How does ECHA check dossier quality?

ECHA performs two kinds of compliance checks: overall checks, going through the whole dossier, and targeted checks, focusing on specific endpoints. Learn more about what happens in both kinds of checks.

From an info card to detailed source data - ECHA’s plans for chemicals communication

ECHA has published on its website over 98% of the information on chemicals submitted to it. The next step is to improve the user-friendliness and accessibility of this information. The aim is to have a new interface that also serves the needs of the general public ready in 2015.

How to get EU-wide authorisation for a biocidal product

Do you want to market your biocidal product in all EU countries or in a number of them? We explain how to do it.

Generating safe use information for mixtures – status and next steps

Our guest writers from the European Chemical Industry Council and the Downstream Users of Chemicals Coordination Group are returning on the topic of generating safe use information for mixtures. The two associations have identified approaches and methods used or being developed by companies and industry sectors for safe use communication. Read more about their findings.
To achieve our third strategic objective on addressing new scientific challenges, we will update and continue implementing our work plan on nanomaterials in line with the Commission’s conclusions and proposals for making REACH work for nanomaterials. We are also kicking off an expert group to support the identification of endocrine disruptors.

The fourth objective, efficiency, means that we are going to streamline the regulatory processes under REACH and CLP to make them more effective. We have learnt from our experiences under this legislation and are already setting up smarter and leaner processes for the Biocidal Products and PIC Regulations.

We are also building for the future with this Newsletter. Based on the 2013 news readership survey results and the visits to individual articles in the Newsletter, we have slightly restructured the top navigation. As you hopefully already know, the top navigation compiles all the stories related to a certain topic in one web page. If you click, for example, on ‘Biocides’, you will find all the newsletter stories written about biocides, and the issue they were published in. Here are the top navigation topics and what you can find under each of them:

- ‘Editorial’ is all the editorial texts;
- ‘REACH’ includes the articles written to help you understand the REACH regulation and your obligations;
- ‘CLP’ collects all articles written about classification, labelling and packaging;
- Under ‘Biocides’ you will find all the stories written about the Biocidal Products Regulation;
- NEW ‘PIC’ collects all articles written about the Prior Informed Consent Regulation;
- NEW Articles under ‘Communicating about safety’ talk about supply chain communication and the challenges.
- ‘News from ECHA’ is a general topic, which includes topical articles about ECHA’s work;
- NEW ‘People and perspectives’ compiles stories about ECHA’s stakeholders or their activities; interviews and guest columns.

For the February issue, we have put together a full package for you to read. With that, I wish you all a great start to 2014.

“In 2014, we want to take stock of all that experience and learn lessons for the future.”

April issue will focus on substitution and innovation.
Register now for ECHA’s Stakeholders’ Day

TEXT BY ADAM ELWAN

ECHA will host its ninth annual Stakeholders’ Day conference on 21 May 2014 in Helsinki.

The conference offers participants the chance to hear and discuss the latest news and updates from ECHA, European industry associations and non-governmental organisations. The annual event covers the REACH and CLP regulations and offers participants the possibility to attend one-to-one sessions with ECHA staff about specific topics.

Participation in the conference is free of charge.

TARGET AUDIENCE

The Stakeholders’ Day is open to all, but it is particularly relevant for those involved in REACH and CLP: industry associations, companies, public bodies, NGOs, third country representatives and the media.

REGISTRATION

Online registration for the conference is now open and will close on Thursday 1 May.

Further information
http://echa.europa.eu/view-article/-/journal_content/title/ninth-stakeholder-s-day

The conference will also be web-streamed live and a recording of the event will be published on ECHA’s website within the week after the event.

Register
https://www.webropolsurveys.com/S/D79DE7D71062B09A.par

Helsinki Chemicals Forum discusses global chemical policy issues

The fifth global chemical industry congress, the Helsinki Chemicals Forum, engages international authorities, politicians, industry leaders, NGOs, academics and the media in an open dialogue on key issues of global relevance regarding chemicals policy and the control of chemicals safety.

The Forum follows ECHA’s Stakeholders’ Day on 22 and 23 May 2014.

See the programme and register at:
http://www.helsinkicf.eu/
How does ECHA check dossier quality?

ECHA checked 5% of the dossiers received for the 2010 registration deadline. That amounts to 1 130 compliance checks on registration dossiers.

Over one third of registered substances were covered by these dossier checks. In 69% of the evaluated cases, the dossiers did not comply with REACH requirements. In these cases, ECHA issued a draft decision, requesting more information from the registrants.

The Agency used a combination of two methods to select the dossiers - concern-based and random selection. For the selected dossiers, ECHA conducted either an overall compliance check (30% of the cases) or a targeted one (70% of the cases). Over one third of registered substances were covered by these dossier checks. In 69% of the evaluated cases, the dossiers did not comply with REACH requirements. In these cases, ECHA issued a draft decision, requesting more information from the registrants.

The annual Evaluation Report 2013 gives detailed information on dossier quality. Its specific recommendations target both the future registrants for the 2018 deadline and the existing registrants who need to update their dossiers.

The report will be published at the end of February 2014. The reports from previous years also include recommendations to registrants on how to improve their dossiers and those recommendations remain valid.

COMPLIANCE CHECKS - HOW DOES ECHA DO THEM?

Dozens of scientific, legal and administrative staff work at ECHA evaluating dossiers. They work on compliance checks, go through proposals for testing and coordinate substance evaluation activities. Marco Valentini and Katrin Halling are scientific officers at ECHA. Work on compliance checking was a priority for them in 2013.

A compliance check requires ECHA to examine registration dossiers to verify if the submitted information complies with the legal requirements set out by the REACH Regulation.

Ms Halling and Mr Valentini explain the steps taken in the checks:

How do you choose dossiers for compliance check?

Marco Valentini: Our database now contains over 42 000 dossiers with information on more than 10 000 substances. For compliance checks, we select dossiers that cover elements necessary for the safe use of the chemical. Some dossiers are picked randomly and others because there are particular concerns. Examples of such concerns are dossiers using a large number of adaptations, using many read-across approaches for higher-tier endpoints or transported isolated intermediate registrations.

How do you do an overall check?

Katrin Halling: An overall check means that we assess all the relevant information contained in one single registration dossier. This can involve looking at thousands of data fields.

Mr Valentini: The hazard information of a substance is shared by all registrants in the joint submission and is pivotal for risk assessment. For each joint submission, ECHA selects the dossiers for checking from both the lead and member registrants.

A specialised team then starts working on the substance identity information. This ensures that the substance described in the dossier is in fact the substance being registered. In parallel, we go through all the information provided in the dossier that is relevant for the safe use of the chemical. In practice, experts with different backgrounds assess the hazard data on physico-chemical properties, human health
and the environment in the technical dossier against the REACH information requirements.

After each expert has assessed the dossier in their area of expertise, the team decides whether a draft decision is needed.

Ms Halling: Let’s not forget that the evaluation also includes the screening of the chemical safety report where it is required. Such a report can have several hundreds of pages.

One check can result in more than one draft decision. This happens because, in many cases, it is more efficient to request some information before continuing with the rest of the dossier. This is particularly the case for those dossiers where the substance identity is not clear.

Why do you also do targeted checks?

Ms Halling: Given that some endpoints are considered highly relevant for the safe use of chemicals, ECHA developed a strategy to focus on these. We screen the whole database for specific parts of the dossiers, based on particular concerns.

These can be for example: substance identity issues; endpoints that are considered highly relevant to risk management and chemical safety; chemicals that may in the near future be subject to substance evaluation; and dossiers submitted outside the joint submission with many adaptations for higher-tier toxicological endpoints - even though reliable data exists in the joint submission.

How do you do a targeted check?

Mr Valentini: A targeted compliance check on a certain endpoint, for example bioaccumulation in fish, means that we first search our database for those dossiers for which this endpoint is a standard information requirement. Secondly, we perform an IT-based selection of those dossiers that do not seem to fulfil the legal requirements for the endpoint.

Thirdly, our experts verify whether the information for the endpoint complies with what the law requires.

If ECHA concludes that the information in the dossier does not comply with the REACH requirements, the registrant receives a decision requesting further information. Regarding the 2010 registrations, this has been the case for the majority of the dossiers.

ECHA is continuing to check the compliance of the registrations received for the 2013 deadline: REACH requires ECHA to check 5% of the dossiers in each tonnage band.

Further information:

Target met for 5% compliance checks of the 2010 registration dossiers, Press release 15 January 2014

5% Compliance checks of the 2010 registration dossiers - results
http://echa.europa.eu/regulations/reach/evaluation/compliance-checks/5-percent-compliance-checks-2010-registration-dossiers

The Evaluation Report 2013 will be published on 26 February 2014.

