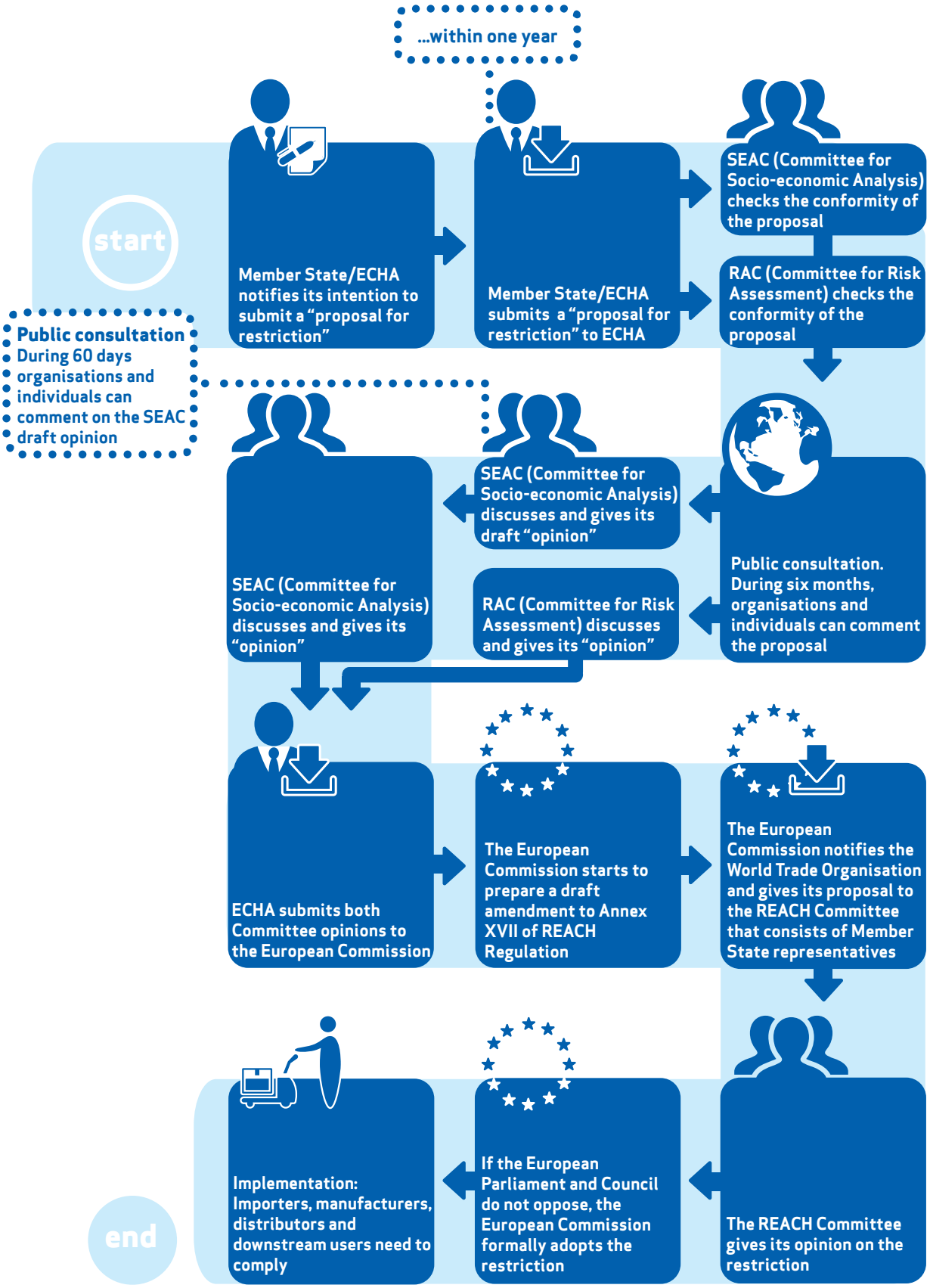

Illustration of the restriction process.

