**REACH 2018: how to meet your information requirements**

ECHA Newsletter interviewed Dr René Hunziker from Dow Europe GmbH to gain an insight into how Dow is gathering information to fulfil the legal requirements for the substances they are preparing to register in 2018. His message is: start now, plan your testing strategy and use the available support to help you.

**How are substances of concern identified?**

Some chemical substances may be of concern for human health and the environment. ECHA, Member States and the European Commission are working together to identify these substances of concern and make sure that they are properly controlled. Read how the work is done.

**No time to lose – active substance suppliers need to get on the list**

The biocides deadline to get included in the list of active substances and suppliers on 1 September 2015 is closer than you think. If you need to be on the list but have not yet submitted your application, this is the last moment to act. ECHA Newsletter spoke with Janssen PMP, one of the companies on the list. Read their last minute tips to help you prepare your application.

**Get wise – use Chesar**

Dr Dirk Schwartz from Bruno Bock Thiochemicals has experience from both REACH registration deadlines. Ahead of the second deadline in 2013, his small and medium-sized company decided to manage their registrations in-house. For the chemical safety assessment included in the registrations, his company uses ECHA’s Chemical Safety Assessment and Reporting tool, Chesar.

**ECHA Newsletter goes interactive!**

I’m delighted to start the April issue by announcing a new functionality in the online version of the ECHA Newsletter. From now on, you can give direct feedback on our articles by posting a comment or rating it.

To get started, you need to create a user account on our website. This is simple to do – click on the link “Sign-in” on the top right hand corner of the Newsletter site. On the next screen you will find a “Create account” link. Answer a few easy questions, follow the instructions to confirm your account and it’s done. Note that if you are a Chesar user, you already have an ECHA account so you don’t need to create a new one.

Once your account is created, sign in to the site and you are ready to post your first comment. We hope that you enjoy this new interactivity and we are looking forward to getting your direct feedback.

Our ongoing efforts to improve continue with the website. You gave us some useful pointers at the end of last year on where our website needs to improve. We are now kicking off a piece of research to find out in more detail what you need and how best to deliver it. If you could be interested in helping us, send us an email to web@echa.europa.eu and we will tell you more.
Finally, I would also like to remind you of a couple of events taking place very soon. The ECHA Stakeholders’ Day takes place on 27 May at our premises in Helsinki and is free of charge. One of the main topics is the upcoming REACH 2018 deadline. You can still register for the event and get the chance to have a one to one session with an expert in person, or you can follow the conference through live web-stream.

As usual, our Stakeholders’ Day is followed by the Helsinki Chemicals Forum where you can continue discussions with your peers on topics such as future of the global chemicals risk management, harmonised system for classification and labelling and communications in the supply chain. The participation fee for the Forum is reduced if you are coming also to the Stakeholders’ Day.

I’m looking forward to seeing your comments and ratings for our Newsletter content and hope to see you here in Helsinki in May.

“In once your account is created, sign in to the site and you are ready to post your first comment.”
Authorisation: it’s a business choice

INTERVIEW BY PAUL TROUTH

LANXESS Deutschland GmbH was the lead company for the registration of chromium trioxide (CrO3) in 2010. Chromium trioxide was subsequently added to the Authorisation List in April 2013. LANXESS were then contacted by members of their registration consortium and asked if they had any plans for the authorisation process. ECHA Newsletter recently spoke to Martin Kleban, Director of Health, Safety, Environment and Quality of the Business Unit Leather at LANXESS, to learn about his experience.

GETTING STARTED

“We contacted the actors in our supply chain to evaluate our options knowing that we had a business decision to make. Authorisation was the route we decided to take. However, it was obvious that the work could not be carried out by any manufacturer or importer alone but would need the heavy involvement of downstream users. So we created the Chromium Trioxide Authorisation Consortium (CTAC) and outsourced the management and technical work to consultants,” Mr Kleban says.

By the start of 2012, the consortium agreement had been signed by 150 companies and later that year CTAC began preparing the documents for an application for authorisation for the use of chromium trioxide for surface treatment.

STARTING WELL IN ADVANCE

They plan to apply for authorisation in May 2015. The work on the application has been ongoing for nearly three years, which shows how important it is to start preparing early.

“The 18-months foreseen in REACH as a minimum period for preparing for authorisation, is clearly an underestimate for a situation as complex as surface treatment with chromium trioxide. Therefore, it is vital to start early,” Mr Kleban warns.

It is also important to be ready for delays and surprises along the way. “We experienced a few difficulties in collecting data and had to make our members aware of how important it is for them to supply the data efficiently. Gathering the data is a big issue,” Mr Kleban says and continues, “some members only sent their data after the deadline had passed. This delayed us a little. With this in mind and with some forward thinking and planning, we could have been a few months quicker in our preparations. However, we expected this sort of timeframe,” Mr Kleban explains.

FINDING THE RIGHT EXPERTISE

Authorisation is a very specific process, unique to the substance, the manufacturing processes, the uses being applied for, and the companies’ role in the process. It is important to have the right expertise when deciding whether to pursue authorisation because if you fail with your application for authorisation, you will be off the market after the sunset date.

“For larger companies, deciding to apply for authorisation may not be overly problematic because they are likely to have their own regulatory affairs departments to help them evaluate their position pretty well,” Mr Kleban points out.

The decision for small and medium-sized enterprises (SMEs) can be more difficult and it is important that they ask for help. “If they do not have the knowhow, they may need to look for help from a competent partner. If they are lucky, their trade associations will already be working towards this goal,” he adds.

UNDERBREAS THE COST

LANXESS estimates that the cost for the joint application is around EUR 4 million. Approximately half of this was spent on managing the consortium and the other was for the application itself. Even if filing as a single applicant would allow you to avoid the costs of managing the consortium, this was not an option for LANXESS. “If we had been doing this on our own, we might not have applied for authorisation,” Mr Kleban stresses and continues, “this is the amount that both we and our competitors were willing to invest to keep using this particular substance.”