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ECHA targets the compliance checks to the endpoints which matter the most for the safety of chemicals.
From an info card to detailed source data - ECHA’s plans for chemicals communication

TEXT BY HANNA-KAISA TORKKELI

On its website, ECHA has published over 98% of the information on chemicals submitted to it through REACH registrations, CLP notifications or biocides applications. The next step is to improve the user-friendliness and accessibility of this information. The aim is to have a new interface that also serves the needs of the general public ready in 2015.

Since 2009, when the registered substances database was initially launched, the Agency has been focused on getting information on chemicals published as required by the legislation. This was followed by investing in improving the database, for example with an advanced search, by including an opportunity to search by non-confidential uses (such as the product category or sector of use). Now, the work is shifting towards making the information simpler and more accessible for non-scientific users.

To kick off the development work, the Agency consulted its stakeholders to better understand their needs and interests as well as to investigate ways to improve the readability and user-friendliness of the information. The consultation included an online survey of all website users and in-depth interviews with accredited stakeholder organisations from industry associations, Member States, NGOs and academia.

One of the main findings of the consultation was that all the information on individual substances should be brought together in one place and that it should be displayed in a very simple and brief summary format.

TIERED APPROACH ON SUBSTANCES

As there is a lot of information and it is often very technical, the Agency has come up with a three-layer tiered approach to improving the presentation – starting from very simple information and ending up with a full set of data. The aim is to show summarised tiers of information, with each tailored for different audiences with different levels of expertise.

The first level is an info card, which will provide basic information on the chemical which anyone can understand and use. The info card will include:
- Information on the hazards of the substance;
- The most relevant concerns;
- The most common uses; and
- The regulatory processes dealing with the substance, for example, whether it needs authorisation for a particular use or if it is restricted.

The second level is a brief profile of the chemical. The brief profile will include:
- Information already in the info card with further details; and
- Information on the environmental, human health and physico-chemical properties of the substance.

The third level is the source data, meaning for example information from:
- Registration dossiers;
- C&L notifications;
- Substance evaluation (Community rolling action plan);
- Authorisation List;
- Restriction List;
- Approved active substances under the BPR; and
- Annex I of PIC (list of chemicals subject to an export notification).

The aim of this tiered approach is to further improve the transparency and traceability of the data.

DID YOU KNOW?

REACH
As of 24 January, information on 12 276 substances from 47 097 registration dossiers is available on ECHA’s website.

A registration dossier may contain up to 18 000 data fields, which means that almost 850 million data fields have been processed by ECHA’s IT tools in order for that information to be online.

CLP
The public C&L Inventory currently includes over 6.2 million notifications covering approximately 116 000 substances.

Biocides regulation
The biocidal active substances list contains 53 approved active substances and there are 2 452 authorised products on the biocidal products list.
The Agency will not be reducing the amount of information or adding new data, but changing the way the data is displayed and accessed.

**WORKSHOP ON BRIEF PROFILES WITH STAKEHOLDERS**

The info card and brief profile are the key tiers for general users. To reach the ambition of improving the usability of information on chemicals, the Agency held a workshop with its stakeholders on 3 December 2013.

It shared the preliminary drafts of the brief profiles with 15 stakeholder representatives to get their feedback. “We wanted to engage our stakeholders in this development early on to be able to take their views and requirements into account. After all, the technical and IT work enabling this revamp will take a lot of work, and we want to make sure that we get it right,” says Mike Rasenberg ECHA Head of Unit for Computational Assessment and Dissemination.

ECHA will continue to collaborate with its stakeholders in 2014.

“We will share and discuss with them the specificities of the brief profiles and how they will be built. The stakeholders will have a chance to comment, for example, on how ECHA is aggregating the data to be displayed,” Mr Rasenberg points out.

The workshop presentations and proceedings will be published on ECHA’s website shortly.

**Further information:**

Information on chemicals
http://echa.europa.eu/information-on-chemicals

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**Infograph. Tiered approach to chemicals communication.**
ECHA Science

Understanding the importance of assessment factors in finding safe human exposure levels

TEXT BY KAREL DE RAAT

Assessment factors play an important role in assessing the health hazards of a chemical substance. They are essential in bridging the gap between toxicological information, usually generated through studies with experimental animals, and the human situation.

This gap is largely determined by the fact that tests are not done on humans and that the real-life exposure of humans often differs from the exposure of the experimental animals. The results of a study with experimental animals can therefore not be directly used to predict what will happen in humans. This holds true in particular for predicting exposure levels and exposure conditions that may or may not lead to any adverse effects observed in an experiment.

Still, we have to get insight into safe human exposure conditions and exposure levels, which is, after all, one of the reasons for performing toxicological experiments. We can use other information on the properties of the substance, for instance information on what the body does with it (uptake from the gut, metabolism in the liver, distribution over the various organs and tissues, excretion by the kidneys, etc.).

General toxicological principles may also help us to bridge the gap, but often we are still not confident when these additional considerations are used. As a result, non-science-based margins are built in to prevent underestimation of the human health hazard.

Additional information on the substance, the general toxicological principles and any residual uncertainty are reflected in the assessment factors. For instance, the average sensitivity of mammals to the toxic effects of substances is related to their size. Large mammals are more sensitive than small ones, at least when the dose of the substance per kilogram of body weight is the same (total dose divided by body weight). Rats, for example, are on average four times less sensitive than humans on a mg/kg basis, and this factor of four is therefore used as an assessment factor when the toxicological experiment is performed with rats. However, differences in sensitivity may be larger (or smaller) than the average difference for reasons specifically related to the nature of the substance. To prevent an underestimation of the toxicological hazard an extra assessment factor is used.

SAFE EXPOSURE LEVELS

A measure of human exposure is needed to mark the border between safe or acceptable exposure levels and hazardous or unacceptable exposure levels. In REACH this measure is called the derived no-effect level (DNEL) or the derived minimum effect level (DMEL).

Generally, we only have the results of toxicological studies with experimental animals as a starting point for the derivation of this measure because adequate human data is rarely available. Under the chemical safety assessment defined by REACH (Annex I), the DNEL or DMEL is then compared with the estimated exposure levels and, if the exposure exceeds DNELs or DMELs, further risk management measures are needed to bring the exposure levels down. Therefore DNELs or DMELs play a crucial role in ensuring safe use of the substance and in fulfilling the REACH obligations.

The derivation of a DNEL begins with the selection of an experimental dose level that serves as a starting point. In most cases, this is the no-observed adverse effect level (NOAEL) of a relevant endpoint, meaning the highest dose applied in an experiment that does not lead to an adverse effect. This dose is subsequently ‘corrected’ for the differences between the study with experimental animals and the human situation. This correction consists of: 1) scaling; where the NOAEL is converted to a measure of exposure comparable with the outcome of the human exposure assessment and 2) dealing with uncertainty; by applying the assessment factors to the scaled exposure level.
ONLY USE THE DEFAULT ASSESSMENT FACTORS PROVIDED BY REACH

ECHA provides extensive guidance on the application of assessment factors to address the differences between an experiment and a human situation, and the uncertainties associated with these differences. A set of default assessment factors is defined in ECHA’s guidance.

Default assessment factors should be applied when there is no information on the substance that would allow the definition of substance-specific or case-specific assessment factors. The defaults can only reflect generic information and remaining uncertainty. When information on the substance is available, it should be used to adapt the default assessment factors. The adaptation is necessary because the substance-specific factors have to provide at least the same level of protection as the default ones and therefore, have to be based on the default factors.

The set of default assessment factors plays an essential role in human hazard assessment under REACH, because:
- They are applied when there is no substance-specific information on the differences between experiment and human situation that have to be addressed for the substance in question, which is often the case;
- They are to be adapted to substance-specific assessment factors based on the substance-specific information.

As with most sets of assessment factors currently applied in regulatory frameworks, the REACH default set is based on the choice of the factor of ‘100’ in the 1950s. This factor was originally chosen to compensate for the uncertainty associated with setting up an accepted concentration of substances (contaminants, additives) in human food, based on a chronic oral toxicity study. This choice was not based in the first instance on scientific information. The factor of 100 has subsequently been differentiated into the default sets currently in use, whereby some generic information has been used.

In many REACH registration dossiers, companies have used different default assessment factors and not those presented in the REACH guidance. Sometimes these assessment factors are based on an explanation provided by the registrant; in most cases, the registrant only refers to a publication and/or an opinion.

Using these alternative default sets seriously undermines the validity of the DNEL derivation for the purpose of REACH. There can only be one default set of assessment factors. This set applies to all DNEL derivations where there is no additional, substance-specific insight into the uncertainties that have to be bridged. Any deviation from the default can only be based on substance-specific information. ECHA cannot accept alternative defaults because to do so would imply that one registration can give rise to different DNELs, depending on the default the registrant has chosen, which is of course an undesirable situation.