Promoting substitution under REACH, CLP and the Biocidal Products Regulation

INTERVIEW BY HANNA-KAISA TORKKELI

The main objective of the European chemicals legislation is to ensure protection of human health and the environment both for present and future generations while ensuring a smooth functioning of the internal market as well as competitiveness of the European chemical industry. Substitution of harmful chemicals with safer alternatives plays an important role in achieving this objective. What is ECHA's role in promoting substitution? ECHA Newsletter reports.

"When people talk about substitution of hazardous chemicals, they often refer to authorisation of substances of very high concern (SVHCs). Of course, that is important, and in line with the SVHC roadmap to 2020 we will work hard on getting all the relevant SVHCs on to the Candidate List, but it's not the complete picture. The whole system of REACH, CLP and the new Biocidal Products Regulation (BPR), is built towards substituting dangerous chemicals with safer ones," says *Jack de Bruijn*, ECHA's Director for Risk Management.

The objectives of REACH and CLP will be achieved **through better knowledge** on the properties and uses of chemicals, which results in e.g. safer use and reduced exposure; and **through using safer alternatives** to substances of very high concern.

"The key drivers for substitution under REACH and CLP are registration, information in the supply chain, authorisation and restrictions," Mr de Bruijn explains.

'GETTING TO KNOW YOUR CHEMICALS'

Registration is not just about submitting a dossier to ECHA and receiving a registration number to be able to do business on the EU market. It is more about the collection, generation and assessment of hazard and exposure data, risk assessment and the identification of risk management measures to ensure the safe use of chemicals.

"The registration obligation forces industry to systematically gather data according to the information requirements of REACH, analyse the data and decide on the right classification and labelling. During that process, companies might identify all kinds of issues which they may have missed before. Industry is getting more aware of what they are producing, using and placing on the market and, in some cases, may come to the conclusion that using a certain chemical is no longer desirable. For instance, a manufacturer may have discovered a less hazardous substance for a particular use and advises his clients against using the 'old'. Collecting data and taking stock of what you have - that's the most important part of registration," says Jack de Bruijn.

Downstream users, on the other hand, have an obligation under REACH to check the instructions for handling and use of chemicals in the exposure scenarios that are provided by the supplier's (extended) safety data sheets. "This obligation is new under REACH. Downstream users should check that they are using a chemical in line with what has been recommended to them. In some cases, they might realise that the recommendation does not make sense or that it is less stringent than what they are actually implementing. The idea of systematically going through risk management will make people ask themselves: Do I really want to use this dangerous substance and bear the consequences of the risk management measures or could I ask my supplier for a better alternative?" Mr de Bruijn says.

The increased and improved information on the classification and labelling of substances will also help companies to make better informed choices towards using safer substances.

"Another important aspect in promoting substitution is the need for article producers to communicate whether their articles contain SVHCs included in the Candidate List. This may trigger requests from retailers to phase out SVHCs in articles, and also enables consumers to make informed purchasing decisions."

SUBSTITUTION ALREADY HAPPENING

Authorisation of hazardous chemicals aims to ensure that risks from SVHCs are properly controlled, and that these substances are progressively replaced with safer alternatives. Companies have the opportunity to apply for an authorisation to continue (or to start) using a hazardous substance. This application has to include an analysis on the availability of alternative substances or techniques, and is subject to a public consultation, where more information on substitutes might become available.

"Clearly substitution is happening. For example, the application deadlines for musk xylene and MDA were in February 2013 and we did not receive any applications. Apparently, the companies using these substances have decided to replace them and they are no longer used in the EU," says Mr de Bruijn, and continues, "ECHA does not have the underlying information on industry's substitution strategies or the reasons behind them. Overall, we

see that the number of applications at the moment is lower than what the European Commission originally estimated when the impact of REACH was analysed."

ECHA's message to companies considering applying for authorisation is to consider its importance from a business perspective. "If you can substitute, you will spare the costs of the process. If you cannot, you will be able to present a good case to get the permission," Mr de Bruijn highlights.

The fee to ECHA for an application ranges from around 5 000 euros to up to a few hundred thousand euros – depending on the number of substances and uses applied for, the company size, and whether the application is submitted by only one company or jointly. The main cost will most probably not be the application itself but the preparatory work.