The financial cost was, however, only one aspect for LANXESS and the consortium to consider. “As part of a multi-tiered supply chain, every member has to take their own decision...
LANXESS Deutschland GmbH is a chemicals company specialising in the development, manufacture and marketing of plastics, rubber, intermediates and specialty chemicals.


**ADVICE FOR DOWNSTREAM USERS**

“...The final decision on whether or not to grant authorisation to use the substance of very high concern (SVHC) lies in the hands of the European Commission. Therefore, suppliers cannot guarantee that they will be able to continue to supply the substance after the sunset date. The most positive assurance a downstream user can receive from their supplier is the commitment to apply for authorisation,” Mr Kleban remarks.

To all actors involved in the authorisation, Mr Kleban says that communication is key. “My advice to downstream users is that they have to be aware of the potential impact of authorisation. Not being granted authorisation at the sunset date means that all operations related to the substance have to stop,” he stresses.

**AN INCENTIVE TO REPLACE HAZARDOUS SUBSTANCES**

Mr Kleban’s main business at LANXESS is in the manufacture of chemicals, used in leather processes, where he deals with end-user articles and the substances contained within them.

“I see many brands starting to pay closer attention to the developments on the Candidate and Authorisation lists and pushing for replacements when SVHCs are identified. This is driven by end-user companies putting pressure on suppliers to change. They are investing time and money in making sure that the SVHCs are also made obsolete in regions outside Europe,” Mr Kleban explains and continues, “the fact that end-user organisations are not limiting their markets only to Europe but are looking at chemical safety on a global level is an indirect benefit of the authorisation process,” he concludes.

**Further information:**


REACH 2018: how to meet your information requirements

INTERVIEW BY ADAM EL WAN

ECHA Newsletter interviewed Dr René Hunziker from Dow Europe GmbH to gain an insight into how Dow is gathering information to fulfil the legal requirements for the substances they are preparing to register in 2018. His message is: start now, plan your testing strategy and use the available support to help you.

Meeting the information requirements on a substance can be a lengthy process with many things to think about. “First, get started straight away,” Dr Hunziker, Product Sustainability Leader at Dow says.

Dow staff are already actively preparing and planning their REACH registrations. “Our first step was to collect all available analytical data and then start generating additional data where necessary. Following that, we collected all hazard-testing information on products and developed a draft test plan. Once the identity of the substances has been confirmed, we will reach out to the substance information exchange fora (SIEFs) to check for any additional information and propose any necessary testing,” Dr Hunziker explains.

CHALLENGES AND OPPORTUNITIES

A major challenge for Dow is to make sure that the many substances produced by third parties and imported by Dow as co-formulated products or as monomers of polymers in their products are compliant. “As a result, our businesses need to take difficult decisions on whether to rely on the manufacturer for compliance or whether to register the substance ourselves,” Dr Hunziker points out.

As some time has passed since pre-registration, it can also prove difficult to determine who is still intending to register a substance that is not currently registered. This makes data generation more difficult as there is first a need to understand what data exists among all the potential registrants.

However, registering in 2018 also brings many opportunities. “A significant number of the substances that we need to register are already registered. The required information is typically available together with a completed hazard assessment,” he informs. This makes it easier to collect all the necessary data to meet the information requirements.

Attention should still be paid to validating at an early stage whether your substance really is covered under the existing registration. “Even if this is the case, there may still be uses unique to your company that require further justification on their safe use,” Dr Hunziker points out.

Another challenge is forecasting the actual volume of the substances that will be registered for 2018. Depending on the volume, the information requirements may be higher or lower, which in turn affects the time needed for the preparations.

START PREPARING NOW

Dr Hunziker suggests a two-tiered approach to your testing strategy. Firstly, assess whether a reliable prediction can be made using QSAR models. “We are looking at opportunities for QSAR and read-across today because, if at the end we find these inappropriate for a given substance, we still have ample time for standard testing,” Dr Hunziker says.

This emphasises the importance of time. “To make best use of the opportunities of an intelligent testing strategy, there needs to be room for failure,” Dr Hunziker says. For substances produced between 10 to 100 tonnes a year, Dow plans for a minimum of one and a half years to perform standard testing. In addition, a six to twelve-month waiting period is planned for scheduling laboratory testing. At the end of the testing, Dr Hunziker recommends at least a further six months for completing the hazard assessment and the documentation of safe use where needed. This amounts to almost three years of planning and testing for each substance.

LETTER OF ACCESS

Dr Hunziker explains that in his experience there is very little room to negotiate on a letter of access. “The agreements that are offered have been adopted already by a large group of data holders and cannot be varied for each new registrant. This applies for small and medium-sized enterprises (SMEs) as well as for larger companies.”

He highlights the importance of ensuring that the proposed agreement only covers the information required for the tonnage band you need and reminds that the cost sharing should always be fair and transparent.

“We have also started to review the disseminated information for substances where we may need a letter of access. We are doing this to verify that the information for selected endpoints meets our expectations,” Dr Hunziker adds.
USING QSAR AND READ-ACROSS

If done properly, the non-animal test methods such as QSAR and read-across can be viable. However, they still represent a significant challenge to both registrants and regulators. “For read-across, we start from a hypothesis and then collect and provide evidence to validate it. The significant opportunity lies in the fact that we can read across to data and studies that are more comprehensive than what is required for the 10-100 tonne a year substances,” Dr Hunziker clarifies.

As a helpful source of information, he recommends reading ECHA’s illustrative example of a grouping of substances and read-across approach. It gives an outline of the level of information ECHA expects and includes explanations.