The default assessment factors are therefore crucial for DNEL derivation. They have a strong influence on the accepted human levels of exposure to a chemical substance. The establishment of the REACH set of default factors was based on a careful process in which many stakeholders were involved. For the reasons explained above, no other acceptable defaults can be used under REACH. This is not to say that the REACH set cannot change. Development of science or policy may lead to an adaptation in the future. However, at the moment, deviations are only possible when based on scientifically sound information on the substance that increases insight into the uncertainty associated with the DNEL derivation for that specific substance.

Further information:

Guidance on Information Requirements and Chemical Safety Assessment, Part B – Hazard Assessment

REACH Regulation, Annex I

Default assessment factors should be applied when there is no information on the substance that would allow the definition of substance-specific or case-specific assessment factors. ECHA provides extensive guidance on the application of assessment factors to address the differences between an experiment and a human situation.
One of the aims of the REACH Regulation is to encourage innovation. To help achieve this aim and to encourage innovating companies, chemicals intended for ‘product and process orientated research and development (PPORD)’ can be exempted from the obligation to register for five years.

Chemicals used in scientific development related to product and process innovation or further development of a substance may fall under the PPORDs definition. However, a substance used in a PPORD activity must not reach the general public at any time - they must be used for research alone.

PPORD substances are also subject to legislation that covers worker and environmental protection, and so ECHA may demand more information and impose conditions on use to make sure that these objectives are met.

Companies that want to benefit from the exemption must submit a PPORD notification to ECHA. This notification is very easy to prepare, with only little information required.

By submitting a notification, companies can get a five-year exemption from registration, which can be extended, on request, for another five years and in special cases for an additional 10 years.

However, while doing the research and development work, the notifier may develop sufficient knowledge of the substance and the market leading him to decide to follow up with a REACH registration.

The initial notification should include at least the following information:

- the name of the manufacturer or importer;
- the identity of the substance;
- the classification of the substance;
- the estimated quantities to be used (during the five-year period);
- the list of customers (including names and addresses).

However, the information needs are greater if the notifier wants a prolongation of the exemption period for their PPORD notification. They will need to submit a research and development programme with sufficient information to justify their request.

HOW TO PREPARE AND SUBMIT A PPORD NOTIFICATION

Before getting started, have a look at the following manuals:

- Data Submission Manual 1: How to prepare and submit a PPORD notification
- Data Submission Manual 4: How to Pass Business Rule Verification ("Enforce Rules")
- Data Submission Manual 5: How to complete a Technical Dossier for Registrations and PPORD Notifications


Create your PPORD notification dossier in the latest version of IUCLID 5

Use the IUCLID 5 validation assistant plug-in (former technical completeness check plug-in) to detect any missing information and to pre-check that your dossier meets the basic 'business rules'.

Apply the IUCLID 5 fee calculation plug-in to estimate the fee to be paid for your PPORD notification dossier. The fee depends on the size of your company. Small and medium-sized enterprises (SMEs) benefit from lower fees.

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</table>

Sign-up and submit your PPORD notification dossier through REACH-IT

If you do not already have a REACH-IT account, you need to create one at http://echa.europa.eu/support/dossier-submission-tools/reach-it/sign-up


Follow-up your PPORD notification in REACH-IT

To complete your notification, you need to pay the invoice you receive through REACH-IT.

ECHA will provide the PPORD notification number after verifying the completeness of the information and the payment of the relevant PPORD fee.

Updates

If you need to submit new information or are planning to request an extension to your PPORD, you need to update the current notification in IUCLID 5 and then submit it to ECHA through REACH-IT.

If an update is submitted to request an extension, it should be done at least four months before the end of your exemption and the fee should be paid within 30 days to guarantee that the Agency has time to process it before the expiry date.

RESTRICTIONS AND AUTHORISATIONS MAY ALSO APPLY TO PPORD CHEMICALS

Substances intended to be used for PPORD that are included in the Authorisation List (Annex XIV of REACH) and in the list of restrictions (Annex XVII of REACH) are subject to authorisation and restriction requirements unless the use for PPORD is specifically exempted.

Information on PPORD exemptions from authorisation is provided in the ‘exempted uses’ column of the Authorisation List, while exemptions from restrictions as well as the maximum quantity exempted, are specified in the restriction entries of Annex XVII.

Additional information is available in the authorisation and restriction web pages on ECHA’s website.


List of restrictions web page http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions

Further information:


DID YOU KNOW?

REACH allows an exemption from registration for substances manufactured or imported at or above one tonne per year, for the purposes of product and process oriented research and development (PPORD).

Substances used for the purpose of PPORD will be exempted from REACH registration for five years. However, companies need to submit a PPORD notification to ECHA. Notifications can be extended for another five years (or in special cases as for medicinal products, for another 10 years), if proper justification is provided.

Article 3(22) of REACH outlines that ‘product and process orientated research and development means any scientific development related to product development or the further development of a substance, on its own, in preparations, or in articles in the course of which pilot plant or production trials are used to develop the productions process and/or to test the fields of application.’

Workshop held on PPORDs

From 23 to 24 January 2014, ECHA hosted a workshop with Member State competent authorities to discuss the application of REACH requirements for PPORD notifications.

Since 1 June 2008, more than 1200 PPORD notifications have been submitted and the Agency has now assessed a vast majority of them. ECHA has also prepared the implementation of two processes related to PPORDs.

The current processes are the result of ECHA assessing PPORD dossiers and of a pilot project set up with four volunteer Member States, which aimed at implementing a decision-making process for PPORD notifications.

In relation to both processes, REACH requires that the Agency will consult on any draft decisions imposing conditions or extending the exemption period. Comments made by the competent authorities of the concerned Member States will be taken into account by the Agency when making its final decisions. ECHA and the MSCAs will be cooperating to ensure that the key objectives of REACH - the protection of human health and environment - are upheld.

During the workshop, Member State competent authorities were informed of the PPORD processes and the principles applied. In particular, Member State competent authorities provided their feedback about:

- The assessment methodology and criteria used to identify PPORD notifications for further consideration;
- The request for further information on a PPORD notification;
- The conditions to be imposed on a PPORD notification; and
- The principles to justify an extension to be granted.
Challenges faced by SMEs

During 2013, the focus of chemicals safety actors shifted to the concerns and needs of small and medium-sized enterprises (SMEs). This shift of attention was partly triggered by the upcoming third REACH registration deadline in 2018. But, it also reflects the common realisation that the success of REACH and other pieces of EU chemicals safety legislation in the coming years depends on the compliance of smaller actors and duty holders.

Looking back, it is evident that implementing REACH has been a learning process for all involved. Close cooperation with industry associations in designing and executing the work has ensured the success of REACH so far with the registration of large volume and hazardous chemicals. Such cooperation now needs to be adapted to the needs of downstream users and registrants for the 2018 REACH registration deadline.

The adoption of REACH in 2006 brought about a paradigm shift by placing the burden of proof for the safe management of chemicals on industry. This regulatory burden has translated into increased costs. On the whole, smaller companies are disproportionately affected by these costs, simply by virtue of economies of scale.

In February 2013, the SME Annex to the European Commission’s REACH Review pointed to the economic burden of SIEF administration and to the need to provide more specific guidance on transparency, non-discrimination and fair cost-sharing in the framework of SIEF formation and operation. Various other studies empirically established the scope of this burden through surveying SMEs. The German Federal Institute for Occupational Safety and Health (BAuA) investigated the experiences of German companies with REACH, and a study of the Netherlands’ Ministry of Infrastructure and the Environment put numbers to the costs borne by SMEs: costs related to data-sharing and SIEF management figured most prominently.

The European Parliament published a study on the consequences of REACH for SMEs, and a report from the Business Task Force of the UK Prime Minister drew attention to the costs of data-sharing that SMEs need to bear. Similar findings also arose from numerous other sources and publications in 2013.

Whilst these insights are not entirely new, they have drawn more attention to the costs of compliance and also revealed an interesting phenomenon. At the time of REACH’s adoption, the legislator deliberately left SIEF management to be self-regulated by industry. However, the studies commissioned last year have exposed a need for public administration to get involved and address the patterns of unfair practice in SIEFs and by guiding fair cost-sharing for data and SIEF operations.

It was therefore timely for the European Commission to host a REACH SME workshop in Brussels from 10 to 11 December 2013. The workshop was dedicated to allowing SMEs to share their experience with the Commission and ECHA, to ventilate their ideas on best practice and on the support that would benefit them in complying with their duties and in exercising their rights and obligations within SIEFs. The workshop was mainly attended by managers of small and medium-sized companies, with a limited presence of large company representatives and consultants.