RESTRICTION MEANS OBLIGATION TO SUBSTITUTE

Restriction of chemicals aims to limit the manufacture and import, placing on the market and/or on specific uses of a substance, which poses an unacceptable risk to human health or the environment. If the restriction takes the form of a ban on all or some specific uses of a substance, substitution has to take place.

REACH has taken over the restriction process from the previous legislation but introduced quite short deadlines for ECHA and the Commission to manage incoming proposals. As a result, the time needed for measures to be adopted and implemented has been substantially reduced.

As in the past, the use of substances that are classified as carcinogenic, mutagenic or toxic to reproduction (CMR) as such or in mixtures by consumers are restricted. New under REACH is a specific simplified procedure, which can be used to limit the use of CMR substances in articles.

The Commission has proposed to use the new procedure for the first time for restricting the presence of polycyclic aromatic hydrocarbons (PAH) in articles.

BIOCIDES AND SUBSTITUTION

The new Biocidal Products Regulation also promotes substitution. In addition to the obligation to have the active substances approved and biocidal products authorised, the following criteria for substituting the most hazardous substances apply:

- The substance meets at least one of the exclusion criteria (CMR, endocrine disruptors; persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB)
- It is classified as a respiratory sensitiser
- Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use
- It meets two of the criteria to be considered as PBT
- It causes concerns for the environment even with very restrictive risk management measures
- It contains a significant proportion of non-active isomers or impurities.

If any of these criteria are met, the substance may be considered as a candidate for substitution. Candidates for substitution are identified during the approval of active substances and further reflected at the product authorisation stage, where the candidates for substitution trigger a comparative assessment of biocidal products.

ECHA TO IMPROVE INFORMATION ONLINE

While REACH, CLP and the BPR promote substitution by their very design, ECHA's role is to broadly promote substitution in all areas of the regulations and give strong incentives for industry to find and use safer alternatives.

To that end, ECHA is working on finding ways to more explicitly explain about the importance of substitution in the context of the REACH, CLP and the Biocidal Products Regulation.

"We will further develop our website to guide users to the relevant explanations on how the substitution mechanisms are foreseen to work. We will also continue our dialogue with the accredited stakeholders on how to further promote substitution," Jack de Bruijn concludes.

ONGOING INTERNATIONAL WORK ON SUBSTITUTION

The Organisation for Economic Co-operation and Development (OECD) established an adhoc group on the substitution of harmful chemicals in June 2012.

ECHA is co-chairing this group with the US Environmental Protection Agency. The group consists of representatives from governments, industry, academia, NGOs and trade unions.

Currently, the group is working on an inventory of the available tools and methods which can be used to characterise and compare hazards and exposures/risks.

The objective is to develop a toolbox that provides guidance on how to use priority tools and identify best practice. ECHA will contribute to this group to improve the knowledge on the costs of different substitution options. The first outcomes are planned to be ready in summer 2015.

Monitoring the effectiveness of enforcement

INTERVIEW BY VEERA SAARI

One of the main conclusions in the REACH review published in June 2013 by the Commission was the need to have a strong and harmonised approach towards enforcement in the Member States. The Forum of national enforcement authorities is developing a harmonised methodology for enforcement projects and focusing efforts to improve information exchange between ECHA and national authorities. The Commission, in liaison with the Forum, will also develop indicators to monitor the effectiveness of REACH and CLP enforcement.

The Forum of national enforcement authorities has kicked off work to establish harmonised methodology for carrying out enforcement projects in the Member States.

"After some years of experience of coordinating enforcement activities, the Forum felt that the time was ripe to establish a harmonised methodology for preparing for key projects," explains *Miguel Aguado*, a Commission representative in the Forum. "We went through the lifecycles of all the Forum-coordinated enforcement projects run so far, analysed the different phases and tried to identify which aspects could be unified."

The aim is to harmonise the organisational aspects of enforcement projects in advance to make them more effective to develop and implement. The methodology in practice means, for example, creating a manual for what an enforcement project should consist of and establishing criteria for choosing topics for harmonised enforcement projects.