Dr Hunziker says that QSAR is a reliable source of information at a reduced cost. “For a series of endpoints, both risk assessment and classification can be covered by QSAR, such as biodegradation or for octanol water partitioning. QSAR methods can also assess all constituents in a substance and provide more confidence in the result on that basis,” he adds.

In his department, the QSAR Toolbox is often used. “I am amazed at the amount of scattering in the data when we pull analogues for a reasonably well defined category. The toolbox helps to show whether the scattering reflects the inherent noise of the data, or points to different mechanisms of toxicity that need to be considered in our assessment.”

AVAILABLE SUPPORT WITHIN YOUR REACH

ECHA has recently launched a website dedicated to the 2018 registration deadline which Dr Hunziker welcomes. “It offers excellent and essential information in multiple European languages,” he describes. ECHA’s workshops and events like the upcoming Stakeholders’ Day also provide essential information that is recorded and available on the website. “The national helpdesks and their websites are another important source of information, and they are all free of charge,” he says.

He goes on to explain that for first-time manufacturers or formulators who can join a registration, the information available in the joint registration will likely be sufficient to help them prepare their own. However, first-time lead registrants should consider establishing a relationship with a competent consultant and with a testing laboratory. “I recommend a consultant independent of the laboratory who can help them through the process – similar to using a site manager in a larger building project who is independent of the building company,” he concludes.

Dr Hunziker is the Product Sustainability Leader for Dow’s chlorine products business. In this role, he is responsible for the safe use of products and for meeting regulatory requirements globally. He will speak about REACH Information requirements at ECHA’s 10th Stakeholders’ Day conference on 27 May.

Further information:

REACH 2018 web pages
http://echa.europa.eu/reach-2018

Information requirements
http://echa.europa.eu/regulations/reach/substance-registration/information-requirements

Grouping and read-across

QSAR Toolbox
http://www.qsartoolbox.org

What about animal testing?

ECHA’s 10th Stakeholders’ Day
http://echa.europa.eu/view-article/-/journal_content/title/10th-stakeholders-day

Terminology – in 23 languages
How are substances of concern identified?

Some chemical substances may be of concern for human health and the environment. ECHA, Member States and the European Commission are working together to identify these substances of concern and make sure that they are properly controlled. Read how the work is done.

SELECTING SUBSTANCES THAT MATTER MOST

Taking regulatory measures on substances of concern aims to increase the protection of human health and the environment. Screening potential substances of concern is vital if all relevant substances of very high concern (SVHCs) are to be on the Candidate List for SVHCs by 2020.

ECHA, the Member States and the European Commission have developed a common screening approach to identify substances with certain hazards, exposures and risk profiles. They will then manage them through the most appropriate REACH or CLP process. The screening is based on information available on ECHA’s registration database and in the C&L Inventory as well as external sources, such as assessments made by other regulatory authorities.

The common screening helps authorities address the SVHCs in a more consistent manner and it should avoid duplicating work.

HOW IS THE SCREENING DONE?

Screening scenarios have been developed which can be used in IT based mass screening exercises. This is the first phase of screening and is conducted once a year.

The substances identified through the IT screening are then manually scrutinised by the Member States. The manual screening better defines the hazard profile or the risk based concerns for each substance. However, it is not a thorough assessment of the information available on the substance. It aims to confirm if further steps need to be taken.

After the manual screening, substances of potential concern will be processed depending on the need for further additional information or for further regulatory action.

One of the outcomes is the need for further regulatory risk management and the need to develop a risk management option analysis (RMOA).

DID YOU KNOW?

ECHA is working towards having all relevant substances of very high concern on the Candidate List for SVHCs by 2020. In March, ECHA published a report on the first years’ work to that end.

The main achievements so far are the setting up of the common screening approach; the streamlining of the different REACH and CLP processes to identify the substances that matter most; and enhancing coordination of activities on these substances among authorities.

ECHA’s weekly e-News will keep you informed about current developments on the screening, risk management option analysis (RMOA) and all REACH and CLP processes.

The information box below explains the other potential outcomes.

**HOW TO ADDRESS THE CONCERNS?**

Where a concern is identified, the Member State, or ECHA at the request of the Commission, can choose to perform a risk management option analysis to conclude on the best way forward. The outcome can be:

1. a proposal for harmonised classification and labelling;
2. SVHC identification and inclusion on the Candidate List of SVHCs. This may eventually lead to inclusion on the Authorisation List;
3. a proposal for restriction;
4. a decision that the substance needs to be discussed under other legislation; or
5. no further action.

**WHAT ROLE CAN YOU PLAY?**

Take the opportunity to consider replacing substances of concern with safer alternatives. Be innovative, do research in order to find substitutes or safer alternatives and develop new production technologies.

The main source of information for screening is the registration database. Therefore, it is important that your registration dossiers are up-to-date and that the information on uses, tonnages and conditions of use are accurate. This information is used to prioritise substances for further work but also to find out if a substance is of lower priority. This could be, for example, a substance that is only used in industrial settings under strictly controlled conditions.

You can see which substances are being examined on ECHA’s website. The tool for advance notice helps you to follow-up the status of your substance. Check it regularly and update your dossier if needed.

**POTENTIAL OUTCOMES OF THE SCREENING**

**Compliance checks**: ECHA examines the registration dossiers to check that they comply with the registration information requirements. If a dossier does not comply, ECHA requests the registrant to submit further information or carry out additional testing.

Member States carry out **substance evaluation**, which aims to clarify whether the use of a substance poses a risk to human health or the environment. As a result, registrants may be asked to send additional information or perform tests that are not part of the standard requirements for REACH registration. Based on the additional information, the Member State may conclude that further risk management measures are needed, such as harmonised classification and labelling, SVHC identification or restriction.