Four dedicated workshop sessions established facts related to the state of small enterprises’ knowledge of REACH, their experience with joint registration and cost-sharing in SIEFs, the conduct of SIEFs and an in-depth discussion of specific themes that emerged during the course of the event. A presentation touched upon the competition law aspects of data-sharing.

The detailed two-day discussions brought to the fore aspects such as: providing support in preparing for the 2018 REACH registration deadline; means to ensure transparency in managing SIEFs; training SIEF managers; the quality of consultants; modalities of payment and cost-sharing for letters of access and data; “orphaned SIEFs”; treating one to ten tonne dossier submissions more favourably; market access and confidential business information; the arbitration of cost-sharing disputes; the duties of lead registrants; language issues; curtailing the danger of substances disappearing from the market; substance identity; and much more.

The output of the workshop was so substantial that ECHA and the Commission are drawing conclusions for its follow-up only after further analysis. Moreover, turning the valid ideas, proposals and discussion points into action will not fall to any single actor. Some conclusions are not only valid for SMEs, some are cost-related and others are related to promoting a better knowledge of REACH through specific communication and guidance or commonly endorsed recommendations. Even if public bodies can follow up on many aspects of the workshop, much will remain in the hands of industry associations and ultimately of companies themselves. Whatever support to duty holders is further provid-
ed, it will always be up to the duty holder to ultimately bear the responsibility for the quality of dossiers, the safe manufacture and use of the chemicals within their portfolio, and lastly the costs for complying with the regulatory requirements.

The Agency has already identified the preparations for the 2018 REACH registration deadline as a main area of activity in its Work Programme 2014. We are establishing a specific plan to this effect. This plan aims to spell out the means of support that we intend to provide to duty holders in the run-up to the deadline, paying special attention to the needs of small and medium-sized enterprises.

Additionally, ECHA will involve its partners in the Directors’ Contact Group (DCG) as well as our accredited stakeholders to maximise this support as well as promote the tools, guidance and information that will help companies.

Andreas Herdina
Director of Cooperation
ECHA’s SME Ambassador

Directors’ Contact Group - supporting registrants

Since January 2010, the European Commission, ECHA and key industry associations have been collaborating in a Directors’ Contact Group (DCG) that provides a platform for an exchange of views on providing support to registrants. Initially, the group was established for the 2010 and 2013 REACH registration deadlines.

Ahead the previous deadlines, the DCG, for example, offered support to registrants in difficult situations. The DCG parties identified exceptional scenarios where registrants were not be able to submit a fully compliant REACH registration, and ECHA then gave these registrants instructions on how to register by the deadline.

On 15 January 2014, the Directors’ Contact Group met to adopt its third Terms of Work for the period from 1 January 2014 to 31 December 2018. For this period, the Executive Director of ECHA, Geert Dancet, has taken over the chairmanship from the Director of the Commission’s Directorate-General for Environment, Guus Borchardt.

Under its new Terms of Work, the DCG members will not only coordinate the support given to duty holders for the submission of dossiers by the 2018 deadline, but also steer a collaborative effort in making information from the CLP notifications and REACH authorisation processes available to them for their registration needs.

As its first action, the DCG will prepare a follow-up to the REACH SME workshop of December with the aim of strengthening support for companies in managing SIEFs and sharing the costs of data fairly and transparently.

The DCG has published a communiqué about its continued activities, which is available along with the new Terms of Work on ECHA’s website.

Further information:

DCG Terms of Work from 1 January 2014 to 31 December 2018

SUPPORT FOR SMES NOW AVAILABLE IN 23 EU LANGUAGES

ECHA has updated the support web pages for small and medium-sized enterprises to make them more user-friendly and published in 23 languages. The pages include, for example, step-by-step instructions for determining the correct company size and more detailed information on potential consequences of false company size declarations.


Further information:

REACH SME workshop

ECHA Work Programme 2014

REACH Review

State of knowledge of entrepreneurs in the area of occupational safety and health in small and medium-sized enterprises (SME) (in German)

Rapport Impact REACH op MKB

Cut EU red tape: Report from the Business Taskforce

As its first action, the DCG will prepare a follow-up to the REACH SME workshop of December with the aim of strengthening support for companies in managing SIEFs and sharing the costs of data fairly and transparently.
Expansion in Europe is the key objective for every full-blooded entrepreneur. However, the biggest obstacle to growth, in fact, the greatest threat to the existence of our medium-sized company, are the extremely onerous and restrictive EU regulations, such as REACH, the Biocidal Products Directive/Regulation, the amendment of the Detergent Regulation, the CLP Regulation and the Cosmetics Regulation. For professional cleaners on the other hand, these regulations are a change for the better as well as an improvement for sustainability and environmental protection.

When REACH and the biocides regulations were initiated many years ago, they were introduced with the admirable intention of making the use of chemicals and biocides even safer in the EU. I believe that the original aim of the EU parliamentarians to improve the protection of the environment and people has actually become barely noticeable. Instead, costly registration and approval procedures for chemicals and biocides that have been around for decades or even centuries have been introduced.

Since the registration and approval procedures according to REACH and the biocides regulation are time consuming and expensive for businesses, many manufacturers have removed new, advanced raw materials used for the production of better disinfectants, better cleaning and maintenance products from their production range. Examples of these are the biocides Biguanide and Glucoprotamines; some peroxciacides and other peroxide chemicals. In my view, this means that we are moving back to the technical standards we had 25 years ago. That said, modern and probably much more environmentally friendly and safer chemicals will no longer be available due to the high costs, especially for basic commodities manufactured in smaller volumes.

The results of high costs are the following:

1. The small, medium and national companies are often no longer able to continue production – only large international corporations can cover costs by their high sales volumes. For example, the new biocides regulation lays down the same regulatory demands for very small and very big quantities. The costs to get an approval for the small quantities are in no relation to the possible turnover. The downside for consumers is that many medium-sized providers, often the motivators of the developments and innovations, will retire from the competition. The result will be fewer manufacturers with higher prices.

2. Innovating chemicals and biocides has already dropped and will continue to decline in the future to the detriment of human health and the environment.

A huge downside of this development is that it becomes extremely difficult, if not impossible, for the medium-sized companies even with the best product ideas and innovations to bring them to the markets.

As a concrete example of the costs, an application for a biocidal product authorisation, toxicological and environmental tests and assessments or letters of access, will be at least € 500 000 for each product. Medium sized companies like ours, who need different biocidal products, have to spend at least € 5 million in only two or three years. This is much more than our annual turnover.

Furthermore, a biocidal product which is licensed in one EU country has to be approved without any further problems and costs in all other EU countries. At present, some countries do not accept the authorisation of other countries without extra demands and, on top, each country takes their own fees unless you are doing a Union authorisation, which is costly.

Speaking on behalf of the medium-sized chemical companies, and especially on behalf of the A.I.S.E. SME Group, we were of course convinced in the beginning and continue to support the chemicals policy with the goal to only use chemicals that are safe for the environment and people in the future.

However, for medium-sized companies to stay in business and to remain competitive, the costs for these companies to comply with the legal obligations must quickly be reassessed at European level. If this is not the case, not only will severe competition distortions to the detriment of consumers occur but innovations by the medium-sized companies will “fall by the wayside” in the future.

Dr Wolfgang Schnell
Managing partner, DR.SCHNELL Chemie GmbH, Munich

The DR.SCHNELL Chemie GmbH from Munich, Germany, is a medium-sized German company with nearly 300 employees and owner-managed. The company develops, produces and sells mainly high-quality cleaning, hygiene and disinfection products for professional use. In addition, it produces a few chemical specialty products, for example, for the automotive industry.
What should small or medium-sized companies be focusing on between now and the last REACH registration deadline? This and other similar questions are gaining momentum in our daily business life and are becoming more important for those SMEs who still have to get to grips with the REACH Regulation.

When thinking about these questions, the story of John, who works for a local chemical manufacturing SME, serves as a good example. In the beginning of 2013, in the midst of preparing for the second REACH registration deadline, I received a call from him. Although he had heard about REACH, he was not sure of the steps he needed to take for his company to become compliant with the regulation and to register by June 2013.

Back then, John assumed that buying the Letter of Access would automatically mean a completed registration dossier which he could then send to ECHA. To his surprise, he found out this was not the case. After our explanations, he realised there was still a significant amount of work ahead to finalise his dossier before submitting it to ECHA. He did manage to submit and receive his registration number. Some of the lessons he learnt are worth sharing, underlining the keyword strategy.

While SMEs understandably continue to pay most of their attention to their daily business, John’s experience clearly shows why they should also begin to identify their strategies for achieving compliance with REACH.