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ECHA's Ulrike Kowalski (left), Miguel Aguado from the European Commission and Katja vom Hofe, the German member of the Forum

"Each enforcement project is preceded by a lot of work and planning in the Forum working group, which develops a manual for the inspectors to highlight what they are actually going to inspect and also creates a questionnaire and a reporting tool to be used by the inspectors to report back," says *Katja vom Hofe*, the German member of the Forum.

STAKEHOLDERS' VIEWS WELCOMED

Along with establishing detailed methodology, the Forum is looking into creating a more systematic approach to Forum-run enforcement activities. *Ulrike Kowalski*, the team leader of the Forum Secretariat at ECHA, foresees that in the future, harmonised enforcement projects will be run back-to-back as a continuous activity.

"Up to now we have organised REACH enforcement projects (REFs) one after the other, but we are planning to develop an on-going cycle where we develop the next project already while the previous is still operational, to improve effectiveness," Ms vom Hofe adds. The planning phase in the cycle will include taking on board the views of stakeholders on the project. "We are opening the doors to our stakeholders to give their views on what enforcement activities they think should be taken up at European level," Mr Aguado highlights.

The third harmonised REACH enforcement project, REF 3, is ongoing in the Member States and will run through the summer. It focuses on cooperation with customs.

INDICATORS TO HELP EVALUATE EFFECTIVENESS

The REACH review called for more consistent and comparable data on the implementation of the regulation. For this purpose, the Commission is launching a project to develop enforcement indicators and will be discussing with the Forum how best to collaborate in the develop-

ment. "We need to have an instrument in order to know whether the regulations are functioning well," Mr Aguado notes.

"The aim is to develop measuring tools that will benefit all parties: for the Commission to know how REACH and CLP are working, and for the Forum and the Member States to help evaluate their work and help report back on their activities in a more harmonised and systematic manner." The conclusions of this work will be publicly available once finalised.

The REACH review altogether recommends 55 actions related to enforcement, from which 21 are directly linked to the Forum. "We have extracted all the recommendations given in the review and right now are developing the tasks for the coming years in the Forum's multi-annual work plan. Some of the actions have already been taken up in Forum working groups," Ms Kowalski says.

TRAINING THE TRAINERS

The administrative structures of enforcement authorities can differ greatly from one Member State to another, and one of the main tasks of the Forum is also to facilitate exchange programmes between Member States to promote best practice. One such initiative is the annual Forum-organised "Train the trainers" event in which inspectors from each Member State are invited to ECHA to receive practical training and act as multipliers of the lessons learnt in their home countries.

As the national authorities are struggling with resources, the enforcement of other EU legislation also plays a key role in improving the efficiency of enforcement activities. "You have to remember that chemicals enforcement does not cover only REACH, CLP and PIC," notes Mr Aguado.

"The coordination of enforcement activities with those under other EU legislation, such as occupational health and safety and customs, should be further studied to bring the expertise together and to benefit from synergies," Ms vom Hofe points out.

The Forum already cooperates with inspectors in other networks, such as IMPEL, which coordinates the enforcement of the industrial emissions directive, and SLIC-CHEMEX regarding occupational safety and health legislation.

"Setting up good communication channels and cooperation between the different levels of national authorities and ECHA is crucial to ensure effective enforcement," Ms vom Hofe stresses.

MULTI-ANNUAL WORK PLAN

The Forum is currently discussing its multi-annual work plan. The three main focus areas in the coming years will be:

- Coordinating harmonised enforcement projects for REACH, CLP and PIC Regulations
- Improving the national enforcement authorities' access to data via REACH Information Portal for Exchange (RIPE) and the electronic information exchange system (EIES)
- Setting up interlinks and communication tools between the national competent authorities, enforcement authorities and ECHA to improve enforcement.

ENFORCEMENT FORUM

The Forum coordinates the network of Member States authorities responsible for enforcement of REACH, CLP and PIC. The Forum spreads good practice, identifies enforcement strategies, sets up harmonised enforcement projects and joined inspections, provides support to inspectors and liaises with stakeholders.