If the substance needs further assessment in terms of its persistence, bioaccumulative nature or toxicity (PBT), or endocrine disruption properties (ED), then Member States can consult the **PBT or ED expert group** before further action. Both groups provide informal, non-binding scientific advice on questions related to the identification of PBT, very persistent and very bioaccumulative (vPvB) and endocrine disrupting properties of chemicals.

**Harmonised classification and labelling** harmonises the hazard classification of a substance at the EU level. This classification is legally binding for all suppliers who place the substance on the EU market on its own or in mixtures. For the SVHC identification of sensitisers and substances that are carcinogenic, mutagenic and toxic to reproduction (CMRs), harmonised classification and labelling is the first step.

In the **authorisation** process, identification of a substance as a substance of very high concern (SVHC) and inclusion in the Candidate List of SVHCs is the first step. Based on ECHA’s recommendation, the European Commission decides if a substance should also be included in the Authorisation List. If a company wants to continue using substances on the Authorisation List after the defined sunset date, they need to submit an application to ECHA requesting authorisation for specified uses.

If a chemical poses an unacceptable risk that needs to be addressed on an EU level, a Member State or ECHA, at the request of the Commission, may propose a **restriction** on the manufacturing, placing on the market or use of the substance of concern.

Other actions may also follow, for example, enforcement at national level. It is also possible that no further action at this point in time will be needed.
Overview of the process of identifying and controlling substances of concern.

**Further information:**

SVHC Roadmap to 2020 implementation

Tool for advance notice

Screening of substances of potential concern

Addressing Chemicals of Concern
http://echa.europa.eu/addressing-chemicals-of-concern

Evaluation
http://echa.europa.eu/regulations/reach/evaluation

PBT expert group

ED expert group

Harmonised classification and labelling

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

Restriction
http://echa.europa.eu/addressing-chemicals-of-concern/restriction

Are there safer alternatives?
http://echa.europa.eu/chemicals-in-our-life/are-there-safer-alternatives

Terminology – in 23 languages
No time to lose – active substance suppliers need to get on the list

INTERVIEW BY PÄIVI JOKNIEMI

The biocides deadline to get included in the list of active substances and suppliers on 1 September 2015 is closer than you think. If you need to be on the list but have not yet submitted your application, this is the last moment to act. ECHA Newsletter spoke with Janssen PMP, one of the companies on the list. Read their last minute tips to help you prepare your application.

Janssen PMP is a supplier of active substances, including Propiconazole which is used in the wood preservation industry. To continue supplying this active substance, the company needed to get on the list of active substances and suppliers, also known as the Article 95 list, before 1 September 2015.

“For the sustainability of our long-term business we decided that it would be in our best interest to be listed as a substance supplier under Article 95. Since our decision would directly impact our customers, it was key to keep them informed throughout the whole process,” Dr Adrian Gray, European Regulatory Manager says.

It takes time to prepare a dossier

According to Dr Gray, submitting the application itself is quite simple but preparing the active substance dossier takes time and should be prioritised. “The first step for us was to understand the active substance data requirements and where waivers could be used. For this, the available guidance on data requirements and information published in the assessment report of the active substance proved to be helpful.” However, he adds that for many active substances currently in the review programme, the assessment reports are not yet available.

Whether your company is large or small, help may be needed when preparing your application. For example, to confirm the data requirements Janssen PMP decided to get support from consultants but they also asked ECHA for answers to some of their questions. “Using consultants in areas where they had more expertise, for example with IUCLID, helped us tremendously,” Dr Gray says and continues, “on the other hand, since we already had an R4BP 3 account, it was not too complicated to submit the actual application.”

He reminds companies to keep an eye on their R4BP 3 account also after submitting their application to follow-up its status and to make sure that they pay the related fee in time. “After the application was submitted, we occasionally contacted the dossier manager at ECHA to get reassurance and further information on likely timelines for the application,” Dr Gray explains.

Dr Gray points out that in many cases companies do not need to produce their own data for the dossier but they can buy a letter of access from a supplier who is already listed.

Check if you need to apply – and act now!

If you use a biocidal active substance in your biocidal product but you are not on the list of active substances and suppliers, ask yourself if you need to be.

Formulators making biocidal products available on the EU market could be covered by their supplier. “If it is clear in your supply chain that your active substance supplier (the importer or manufacturer) is already listed for the relevant product type, fine. But if your supplier is not listed and they cannot convince you that they will be listed by the September 2015 deadline, it could be worthwhile checking with a...
substance supplier that is included in the list if they could supply your needs. This way you may not need to be on the Article 95 list yourself,” Dr Gray advises.

**Negotiate for a letter of access**

If you come to the conclusion that you need to be on the list, you have to act immediately. This, however, does not mean that you necessarily need to produce your own data for the dossier. In many cases, you can buy a letter of access from a supplier who is already listed.

The first step is to contact the data owner. “Since time is now short, negotiating for a letter of access is potentially the quickest route to the Article 95 list, but like many commercial negotiations, it can still take some time. From what we have learned of the overall Article 95 process, it is already rather late to do this, unless your data access negotiations go smoothly,” Dr Gray points out.

According to Dr Gray, submitting a dossier based entirely on a letter of access would result in a quicker and more straightforward evaluation of the application. “If the letter of access from the data owner does not cover all the required data, you need to conduct a data gap analysis. To be honest, it is a good idea to do this in advance in any case. It will give you an idea of what other data may be needed and the implications regarding costs and timelines,” he emphasises.

He recommends companies to have a look at the published list of active substances and suppliers on ECHA’s website to find the possible data owner. Another helpful source of information is ECHA’s Guidance documents on active substance suppliers and data sharing. They can help you to understand the obligations of the different parties and give you useful tips for the data negotiations.