Companies dealing with one or two chemicals should not have any major concerns except for the financial costs they need to budget for. They can easily adopt the approach of ‘let’s get it over with and just register’. After all, registering their core substances will secure business continuity and reassure their customers that they are REACH compliant.

Companies with more than just a handful of chemicals should focus on adopting and implementing their strategies for financial and human resources. Priority should be given to the substances to be registered by determining a clear date for each of them. This will also ease the budgeting effort for the coming years. As for resources, the company should always be in control of the tasks even if they do not carry all of them out by themselves. A project manager aware of REACH obligations would be a good solution. Training is available. With two registration deadlines behind us, well prepared project managers can manage the tasks comfortably and remain in control.

Finally, those companies with a large number of chemicals can no longer push REACH away and need to take stock of the situation now. All of the recommendations given above also apply to these companies, just on a larger scale. Additionally, they should consider whether to prepare a dossier for each and every chemical or try to bring a family of chemicals together in a consortium in order to share data more effectively. These consortia of data have proven their worth in the past and the same holds true for 2018. This, however, needs careful consideration, an in-depth analysis of the benefits and some experienced players to lead the way in order to benefit from the true value of a consortium.

Companies must not let the fear of getting started in the REACH process hold them back. Instead of waiting for the deadlines to approach, business units and regulatory affairs units should take strategic decisions on prioritisation of substances. This will help them realise the benefits that REACH registration gives them.

There is much work to be done before 2018 and it needs to start now. ECHA, the Member States and national chemical associations are there to support SMEs on this journey.

Francesca Furlan, Marketing and Public Relations Officer at ReachCentrum
Vincenzo Girardi, Training Manager at ReachCentrum

ReachCentrum is the professional service provider established by Cefic, the European Chemical Industry Council. It aims to help companies throughout the value chain to fulfil their REACH requirements. ReachCentrum provides guidance on the REACH requirements, as well as advice for managing consortia, organising workshops and delivering in-company training. ReachCentrum also runs solutions for CLP and Biocides. Services are available for EU and non-EU chemical companies.
How to get EU-wide authorisation for a biocidal product

TEXT BY PÄIVI JOKINIEMI

Do you want to market your biocidal product in all EU countries or in a number of them? The Biocidal Products Regulation introduces a new concept of Union authorisation. Once the Union authorisation has been granted for a biocidal product, it applies to the entire Union market. You can apply for Union authorisation both for a single biocidal product or a product family with similar conditions of use across the EU.

The steps below will guide you in applying for Union authorisation. Before getting started, remember that the following products are excluded from Union authorisation:

- Products containing substances that fulfil the exclusion criteria, e.g. substances that are classified as carcinogenic, mutagenic or toxic for reproduction. The complete list of exclusion criteria can be found in Article 5 of the Biocidal Products Regulation.
- Product-types 14, 15, 17 and 20, covering e.g. products to control rodents, birds, fish and other vertebrates.
- Product-type 21 covering anti-fouling products.

Check when the Union authorisation can be granted for your product

If your product contains new active substances, alone or in combination with existing active substances, you can apply for Union authorisation.

For products containing existing active substances, Union authorisation can be granted in three stages, depending on the product-type:

1. From 1 September 2013 for product-types 1, 3, 4, 5, 18 and 19.
2. From 1 January 2017 for product-types 2, 6 and 13.
3. From 1 January 2020 onwards for the remaining product-types.

Considering that the evaluation of the application can take up to 18 months, the application can be submitted earlier than the dates listed above. However, the decision on the Union authorisation will only be given on or after the dates indicated above.

Prepare your application

1. Pre-submission

The purpose of pre-submission is to confirm that the product falls within the scope of the Biocidal Products Regulation; has similar conditions of use across the Union; and that you have identified the appropriate product-type.

Contact the ECHA Helpdesk for further information and feedback related to pre-submission well before you plan to submit your Union authorisation application. Only after you have received ECHA’s feedback on your pre-submission, can you submit your application in IUCLID format through R4BP 3, the online submission tool.


Create a IUCLID 5 dossier

1. Include all required information


2. Create IUCLID dossier

The Biocides Submission Manual 4a: Biocidal Products Part A, Initial submissions provides you with a checklist of elements that need to be included in the substance and product datasets of your IUCLID dossier.


If you need more instructions on how to create and build a IUCLID 5 dossier, you should also have a look at:

- The video tutorial Creation of a biocidal product dossier with IUCLID. http://www.youtube.com/user/EU-chemicals

Submit and follow-up your application

1. Use R4BP 3 to submit your application
Remember to upload your IUCLID 5 file to your application. The Union authorisation application wizard in R4BP 3 will guide you through the submission steps. A checklist for Union authorisation can be found in the Biocides Submission Manual 4a: Biocidal Products Part A, Initial submissions http://www.echa.europa.eu/documents/10162/14938692/bsm_04a_bproducts_initial_submissions_en.pdf

If you are not familiar with R4BP 3 yet, have a look at the Biocides Submission Manual 2: Using R4BP 3 for biocide applications to get useful information on the basic functions of the software. http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

2. Remember to follow up your application in R4BP 3

All important information related to your application will be communicated to you through R4BP 3. Therefore, it is essential to keep checking your account after you have submitted your application.

In the Events history tab of the case, you can monitor how your application goes through the different stages of the process and which steps have been completed so far.

To complete your application you need to pay the invoice that you receive through R4BP 3. More information related to invoicing and R4BP 3 can be found in the Biocides Submission Manual 5: Invoicing in R4BP 3 http://www.echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals

All fees related to Union authorisation are explained in Table I of Annex II of the BPR Fee Regulation http://www.echa.europa.eu/regulations/biocidal-products-regulation/legislation.

Any requests for additional information related to your application will be sent to you through R4BP 3 during the evaluation process.

5. After the Biocidal Products Committee has given its opinion

Once the Biocidal Products Committee has given its opinion on your biocidal product, you have 30 days to prepare and submit the summary of product characteristics (SPC) in all the official languages of the Union to ECHA. The European Commission can only grant the authorisation after they have received all translated SPCs from ECHA.

FURTHER INFORMATION:


IUCLID 5 support documents http://iuclid.eu/index.php?fuseaction=home.documentation


ECHA’s YouTube channel with video tutorials http://www.youtube.com/user/EUchemicals


1) Check when the authorisation can be granted for your product-type

2) Prepare your application

→ Pre-submission phase

Biocides Submission Manual 4a

3) Create IUCLID 5 dossier

Annex III of BPR

Guidance for info requirements

Biocides Submission Manual 4a

4) Submit application

Use R4BP 3

Biocides Submission Manuals 2 & 4a

5) After BPC opinion

Translate SPC in all official EU languages

Infograph. Steps towards EU-wide authorisation of biocidal products.
Biocidal Products Committee Working Groups start their journey

The Environmental Working Group of the Biocidal Products Committee was the first of the Working Groups to kick off its meetings at the end of January. There are altogether four permanent and two Ad hoc Working Groups to support the Biocidal Products Committee.

The Working Groups under the Biocidal Products Regulation continue the work of the Technical Meetings that took place under the Biocidal Products Directive. In addition to the permanent Working Groups – Efficacy; Analytical methods and Physico-chemical Properties; Human health; and Environment – there are currently also two Ad hoc Working Groups – Human Exposure and the Assessment of Residue Transfer to Food. A third Ad hoc Working Group for Environmental exposure is being discussed.

The permanent Working Groups support the work of the Biocidal Products Committee by discussing the open scientific and technical issues identified during the peer review of the Competent Authority Report. The Competent Authority Report is drafted by the evaluating competent authority and it is based on the information given in the application dossier.

The discussions in the permanent Working Groups focus on whether the proposed use of the specific active substance or biocidal product is safe for the environment and human health. When requested by the permanent groups, the Ad hoc Working Groups find scientific consensus between the Member States for creating the scientific basis, for example by developing emission scenarios and tools to support human or environmental exposure assessment.

The permanent Groups meet five times a year in Helsinki. These meetings take place before the Biocidal Products Committee meetings so that open issues are solved and the Competent Authority Report can be revised before the Committee forms its opinion. In general, all of the permanent Groups have their meetings during the same week. The work of the Ad hoc Working Groups will be carried out more continuously and therefore no regular physical meetings are scheduled.

COLLABORATION BETWEEN THE MEMBER STATES AND ECHA

The Working Groups are composed of representatives from the Member States and the EEA and are chaired by ECHA. Each Member State can nominate core members, who will attend all meetings, and/or flexible members, who can choose which meetings to attend.

ECHA provides a chairperson for all permanent and Ad hoc Working Groups. Additionally, a dossier manager, supported by other experts on the case and the active substance in question, represents ECHA in the meetings. The meetings of the Working Groups are open to observers, such as applicants whose dossier is discussed in the meeting and nominated the representatives of ECHA's accredited stakeholder organisations.