Further information:

Forum on the ECHA website
http://echa.europa.eu/about-us/who-we-are/enforcement-forum

Strategies for enforcement of REACH and CLP
http://echa.europa.eu/documents/10162/13577/strategies_enforcement_reach_2011_en.pdf

REACH review
http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/

Fair sharing of costs for active substance approval

TEXT BY PÄIVI JOKINIEMI

The Biocidal Products Regulation introduces new requirements to manufacturers and importers to ensure that costs related to the approval of active substances are shared in a fair way. This means that all parties placing a certain active substance on the EU market must contribute to the costs of its approval.

To guarantee that everyone takes part in the costs of the assessment of the active substance, the regulation places a special obligation on those manufacturers and importers who did not contribute to the establishment of the application dossier. These companies need to make a submission to get to the list of approved suppliers maintained by ECHA.

This can be done - either by submitting a letter of access, a full dossier including all the required information or a combination of the two. The dossier is to be sent to ECHA through the Register for Biocidal Products (R4BP 3.0).

ECHA encourages companies to submit their dossier or letter of access as soon as possible after the application date on 1 September 2013. The list of approved suppliers will be published on ECHA's website.

After 1 September 2015, biocidal products are allowed to remain on the market only if both the active substance and its manufacturer or importer are on the list.

Guidance will be published on ECHA's website during summer 2013.

All parties placing a certain active substance on the EU market must contribute to the costs of its approval.

DEFINITIONS

Letter of access

Letter of access is an original document, signed by the data owner, which states that the data can be used for the benefit of a third party.

Review programme

Review programme refers to the systematic examination of all existing active substances carried out by the Commission in accordance with Biocidal Products Directive.

BIOCIDES WEB PAGES REVAMPED

ECHA's website section for biocides is being updated to contain more information related to the Biocidal Products Regulation.

The most essential content for applicants preparing for the 1 September entry into operation will be available by the Biocides Stakeholders' Day on 25 June.

New biocides guidance coming

TEXT BY PÄIVI JOKINIEMI

ECHA is preparing a set of new biocides guidance documents to support applicants preparing for the Biocidal Products Regulation.

Guidance documents on information requirements, technical equivalence and active substance suppliers will be published by the application date on 1 September 2013.

The Guidance on Information requirements will describe what information the dossier for active substance approval or biocidal products authorisation must include according to the Biocidal Products Regulation.

The Guidance on Technical equivalence will inform the potential applicants on their obligations under Article 54. This article explains when the applicants need to apply for an assessment of technical equivalence and what the related procedural steps are.

The Guidance on Active substance suppliers will explain what obligations active substance suppliers have under Article 95. It will also provide direction on the procedural aspects and regulatory consequences of the submission.

CHANGES IN THE STRUCTURE WILL FOLLOW

The new guidance for Biocidal Products Regulation will have a different structure than guidance under the Biocidal Products Directive. This will however be implemented in full only at a later stage.

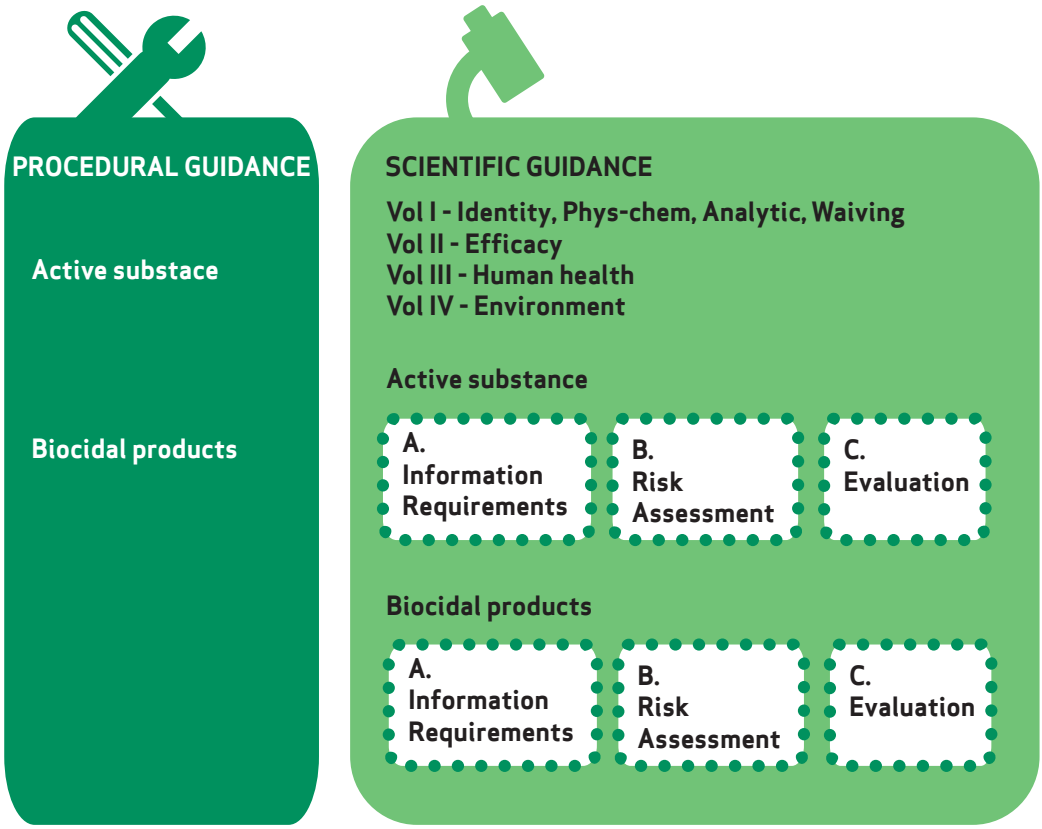
One of the aims behind the new structure is to create a user-friendly set of documents where each reader can easily find the parts that are relevant to their work, reducing the time spent on searching through intensive documentation.