**Further information:**

Biocides 1 September 2015 – Apply now to stay on the market

List of active substances and suppliers
http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

Guidance on biocides legislation

R4BP 3 – Register for Biocidal Products
http://echa.europa.eu/support/dossier-submission-tools/r4bp

ECHA Helpdesk contact form
http://echa.europa.eu/contact/helpdesk-contact-form

Terminology – in 23 languages

**Janssen PMP**

Janssen Preservation & Material Protection (PMP) is a division of Janssen Pharmaceutica NV. They develop and formulate active substances and end-use products for the protection of materials and produce, for example, for wood protection, antifouling and microbial control. The company acts as an active substance, technical concentrate and biocidal product supplier. Janssen PMP are established in Belgium, the United States, Argentina, Singapore and Japan.

www.janssenpmp.com
Get ready for IUCLID 6

TEXT BY PÄIVI JOKINENI

In summer 2016, a new version of IUCLID, the tool used to compile regulatory data on chemicals, will be released. This new version will include many improvements and will be based on an entirely new technical platform. In May 2015, ECHA will release a beta version of IUCLID 6 that will allow you to prepare for the update. If you use IUCLID from your company server, it is particularly important to know what is going to change and how to prepare your company’s IT environment for IUCLID 6.

PREPARE YOUR ORGANISATION’S IT ENVIRONMENT

The beta version will give organisations that have IUCLID installed on their company server an opportunity to prepare their IT systems and user management practices. The beta version lets you:

• Start introducing the software changes that will be needed to run IUCLID 6. For example, Tomcat needs to be replaced by GlassFish as the application server which makes the components of IUCLID work together. This change can be done and tested with the beta version. You can also use the beta version to test the integration of IUCLID with other software that you use to manage your information on chemicals.

• Start making use of the new user management features of IUCLID 6. For example, you can appoint a user manager who can manage other users and their user rights, but who cannot access other data in the application. Different user groups can also be created and be granted access only to specific data – all within one central database. This feature can already be set up with the beta version.

The beta version does not contain all the data structures and functionalities of the final IUCLID 6 release. This means that you will need to make a final upgrade of IUCLID 6 when it is released. However, by using the beta version to set up a IUCLID 6-ready IT environment in your organisation, you can ensure a smooth transfer in 2016.

When the beta version is launched, there will be a set of instructions, a list of solutions to known installation issues, and a video tutorial. Additionally, the ECHA Helpdesk will be ready to answer your questions.

IUCLID ON YOUR DESKTOP PC – GET FAMILIAR WITH THE NEW LOOK-AND-FEEL

If you have installed IUCLID directly on your desktop computer or laptop, you do not necessarily need to install the beta version. However, it will give you a chance to get familiar with the new look of the user interface. You can also familiarise yourself with the streamlined data management where all sections for endpoint studies have a record-based structure, making it easier to copy and paste and share information.

IUCLID 6 IN 2016 – WHAT CHANGES?

Many users reported that installing IUCLID has been complicated in the past. IUCLID 6 is simpler to install on your desktop computer. It will, for example, no longer require any additional software.

Many of the changes aim to help both registrants and authorities. For example, the improved structure of information follows the OECD harmonised templates; a new version of the templates will be published by the OECD in 2015 and made available in IUCLID 6 in 2016. It also means that data can be searched and disseminated better.

IUCLID 6 will be easier to customise so that it can be used for other purposes than those currently managed in IUCLID 5. This is particularly useful for authorities in OECD member countries. They will be able to create their own templates and reports in IUCLID 6 whereas until now this has only been possible for ECHA.
The 2016 release is linked to a bigger update of ECHA’s IT tools with new versions of REACH-IT and Chesar. Once the new version of REACH-IT is available, all dossiers submitted to ECHA must be created in the IUCLID 6 format. Therefore, if your organisation runs IUCLID from a company server, take advantage of the IUCLID 6 beta version and make sure you are prepared.

Further information:

IUCLID website
http://iuclid.eu/

ECHA Helpdesk contact form
http://echa.europa.eu/contact/helpdesk-contact-form

DID YOU KNOW?

IUCLID is the tool used to prepare, for example, REACH registration dossiers and applications for authorisation of biocidal products. IUCLID is available in two versions:

- The desktop, or workstation version, is installed directly on your desktop computer or laptop. Any information you have in your workstation IUCLID is only available for you, not for any other users.

- The server, or distributed version, runs on a company or organisation server. The data in this IUCLID version can be accessed simultaneously by several users.

The IUCLID 6 beta version is a preliminary version of IUCLID 6 that will help you prepare for the changes needed in your IT infrastructure and user management for organisations using the distributed version. It does not yet contain the final data formats and cannot be used to prepare a dossier for submission to ECHA.

IUCLID 6 will be officially released in summer 2016 and must be used for dossier submission. Until then, dossier submission to ECHA must be done with IUCLID 5.

ADVICE FROM A STAKEHOLDER

Dimitri Friedmann, Cefic – Industry representative of REACH-IT and IUCLID Working Group

“We have been involved in the testing of IUCLID 6 since 2013 and I believe we have helped to make it a better functioning tool.

Those users running IUCLID on their company server need to get prepared for the future data migration and make sure, with the help of IT-colleagues, that their IT systems are compatible with the requirements of the new IUCLID version.

It is important to keep in mind that, until the migration of the production environments has been done in 2016, you should be prepared to support two completely different IUCLID systems. Therefore, don’t wait for the official release of IUCLID 6. Start the testing of the beta version as soon as it is available.”
Implementing REACH is one of the most challenging tasks that the European chemicals industry has faced. At Kao Chemicals Europe (KCE), we have a team of five professionals working to fulfil the regulatory obligations as a manufacturer, importer, downstream user and only representative. We describe some of our experiences with REACH here, particularly from a downstream user perspective.

22% REGISTERED

As a downstream user, we buy over 1,000 raw materials a year and about 22% of these have been registered so far. We have received extended safety data sheets for about 16% of these registered substances. These extended safety data sheets summarise the key information from the chemical safety assessments carried out as part of the registration process.