ECHA Newsletter met with the chairpersons of the four permanent Working Groups to find out their expectations for 2014.

Heike Schimmelpfennig: I think that the biggest challenge in our work is to cope with the new legal deadlines that are very tight. Before the substance could be discussed in several Technical Meetings but now we only have one Working Group meeting before the Biocidal Products Committee meeting, in exceptional cases maybe two. Therefore, we have to take the deadlines very seriously to be able to keep them.

Antero Airaksinen: Stabilising the new processes within the tight legal deadlines requires very good coordination and cooperation between all the players – it is essential that we are all on the same page. We will have a lot to do since the Biocidal Products Committee meeting aims to give 50 opinions during 2014. It means that we have to take the deadlines very seriously to be able to keep them.

Berhard Krebs: I feel that one of my tasks is to make sure that the meetings are conducted in a good
spirit and that the cooperation between all parties involved is continuously developed. I see that the Member States are the drivers in the discussion and my job is to make sure that these discussions run smoothly and the tight deadlines are kept.

**Ann Thuvander:** It is always challenging to set up the procedures for a new Working Group and to make them work in a smooth and efficient way. As part of that, it is important that all members share a common understanding of the tasks that we have and agree on the principles and criteria for the work that should be carried out. We also plan to devote most of the Efficacy Working Group’s time on finalising guidance documents in 2014.

**What advice would you give to new applicants who are preparing their applications?**

**Heike Schimmelpfennig:** I think the key is to make sure that the application is prepared properly. This means that, if relevant for the application, the uses are clearly described and an appropriate risk assessment is presented and well explained. I would also encourage the applicants to contact the rapporteur in the evaluating competent authority in good time to agree on the outlines.

**Antero Airaksinen:** My advice for new applicants is to make use of all the available material to get to know the Biocidal Products Regulation and its processes. Therefore, I would encourage any new applicants to familiarise themselves with the regulation and ECHA’s website to understand their responsibilities. Some industry stakeholder organisations are also well aware of the new regulation and might be able to support new applicants.

**Bernhard Krebs:** To be able to meet the tight deadlines, the applicants need to understand the changes that the regulation has brought along, as Antero points out.

Compared to the former biocidal products directive, there is also a new submission system (R4BP 3) and the applications must be prepared in IUCLID 5 format. Therefore, any new applicant needs to learn how to use the new tools.

We at ECHA are here to support the applicants and they are welcome to send their questions to the ECHA Helpdesk.

**Ann Thuvander:** I would like to remind applicants to keep themselves up-to-date on the latest guidance and information as there is more material to come. Our aim is to help applicants to prepare high-quality applications. The discussions in the Working Groups will also be more focused when the applications include all the necessary information which in turn will lead to timely and efficient opinion-making in the Biocidal Products Committee.
An industry perspective

Generating safe use information for mixtures – status and next steps

TEXT BY CONTRIBUTORS FROM CEFIC AND DUCC

Our guest writers from the European Chemical Industry Council (Cefic) and the Downstream Users of Chemicals Coordination Group (DUCC) are returning to the topic of generating safe use information for mixtures featured in the October 2013 Newsletter. The two associations have identified approaches and methods used or being developed by companies and industry sectors for safe use communication for mixtures. They report here on their findings and on the next steps.

An inventory of methods and approaches to identify and communicate safe use information for mixtures was made in order to have a general overview of the ways that are currently being used or developed. Fifteen different methods were identified, and they were presented and discussed at ENES 5. Naturally, this is not an exhaustive compilation of methods, nor is it a list of recommended methods. However, it reflects the level of activity and the overall approaches that are being taken.

It was found that each approach has its merits and there is no ‘one size fits all’ methodology. General observations from the exercise were:

» Several industry sectors (e.g. lubricants, detergents, paints) are working on methodologies to identify safe use information for sector specific products and related uses. These methodologies are typically so called ‘bottom up approaches’ because the starting point is the mixture, its composition, use description and use conditions.

» In contrast to the sector specific approaches, more generic methodologies (or ‘top down’ approaches) are being developed that can be used to identify safe use information for each type of mixture, regardless of the composition and/or intended use. However, in many cases these methodologies also include mechanisms to take into account the mixture composition and the intended uses.

Looking in more detail at the several methodologies we see that:

» In almost all of the cases, whether it’s a sector specific or more generic approach, safe use information for mixtures is highly driven by risk driving substances (RDS).

Until now the selection of risk driving substances is mostly done using the DPD+ methodology developed by Cefic, but the Critical Component Approach (CCA) referred to in the ECHA guidance appears to evolve as a future alternative. However, the CCA is not yet fully elaborated and there is the need to develop an agreed and widely accepted convention on how to apply the CCA.

» Once risk driving substances have been identified, the next step is to extract and/or consolidate relevant safe use information. Transparent rules for the systematic selection and/or scaling of the operational conditions and/or risk management measures for the relevant risk driving substances are needed and may be standardised to allow automatic or partly automatic processing of such data in the future. A concept was presented including a simple calculation tool (working prototype) that can be further developed to support formulators in the consolidation.

» Communicating safe use information for the mixture through an annex to the safety data sheet is regarded as the preferred way so far, for reasons of practicality and clarity. However, inclusion of this information in the main body of the safety data sheet is also an option in most of the cases.

» Each methodology aims to keep the burden for the formulators as small as possible through automation and by keeping the required level of expertise needed to apply a methodology as low as possible.

» In all cases, more testing on a large variety of mixtures from different sectors will be needed to further identify benefits and limitations of each approach.
More detailed information on the methodologies can be found on the ENES section of ECHA’s website. ECHA will publish more information on the methodologies in the coming months.

**GENERAL CONCLUSIONS AND THE WAY FORWARD**

Although industry has already invested a lot in the development of methods and approaches to compile safe use information for mixtures, further work and testing are needed to gain more experience in using the methods. When doing so, it’s important that experiences are shared among the parties involved in order to get the best out of the different approaches.

As mentioned above, the ‘one size fits all’ method doesn’t exist. Nevertheless, there are many more similarities than differences in the various generic approaches.

Therefore it would be beneficial to create a common concept addressing aspects like the selection of risk driving substances. This could lead to one or two generic methodologies broadly used within industry. Sector specific methodologies may also benefit from such a common framework as they have some similar challenges.

Industry and its stakeholders will exchange experiences and start developing a common concept for a generic approach in the coming months. Feedback on the progress will be given at the upcoming ENES meeting in May 2014.

*Cefic has prepared a methodology based on the Dangerous Preparations Directive (DPD), enhanced for certain health exposure pathways with consideration of the volatility of the substances concerned. It is known as the DPD+ method.

Further information:

October 2013 Newsletter
http://newsletter.echa.europa.eu/home/-/newsletter/entry/5_13_challenges-for-generating-safe-use-information-for-mixtures

ENES web pages:

ECHA cooperates with other EU agencies to save costs

As a member of the **Network of EU Agencies**, ECHA is closely cooperating with other decentralised agencies in order to avoid duplication of work and to realise efficiencies and economies of scale.

The cooperation with other agencies is not limited to those that work in similar regulatory fields such as the Food Safety Agency in Parma or the Medicines Agency in London. ECHA is looking into ways of making best use of the available resources in matters related to the daily administration of the Agency. For example, joint procurement or selection procedures are organised and training events are open to other members of the Network.

Within the Network, the agencies also offer each other services, ranging from tailor made IT tools for administrative purposes to meeting facilities.

The aim is to save public money by joining forces and making use of experience and know-how in similar organisations.

Recently, ECHA started to cooperate with the new Tallinn based Agency eu-LISA, which manages large scale IT systems in the area of border control, visa or asylum. The potential areas of cooperation will be mainly in the areas of administration, security, IT and building infrastructure, procurement and recruitment. In particular, in the area of IT, the two agencies found similarities. As with ECHA, secure connections with Member States for exchanging data are also very important for eu-LISA.

Delegation from eu-LISA visited ECHA in January. Executive Director Krum Garkov on the left.
ECHA’s role under the PIC Regulation

INTERVIEW BY HANNA-KAISA TÖKKELI

ECHA has been actively preparing to take over the operational tasks of the new Prior Informed Consent (PIC) Regulation since the beginning of 2013. On 1 March 2014, when the new law becomes operational, the Agency will take over from the Joint Research Centre of the European Commission. But what exactly is ECHA’s role under PIC? ECHA Newsletter spoke with Kevin Pollard, Head of Unit for Dossier Submission and PIC, to find out.

Mr Pollard, what is ECHA responsible for under PIC?