DEFINITIONS

Technical equivalence

The new regulation requires that the active substances used in a biocidal product are technically equivalent to approved ones. This is assessed by ECHA if any of these applies:

- The manufacturer of the active substance is different from the one holding the original approval.
- The manufacturing process of the active substance is different.
- The manufacturing location of the approved manufacturer of the active substance has changed.



Plan for biocides guidance.

What do exposure scenarios look like in reality?

INTERVIEW BY LAURA WALIN

Exposure scenarios are an innovative communication instrument under REACH, designed to convey use-specific information on the safe use of chemicals. In autumn 2012, the Finnish Safety and Chemicals Agency (Tukes) conducted a survey on exposure scenarios. They reviewed nearly 90 extended safety data sheets provided by Finnish companies who registered substances. ECHA Newsletter interviewed the project coordinator *Jouni Räisänen* from Tukes.

Why did you conduct a survey on exposure scenarios?

We wanted to see how this novel instrument is put into practice. The aim of the survey was to evaluate the quality and usability of exposure scenarios from the perspective of both downstream users and enforcement authorities.

Did exposure scenarios fulfil the task for communicating safe conditions of use?

In 50% of the exposure scenarios, the recommended risk management measures were consistent with the classification of the substance. There was a connection between classification and risk management advice in a further 35%. In this latter group, the information can be further developed to make it more practically relevant.

However, the risk management measures described in the main body of the safety data sheet were not always consistent with those in the exposure scenarios.

Environment related parts of the chemical safety assessment are clearly a novelty, as environmental risk management measures were not provided in 27% of the exposure scenarios. If they were, they typically covered the water compartment only.

Were the exposure scenarios similar in terms of structure and terminology?

A little over 40% followed the ECHA format; the rest consisted of a variety of modifications. The length of exposure scenarios varied largely. On the positive side, ESCom standard phrases and use descriptors were widely used.

In summary, how easy was it to understand the exposure scenarios?

It required quite a detailed scrutiny even from a regulatory expert and this check often revealed inconsistencies or even missing information. There is a lot of room for improvement. Language was also an issue: exposure scenarios were in English only, or – which was even worse – a poor Finnish translation was provided.

What do you think would result in the greatest improvements?

For me, the most important thing would be to establish a harmonised format for exposure scenarios. More guidance and practical examples from ECHA would also help. Finally, the national enforcement authorities should be properly and uniformly trained on issues related to exposure scenarios.

Exposure scenarios provide use-specific information on operational conditions and risk management measures that guarantee the safe use of the substance.

Exposure scenarios are based on the registrants' chemical safety assessments and are forwarded in the supply chain as attachments to the safety data sheets.