We require all of our European and non-European suppliers to complete a so-called “Certificate of Regulatory Compliance”. With this document, we gather information about the pre-registration and registration status of substances and products supplied to us.

Sometimes it can be difficult to receive all the answers through this certificate but, if needed, we follow up by contacting the supplier directly. Since the certificate is integrated into our internal chemicals management, all communications are archived so that they are easy to retrieve if we have inspections, internal audits or receive questions from customers.

We ourselves have registered over 100 substances. After our registrations are finalised, we communicate all relevant information to downstream users through the extended safety data sheet.

MISSING USES?

As a supplier, we have been surprised to have only received a few requests to cover missing uses in our extended safety data sheets. This might be because of the complexity and length of these documents but also because there is no standardised way to communicate uses and exposure scenarios yet. This can cause misunderstandings and difficulties when trying to interpret the information. We are aware that ECHA and industry are working on this issue, and we think this is a positive step.

In all cases where a missing use was reported to us, we checked the registration and noticed that the use was covered but the exposure scenario for it was not added to the extended safety data sheet that was sent to our customer. In these cases, we have been able to send an updated extended safety data sheet including the exposure scenario without needing to update the registration dossier.

CHECKING EXPOSURE SCENARIOS

When we receive an extended safety data sheet for our raw materials, we check that our uses are described in it. If they are not, we contact the supplier to discuss if the missing uses can be included and whether a new extended safety data sheet can be provided. In most cases, an informal discussion showed that the use was already considered by the registrant, but not communicated.

If the use is not covered, the necessary assessment can be done either by the supplier or the downstream user. In our experience, the supplier has usually agreed to carry out the necessary chemical safety assessment, create the chemical safety report and adapt the extended safety data sheet.

In certain cases where we wanted to keep our use confidential, we decided to carry out the assessment of the use ourselves. Consequently, we also prepared the chemical safety report. For this, communication between the supplier and downstream user is vital because the supplier has much of the information needed for the assessment.
SUPPORT FROM SECTOR ASSOCIATIONS

Sector groups of European associations can offer support and help to share the workload of downstream users. We have been involved in the REACH activities of several associations from the very beginning.

One of the main activities has been providing support for downstream users. They have, for example, promoted the use maps for each industrial sector. As registrants we have used the use maps relevant to our specific sector (such as those developed by, for example, AISE, Cosmetics Europe or IFRA) to make communication easier through the supply chain. Even though the use maps can be too broad for our particular need, we feel that they are very useful when we are trying to harmonise use descriptions. However, this may result in a huge number of exposure scenarios.

Companies and sector associations have also been working together to develop new ways of communicating safe use information. One example of this is the Safe Use of Mixture Information (SUMI). The SUMI aims to make the safe use information for mixtures more understandable for downstream users. We are currently collaborating with a sector association to develop a SUMI for one of our products.

We also recommend downstream users to look for further information on ECHA’s website, which contains information on registered substances, questions and answers, and many useful guidance documents. You should also contact your national helpdesks for advice. Our national Spanish helpdesk has been an excellent first point of contact for many of our questions.

REACH COMPLIANCE AS ADDED VALUE

One of our aims at KCE is to take responsibility for the environment and for health and safety throughout the life cycle of our products. We find that it brings added value to our products when the substance’s hazards and risks are taken into consideration at the very early stages of product development.

From a downstream user’s point of view, we want our suppliers to have the same aim and to fulfil it. For this, REACH is helping a lot.

Further information:

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

Who is a downstream user under REACH and CLP? (video)
https://www.youtube.com/watch?v=eohk3IPI2zs

Q&As on REACH
http://echa.europa.eu/support/qas-support/qas

Guidance documents
http://echa.europa.eu/support/guidance

Helpdesks
http://echa.europa.eu/support/helpdesks/

Terminology – in 23 languages

KAO CHEMICALS EUROPE, S.L.

Kao Chemicals Europe (KCE) is the European branch of the Kao Corporation Japan. Kao Japan is known on the Asian market as a producer of cosmetics and household products, but also has a large chemical branch.

KCE has its origins in surfactant technology and deals with products that are, for example, addressed to personal care, laundry and cleaning, and technical application markets. The implementation of REACH is organised centrally by the KCE Product Safety department. Five of its members are dedicated to work on REACH.

http://www.kaochemicals-eu.com/
Get wise – use Chesar

INTERVIEW BY HANNA-KAISA TORKKELI

Dr Dirk Schwartz from Bruno Bock Thiochemicals has experience from both REACH registration deadlines. Ahead of the second deadline in 2013, his small and medium-sized (SME) company decided to manage their registrations in-house. For the chemical safety assessment included in the registrations, his company uses ECHA’s Chemical Safety Assessment and Reporting tool, Chesar. “For me, Chesar is a key tool for managing the safety and exposure of our chemicals,” he says.

For the first registration deadline in 2010, Bruno Bock registered eight substances with the help of an external consultant. In 2013, 10 more substances were registered. “We decided in 2011 that we would use the IUCLID and Chesar tools and do everything on our own. We really felt confident that an SME could manage its own registrations,” Dr Schwartz mentions.

A clear advantage was that the company has detailed knowledge of the chemicals it produces. “Our substances have a very clear chemistry; we know the uses, the toxicology and we have everything very well documented. We don’t have any CMRs (carcinogenic, mutagenic or toxic to reproduction) or PBTs (persistent, bioaccumulative and toxic) in our portfolio – the hazard we have to care for is sensitisation and toxicity in general. We thought that with this knowledge it must be possible to submit a registration.”

INCREASED INDEPENDENCE THROUGH CHESAR

Dr Schwartz was not familiar with Chesar and needed training before he could start using the tool. “I attended a two-day webinar on the use of Chesar. This reassured me that I could start with the tool!”