Basically, we will take care of the technical and administrative aspects of the legislation while the policy work remains under the responsibility of DG Environment of the European Commission. In practice, our main task will be processing and forwarding industry’s export notifications to importing countries outside the EU. We will manage the notifications first in the existing IT tool EDEXIM and then later in the new ECHA-developed tool called ePIC. We will also be managing any import notifications received from non-EU countries.

We help the companies and PIC authorities through our ECHA Helpdesk and will report on the annual notifications and actual exports on our website.

What is the current status of the new IT tool ePIC?

We are currently finalising ePIC to get it ready for the summer, when we will start migrating the information from the current tool EDEXIM to ePIC. Here we will need cooperation from industry. The notifiers have already received instructions on how to prepare for the migration. There is a field in EDEXIM where they are encouraged to tag their company identifier, the so called Legal Entity Universal Unique Identifier (or UUID), so that we can link the migrated information to the right company.

If you are not a REACH, CLP or biocides customer, you need to create this identifier in REACH-IT. If you already have a company identifier for REACH, CLP or the biocides regulation, you need to retrieve the existing identifier from REACH-IT and copy it to EDEXIM. For industry this step is very important – only then are we able to move your account data to the new system.

ECHA will do the migration in the summer - ePIC will be available for the notifiers later. The new tool will be easier to use and have more automated steps which should streamline the work.

You said that the ECHA Helpdesk is there to help companies and authorities. How can companies contact the Helpdesk?

We will launch a new web form on the contact page of our website by 1 March specifically for PIC-related questions. There will be a form for general enquiries related to the regulation itself and another form for specific enquiries related to individual notifications.

The general enquiries and non-urgent questions about notifications will be handled in the established way within a maximum of 15 working days. For urgent enquiries on notifications or related transactions, we have a prioritised service and will make every effort to reply as soon as possible.

I want to emphasise that contacting the ECHA Helpdesk by using the web form is really the best way to get help from ECHA – that’s where we have experts ready to give you a quick response.

What about publishing information about PIC transactions? What exactly will be available?

Firstly, we will continue to make up-to-date regulatory information on the chemicals subject to PIC publicly available together with statistics on exports and imports.

Then, we also have reporting obligations. Every year in spring, exporters and importers of PIC chemicals must send us a report on the actual transactions that have taken place: for which chemicals, which volumes, between which countries, etc. As you are probably aware, a notification is not binding; it’s merely an indication of a potential export or import. So, we also need to follow up on the actual exports and imports that have taken place.

We then aggregate this information into two reports. The first one contains all the data, and is therefore considered confidential. This report is made available only to the Member States and the European Commission. The second report is a non-confidential version of the first one and will be published on ECHA’s website as soon as it has been finalised.

The Commission has responsibility for the policy work on PIC. What does this mean in practice?

The European Commission are responsible for any changes to the legislation. They, together with the Member States, are taking the decisions on which chemicals will be added to Annex I of PIC, meaning the list of chemicals subject to export notifications and explicit consents.
ECHA Committees adopt first opinions on authorisation

Applications for authorisation on the increase

TEXT BY HANNA-KAISA TORKKELI

ECHA has now made a positive recommendation to the European Commission on the first authorisation application from Rolls-Royce plc. on the use of the phthalate DEHP to manufacture aircraft engine fan blades. The Agency has already started work on the next seven applications for 16 uses of the phthalates DEHP and DBP. The public consultation for alternatives to those uses ended on 8 January 2014 with more than 120 comments from third parties.

“The first application by Rolls-Royce was quite straight-forward. The company demonstrated that adequate control has been achieved for the specific use, had analysed alternatives and described how they are planning to substitute the substance,” says Thierry Nicot from ECHA’s Risk Management Implementation Unit, and continues, “the Committees for Risk Assessment and Socio-economic Analysis therefore adopted positive opinions on the application.”

As for the next seven applications in the pipeline, the opinion making may be more complex. “Some of the uses applied for are less specific, which has resulted in a larger number and variety of comments received from the public consultation. We got comments not only from NGOs, but also from Member State competent authorities and industry. The applications also raised interest worldwide, for example, in the United States and Japan,” Mr Nicot mentions.

The comments concerned mainly the use of DEHP as a plasticiser in soft PVC. This is a large-volume use resulting in a broad range of consumer plastic articles. “The amount of information coming in from third parties puts pressure on the applicants to thoroughly assess the potential alternatives. This will help to meet one of the aims of authorisation: hazardous substances being progressively substituted with safer ones.”

TRIALOGUE DISCUSS THE INFORMATION SUBMITTED

To start the committees’ opinion forming on the applications, triilogue meetings may be held between the RAC and SEAC rapporteurs and the applicants. The triologues for the seven DBP and DEHP applicants will be held in mid-February. “In these meetings, the outcome of the public consultation is discussed and rapporteurs can ask questions from the applicants. In some cases, the third party submitting the information on potential alternatives may be invited to the meeting,” says Denis Mottet of ECHA.

These triologue discussions can help rapporteurs to better understand the applicability of the suggested alternatives, and support RAC and SEAC in swiftly adopting their opinions.

KEEPING IT TRANSPARENT

The Agency has put a lot of effort into keeping the application process open and transparent. The public version of the application as well as the comments made during the public consultation and the applicants’ responses are all published on ECHA’s website.

“We encourage applicants to include as much information as possible in the public version of the application. This follows the general transparency principle and enables others to openly see the arguments and reasoning behind the application,” Mr Mottet says.

ECHA has so far received one access to document request for information that was not included in the public version of four authorisation applications. Dealing with the request is a heavy process for applicants, and another reminder of why it pays to make the maximum of their information public.

APPLICATIONS FOR CHROMATE USES EXPECTED

In 2014, ECHA expects to receive the first applications for different uses of chromium-containing substances. It is working closely with industry to make sure that the chromate applications that involve different kinds of large-volume uses are submitted early to enable downstream users to see which applications are coming. “The latest application date for these chromates is 21 March 2016 but we hope to get many of them in well before that,” says ECHA’s Markus Berges.

The European Chemical Industry Council (Cefic) and the European
Association of Metals (Eurometaux) will organise a workshop with ECHA in March to support potential chromate applicants in submitting their applications. More about the workshop at: http://echa.europa.eu/applying-for-authorisation

ECHA will organise a seminar/workshop for future applicants from 28 to 30 April. More information is available at:
http://echa.europa.eu/applying-for-authorisation

**Further information:**

Authorisation to use a substance of very high concern - first opinions adopted, Press release: 3 January 2014

Authorisation process
http://echa.europa.eu/addressing-chemicals-of-concern/authorisation

Public consultations on alternatives
http://echa.europa.eu/addressing-chemicals-of-concern/applications-for-authorisation

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**DID YOU KNOW?**

▸ Companies wishing to continue to use substances of very high concern which are subject to authorisation after the sunset date have to apply for authorisation and assess potential alternatives. To make sure that applicants have done this properly, third parties are encouraged to submit additional information on alternatives during an eight-week public consultation period.

▸ All the information submitted will then be considered by the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC). The final opinions of the two committees will be sent to the European Commission, who will decide whether to grant the applicant an authorisation for the use.

▸ The first REACH authorisation application passed from ECHA to the European Commission with the adoption of positive opinions by RAC and SEAC in December 2013. The committees have proposed to review the authorisation in seven years’ time.

▸ This application, from Rolls-Royce plc., covers the use of bis(2-ethylhexyl)phthalate (DEHP) to manufacture aircraft engine fan blades.

▸ The next opinions of the committees on seven applications for 16 uses of the phthalates DEHP and DBP are expected to be adopted by September 2014. The public consultation for alternatives ended on 8 January 2014.

▸ In 2014, ECHA expects to receive approximately 20 authorisation applications, in particular for chromium substances and trichloroethylene.

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**Upcoming**

**February - April 2014**

Endocrine disruptor expert group meeting: 13-14 February

Evaluation Report 2013 published: 26 February

Prior Informed Consent Regulation enters into operation: 1 March

Committee for Risk Assessment: 4-7 March
Committee for Socio-economic Analysis: 10-14 March

Committee for Risk Assessment: 11-14 March

ECHA Management Board: 19-20 March

Enforcement Forum: 25-27 March

HelpNet: 1-3 April

Member State Committee: 7-11 April

Biocidal Products Committee: 7-11 April

PBT expert group meeting: 28-29 April

Seminar on applications for authorisation: 28-29 April

Workshop on applications for authorisation: 29-30 April

**Webinars**
http://echa.europa.eu/support/training-material/webinars
Best practise from Hungary
Learning chemical safety through play

TEXT BY MR ANDRÁS TENGE LITS, HEAD OF EXTERNAL COMMUNICATIONS OF THE OFFICE OF THE CHIEF MEDICAL OFFICER AND MS SZILVIA DEIM DEPUTY DIRECTOR GENERAL OF THE NATIONAL INSTITUTE OF CHEMICAL SAFETY

Board games, colouring books, stories and cards – all to teach children about hazard symbols and chemical safety in general.
A programme developed by local chemical safety inspectors in Hungary has become extremely successful, involving 3 500 children, their parents and 200 teachers over recent years.