He is now convinced that Chesar is the best tool for chemical safety assessments. “The charming idea of Chesar is that you can do the chemical safety report (CSR) on your own. It is automatically created through a IUCLID plug-in, and integrates IUCLID and Chesar data to generate a complete CSR. So the data is consistent in the dossier. In my opinion, this is a prerequisite for companies producing chemicals.”

Other benefits of Chesar for an SME are that it is free-of-charge and easy to install. “On top of the CSR, you can also use Chesar to create the extension to your safety data sheet (eSDS) to communicate the risks to your customers. This is very important, because SMEs don’t always have the budget to hire a consultant to do this,” Dr Schwartz says.

Chesar also allows companies to manage the safety information independently when there are changes in the dossiers. “I can update the information whenever I need to, without external help. This saves time and money. It is also a plus that Chesar is built by an authority. Using the tool gives me reassurance that we are applying the regulatory standards.”

STARTING WITH PRACTICAL EXAMPLES

ECHA has published an illustrative example of a CSR on its website to help companies compile their chemical safety report with Chesar. Dr Schwartz recommends this material to all Chesar newcomers.

BRUNO BOCK THIOCHEMICALS

Bruno Bock Thiochemicals is a privately owned company founded in 1937 in Hamburg. It employs 100 people in Germany and another 70 in its subsidiary in the United States. The company specialises in manufacturing organic sulphur chemicals and is the world’s leading producer of Thioglycolic Acid, 3-Mercaptopropionic Acid, Thiolactic Acid, and their derivative esters, Polythiols and salts. The main uses for these chemicals are in cosmetics, plastic additives, leather products, the polymer industry, water treatment and oilfields, and cleansing products.

http://www.brunobock.com/
“Playing around with the case study files is a good way to get the feeling of how the tool works. In addition, the practical examples for exposure scenarios are helpful too. Unfortunately, not all of the examples include the related Chesar files, which would help you to understand and compare the exposure scenarios from different industries,” Dr Schwartz says.

CHALLENGES WITH SUPPORT

At present, only around 10% of industry use Chesar for their safety assessments. According to Dr Schwartz this is a pity. “Big companies and associations should focus more on Chesar. For example, the registration of specialty chemicals in a small tonnage band, such as additives, is also important for big firms. So, industry associations should provide companies with specific environmental release categories (spERCs) in a Chesar format,” Dr Schwartz explains.

REACH 2018

Bruno Bock will register most of their substances, 20-30, by the last deadline of 31 May 2018. The preparations are already underway, but important business decisions still need to be taken. “The difference in costs for registering substances below or above 10 tonnes is significant. Of similar importance is the decision to register substances at either below or above one tonne. The decision on the tonnages has to be reflected in our business strategy for the next three to five years. We have to see whether it is in the interest of our customers to have a registration above 10 tonnes or not,” Dr Schwartz says. For registrations below 10 tonnes, a chemical safety report and toxicity screening tests are not needed.

For the 2018 deadline, Bruno Bock will most likely need help from consultants. However, it still wants to store all registration data in-house. “We will continue with Chesar, that’s for sure. If we outsource some of the registration preparations, the prerequisite will be for the consultant to work with Chesar,” Dr Schwartz concludes.

Further information:

Chesar
https://chesar.echa.europa.eu/

Practical examples of chemical safety reports

DID YOU KNOW?

The chemical safety report (CSR) documents the chemical safety assessment performed as part of the REACH registration. It is the key source from which the registrant provides information through exposure scenarios to all downstream users of chemicals. The CSR is also used as a basis for other REACH processes such as substance evaluation, authorisation and restriction.

ECHA’s Chemical Safety Assessment and Reporting Tool, Chesar, helps registrants to carry out the exposure and risk related parts of their chemical safety assessments to generate their chemical safety reports. It also allows the exposure scenarios to be exported for communication in the supply chain.

A new version of Chesar – Chesar 3.0 – will be available in 2016, together with IUCLID 6 and a series of CSA-related Guidance updates. The new release will improve the user friendliness of the tool and include the possibility to assess more complex substances.
The REACH information requirement for reproductive toxicity was recently amended by the European Commission. It replaced the two-generation reproduction toxicity test with the extended one-generation reproductive toxicity study (EOGRTS). You need to check that the information in your registration dossier complies with the new requirement.

WHAT IS EOGRTS?

The extended one-generation reproductive toxicity study (EOGRTS) is an OECD test method to assess the reproductive toxicity of chemical substances (OECD test guideline 443). The basic one-generation study design can be expanded by adding one or more further test packages:

- testing of reproductive performance of the offspring by mating them to produce the second filial generation;
- testing for developmental neurotoxicity; and
- testing for developmental immunotoxicity.

The situations where a further test package needs to be included are described in the REACH annexes and further explained in ECHA’s draft guidance on reproductive toxicity.

WHY EOGRTS?

EOGRTS allows you to gather rich toxicological information. It is capable of detecting effects which may be due to certain endocrine disrupting modes of action. It also offers the possibility to examine developmental neurotoxicity and developmental immunotoxicity in the same study.

In addition, the method has the potential to reduce the number of animals needed. Testing the offspring’s reproductive performance is conducted only when necessary, for example, if there is a significant exposure of consumers combined with specified toxicological properties.

Due to the improved sensitivity and level of information, the European Commission and the Member States considered this method to be suitable to meet the requirements of protecting human health.

WHAT DOES THIS MEAN FOR YOU?

Start by getting familiar with the amended REACH annexes and the draft guidance on reproductive toxicity. Then consider what the implications are for your registered substances. In particular, pay attention to the various study designs and decide whether the study design for your substance needs to be expanded.

EOCRA has contacted over 40 registrants whose testing proposals for reproductive toxicity are being examined by ECHA to explain the changed information requirements and give timelines for the next steps. Those who need to update their dossiers with revised testing proposals will receive further advice through REACH-IT in the next few months.

In addition, there are more than 200 draft dossier evaluation decisions with requests for information on reproduction toxicity, pending decision by the European Commission.

Even if you have already addressed the information requirements for the reproductive toxicity endpoint, you should familiarise yourself with the amended annexes and the respective guidance. If you do not already have an existing two-generation reproductive toxicity study in your dossier, you may need to update your registration to comply with the amended requirements.

WHAT SUPPORT IS THERE FOR REGISTRANTS?

ECHA is updating its guidance on reproductive toxicity to reflect the regulatory changes and aims to finalise it by July 2015. The draft is already available on ECHA’s website.

Further information:

- European Commission on EOGRTS
- Amended REACH annexes
- Draft guidance on reproductive toxicity (Guidance on IR&CSA – Chapter R.7a, Section R.7.6)
- EOGRTS in the EU Test Methods Regulation
- OECD Guidelines for the Testing of Chemicals – Health effects
- What about animal testing?
- Terminology – in 23 languages
New toolbox to find safer chemicals and alternative test methods

INTERVIEW BY PÄIVI JOKINENI

Do you need help to find safer chemicals or alternatives to testing on animals? There are a number of tools available – also now from the Organisation for Economic Cooperation and Development (OECD). At the end of January, the OECD published a Substitution and Alternatives Assessment Toolbox. ECHA Newsletter spoke with Dr Eeva Leinala and Ms Baucher from the OECD, who are responsible for risk reduction projects, to learn more about the toolbox and its benefits.

“The toolbox is a compilation of resources including pointers to relevant information and tools on chemical substitution and alternatives assessment,” Dr Eeva Leinala, Principle administrator in the Environment, Health and Safety Division of the OECD says.

CHOOSE THE RIGHT TOOL

All tools included in the tool selector section deal with chemical hazard assessment. It has been built on an interactive platform which helps users to find the tools that could be most useful for them. “For example, if the user is interested in ecotoxicity but also wants to find a tool that is free of charge and has some guidance included, they can select these three attributes in the tool selector which then filters its contents and identifies the suitable tools,” Dr Leinala explains.

Using the tool selector makes it easier and more efficient to choose the right tool. It also allows the user to compare the different tools to see what would be most useful for their needs.

The tool selector includes around 40-50 hazard assessment tools and links to around 30 non-hazard assessment tools. “In terms of the non-hazard assessment tools, it is an early compilation and we know that it can be later expanded upon to include additional tools on areas such as exposure assessment, lifecycle analysis, material availability and some socio-economic analysis,” Dr Leinala summarises.

FINDING SAFER ALTERNATIVES

The toolbox contains guidance documents and different alternatives assessment frameworks. This framework section also includes the OECD Meta-Review that was published in 2013. “The Meta-Review, which is a literature review, looked into the current landscape of substitution and OECD practices in member countries. The toolbox was based on this publication,” Ms Marie-Ange Baucher, Administrator in the Environment, Health and Safety Division of the OECD adds.

Industry, academia, governments and non-governmental organisations have provided case studies that look at specific substances or specific methodologies. This first version of the toolbox includes around 40 case studies but more examples will be added in the future. “There are also links to toolkits and product rating systems where the user can find examples of what others in the field have done so far,” Dr Leinala notes.

Finally, a list of regulations and restrictions in OECD member and non-member countries, and industry and NGO restriction lists have been included in the toolbox to show which chemicals have been regulated or restricted in different areas. This can help users to find safer alternatives.

AVOID RECREATING SOME-THING THAT ALREADY EXISTS

“One of the main ideas of the toolbox was to help those people who
The development of the OECD Substitution and Alternatives Assessment Toolbox has been part of the work plan of the OECD ad hoc group on substitution of harmful chemicals and was started in 2012. The ad hoc group is co-chaired by the U.S. Environmental Protection Agency and the European Chemicals Agency. Its members come, for example, from government agencies, industry stakeholders, trade associations and non-governmental organisations across OECD member countries.

DID YOU KNOW?
Are you starting to think about chemical substitution and alternatives assessment, be they in a government agency, a company or a consultant. One of the difficulties is finding all the existing tools and getting an early indication of what the different attributes of the tools are. The toolbox is therefore a good starting point showing what tools could be used and what frameworks already exist,” Dr Leinala points out. She reminds also that one of the goals of the toolbox is to reduce duplication. With the help of the resources available in the toolbox, users do not need to recreate something that already exists.

MORE EXAMPLES AND TOOLS TO BE ADDED
“We aim to regularly update the toolbox, particularly by adding new tools to the tool selector. This is done partly in discussions within the OECD, but we invite all stakeholders to submit information that can be added to the toolbox. General comments on how to improve it in the future are also very much welcomed,” Ms Baucher concludes.

If you have any comments or suggestions related to the toolbox, or have ideas for new functionalities, send your feedback to: ehscont@oecd.org.

Further information:
OECD Substitution and Alternatives Assessment Toolbox
http://www.oecdsaatoolbox.org
OECD
http://www.oecd.org/
Are there safer alternatives?
http://echa.europa.eu/chemicals-in-our-life/are-there-safer-alternatives

Upcoming

April - June 2015

Member State Committee: 20-24 April and 8-12 June
Meeting of Exchange Network on Exposure Scenarios (ENES): 20-21 May
ECHA’s 10th Stakeholders’ Day: 27 May
Helsinki Chemicals Forum: 28-29 May

Committee for Risk Assessment: 1-5 June
Committee for Socio-economic Analysis: 8-12 June
Biocidal Products Committee: 15-18 June
ECHA Management Board: 17-18 June
Enforcement Forum: 23-25 June

Webinar recordings
Presentations and material from webinars are available on ECHA’s website
http://echa.europa.eu/support/training-material/webinars