According to the annual report of the National Institute of Chemical Safety, children are involved in up to 20% of human poisoning cases in Hungary. Therefore, chemical safety inspectors in Somogy County, in the southern part of Hungary, started a new prevention programme aimed at nursery schools to avoid accidents with chemicals. The programme – called ‘Learn it! - Beware of the risks!’ – was the inspectors’ own initiative planned outside work time.

The programme was extremely well received on the annual Chemical Safety Day organised by the national competent authority; its popularity exceeding the work on water pollution, endocrine disruptors and enforcement practices.

ENCOURAGING RESULTS
The Hungarian inspectors contacted nursery schools to establish a partnership. The aim was to familiarise children with hazard symbols and their meanings. The programme also involved parents, providing them with useful information about key questions like how to store and use chemical agents.

A whole collection of educational materials was developed by the inspectors to promote the initiative including posters, educational stories and nursery rhymes, board games and interactive sessions. The purpose was not only to teach children something new but also to focus on the knowledge that they already have.

To measure the knowledge of the children before and after the lessons, the inspectors used a test sheet with eight exercises to be filled with stickers. Before the programme, the children got on average only two or three answers correct. They typically recognised the symbols indicating toxic and environmentally hazardous chemicals. Three weeks later, when the programme had finished, the children were able to correctly answer at least six or even seven questions out of eight.

AWARD WINNING INITIATIVE TO CONTINUE?
Chemical safety education helps children to recognise danger as well as making them more aware of health and environmental hazards. Education also helps children to recognise the importance of risks posed by chemicals. Furthermore, not only is the initiative important for the children, but even the kindergarten teachers said that it is very useful to get to know more about toxicity and the safe use of chemicals.

The ‘Learn it! - Beware of the risks!’ initiative won the United Way Hungary’s Safety Award in 2010 and was further developed for elementary school children by the colleagues of the health authority in another county. However, further success of the programme will depend on the availability of financial resources.

Further information:
TV package of the programme http://youtu.be/02AnKcw0Wzl

Examples of the material produced for the Hungarian CLP programme, and children playing.
ECHA Member State Committee chairperson Anna-Liisa Sundquist retires

Career of a skillful negotiator

INTERVIEW BY LISA LOCCHI

REACH, CLP, GHS and much more - retiring from ECHA Anna-Liisa Sundquist recounts her remarkable career in the public service.

Her university background in chemicals engineering paved the way to a successful carrier in the public service, but Anna-Liisa Sundquist has also experienced firsthand the momentous negotiations that have marked the legislative history of the chemical sector over the past three decades.

Her first important international assignment came in the late eighties when, as a member of the Finnish delegation, she negotiated the chemicals acquis* for the European Economic Area (EEA) agreement.

“Together with the European Commission, we went through all the Community chemical legislation,” she recalls, “We had very in-depth discussions, and it was quite a learning experience for me.”

When the EEA agreement came into force, Mrs Sundquist was already engaged in the negotiation of a new chemicals acquis, but this time for the accession Treaty of Finland to the EU. “Having already discussed all issues with the Commission during the EEA negotiations, reaching an agreement was really easy,” she recollects.

After Finland joined the European Union in 1995, she decided to spend more years in Brussels at the Commission as a seconded national expert. Yet again, she started negotiating as a member of the EU delegation to the United Nations to set up the new internationally-harmonised system for classification and labelling - the GHS. “It took some years to reach an agreement, but I am proud of the work we did with EU colleagues and others because it served as the initial basis for the CLP Regulation,” Mrs Sundquist says.

A few months after her return to Finland, she received a phone call from the Commission asking her to contribute to the drafting of a new strategy paper for a future chemicals policy. It was the beginning of REACH.

Working as a Ministerial Advisor at the Finnish Ministry of Social Affairs and Health, Ms Sundquist was involved in all sorts of negotiations. So, when Finland had the EU presidency in 2006, she was selected as Chairperson of the Council working party on REACH. “It was really an experience, and the most exciting part was the final deal on the REACH text,” she explains.

In 2008, when she joined ECHA as Chairperson of the Member State Committee (MSC), she was already a well-known and successful negotiator. At ECHA, she has chaired 34 MSC meetings moving debates forward when needed and helping to calibrate the discussion amongst delegates with her fair and balanced style. She confesses that she will miss the intellectual challenges that her work provides. “Chairing the MSC was a very good time for me; together with my colleagues from ECHA and the EU Member States. We have really accomplished many important goals, and managed to set a sound governance framework that ensures effective and efficient decision-making in the Committee.”

Indeed, Mrs Sundquist’s career has been a model to follow. Thanks to her warm personality and consensual style, she has created a unique career path for herself. The history of the EU chemicals legislation is testament to the soft skills of this talented negotiator and the sharp mind of a chemical engineer.

* The acquis is the body of common rights and obligations, which bind all the EU Member States. Applicant countries have to accept the Community acquis before they can join the EU and have to transpose it into their national legislation and implement it from the moment of their accession.

**SAID ABOUT ANNA-LIISA SUNDQUIST:**

“Anna-Liisa knows the chemicals world and the chemicals world knows Anna-Liisa. Her achievements are numerous. She not only masterly chaired the Council ad-hoc working group during the Finnish presidency bringing REACH to a successful closure, she also brought the Globally Harmonised
System (GHS) to the world and now delivered on REACH as the Member State Committee chairperson. Thank you Anna-Liisa, hoping retirement will bring you as much fun!"

**Bjørn Hansen, Head of Unit, Chemicals, DG Environment**

"My experience of working with Anna-Liisa in the Member State Committee has only ever been positive, right from the beginning. The first memory I have of meeting her was just before the first MSC meeting, where she went around to each member individually, spent a few minutes with them introducing herself and welcoming them to the Committee. In my many years of working for the Irish competent authority and attending EU meetings, that was a first. It was a great start to the Committee’s work and set the tone for the many meetings to come, as we all felt included from the beginning.

Anna-Liisa has been an inspirational chairperson, bringing much knowledge and skills to the group, along with an incredible ability to stay focused during many long and complicated discussions. The MSC is a lovely, hardworking and successful group to be part of. A lot of the respect and success within the group comes from Anna-Liisa, as she has fostered these values within the group since the Committee was set up. She will be greatly missed by all of us as she now starts the next, exciting chapter in her life.

For her retirement, I wish her good times and lots of laughter, happiness and long days filled with those things she has never had the time to do! Go raibh mile maith agat Anna-Liisa, agus go n-éirí an t-ádh leat."

**Majella Cosgrave, Irish Health and Safety Authority**

"It has been a pleasure to have Anna-Liisa as Chairwoman of the MSC. I’ve always appreciated her correctness and ability to successfully calibrate political biases during the meetings. She always made sure that everyone was playing the same game so it gave all delegates a fair chance to join the discussions.

I wish her to take her retirement as a new beginning and find new endeavours that really please her."

**Erwin Annys, Director REACH / Chemicals Policy, European Chemical Industry Council**

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**New MSC Chairperson appointed**

ECHA has appointed Watze de Wolf as new Chairperson for the Member State Committee. As of 1 March 2014, he will replace Anna-Liisa Sundquist, who is retiring. Dr de Wolf joined ECHA in 2010 as Head of Unit with responsibility for dossier and substance evaluation activities.

“I am looking forward to my new challenging role and aim to reach the high standard set by Anna-Liisa. I’ll work closely together with the Member States for scientifically and legally sound opinions that support the implementation and further advancement of the goals of REACH,” Dr de Wolf says.

Before joining ECHA, he worked as a regulatory toxicologist in the chemicals industry and a consumer products company. He is a Eurotox Registered Toxicologist (ERT), holds a Ph.D. degree in environmental toxicology and a masters’ degree in biology. Dr de Wolf is an active member of the Society of Environmental Toxicology and Chemistry (SETAC) and was President of the SETAC World Council in 2006.

“When it comes to my past in the chemicals industry and me new role as Chair of the MSC, I will of course follow our very strict policy on conflicts of interest, and - as I’ve done for the last four years as a Head of Unit - take myself out of all discussions for which a potential conflict could arise,” Dr de Wolf says.

The first MSC meeting chaired by Dr de Wolf will take place in the beginning of April.

**Further information:**

Member State Committee
http://echa.europa.eu/about-us/who-we-are/member-state-committee

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_People and Perspectives_