ECHA
EUROPEAN CHEMICALS AGENCY
1 NO
February 2016

Newsletter

A look ahead at 2016 and beyond...

Welcome to our first newsletter of 2016. I hope you are feeling refreshed and ready for the year.

For us, the year started with a big bang. In January, we launched our greatly improved **portal of information on chemicals.** You can now easily find information on 120 000 substances used in Europe, in three layers: a simple infocard giving summarised safety information on substances in plain English, a more detailed brief profile and, finally, the full source data. We see this revamped portal as an important contribution to advancing the knowledge and safe use of chemicals in Europe and the rest of the world. You can access it directly on our homepage and I invite you to test it out and give us your feedback.

We also have our eyes firmly set on the last **registration deadline in 2018**. This is the last and – with many small and medium-sized companies affected – the most challenging leg on the journey of having a full picture of the chemicals on the EU market.

If you already know that you have obligations for REACH 2018 but have not yet started to prepare, my advice is to get moving now. There is a lot of material on our website to help you. If this is your first time, I invite you to follow our six steps to successful registration. So far, we have launched the first two steps and will help you through the remaining four steps throughout the course of this year – so that you are in time for 31 May 2018.

As you know, we are working on making our processes and tools simpler. This spring, we will launch more user-friendly IT tools: IUCLID for creating dossiers; REACH-IT

for submitting them; and Chesar for preparing your chemical safety assessments. These tools will not only become easier to use, but will also include more steps, which will improve the completeness of information in your registrations.

This year, we are increasing our communication to **downstream users**, formulators and end users of chemicals, many of whom are still not aware of their roles and responsibilities under REACH. Downstream users are a very important audience as they play a key role in improving the safe use of chemicals in workplaces and in communicating safe use information both up to their suppliers as well as down to their customers – even all the way to consumers if they use substances of very high concern (SVHCs) in articles placed on the market.

We are playing our part in speeding up Europe's efforts for the **global sustainable development goal** of protecting the world from the adverse effects of harmful chemicals by 2020. This is a big challenge but achievable one as long as we all work together.

Finally, a warm thank you to the 39 small companies who welcomed ECHA staff to visit their business. Our **visits programme to small companies** took place at the end of 2015 and gave 40 of my colleagues an opportunity to gain first-hand insight into the challenges faced by small and medium-sized businesses in 12 different EU countries. My staff participated enthusiastically and brought back many views, ideas and lessons learnt from their meetings with you – making it a beneficial learning experience for our entire Agency. We will use this feedback to further improve our service.

I wish you all a successful year ahead and look forward to seeing you at one of our events at ECHA.

REACH 2018: http://echa.europa.eu/reach-2018
Downstream users: http://echa.europa.eu/downstream
Getting started with EU chemicals legislation: http://echa.europa.eu/support/getting-started

Geert Dancet
Executive Director

"We are playing our part in speeding up Europe's efforts for the global sustainable development goal of protecting the world from the adverse effects of harmful chemicals by 2020."

Next issue of the Newsletter will be published in mid-May.

In this issue:

To subscribe to ECHA news, register at: http://echa.europa.eu/subscribe

Disclaimer: The views presented in the quarterly Newsletter do not necessarily represent the official position of the European Chemicals Agency. All the links are up to date at the time of publication.

ISSN: 1831-4953

Editor-in-chief: Lindsay Jackson
Editors: Päivi Jokiniemi (on maternity leave), Hanna-Kaisa Torkkeli

European Chemicals Agency
Annankatu 18, P.O. Box 400,
FI-00121 Helsinki Finland
Tel. +358 9 6861 80

newsletter.echa.europa.eu
echanewsletter@echa.europa.eu
Follow @ EU_ECHA on Twitter
Like us on Facebook
Follow us on LinkedIn

New generation of IT tools - what changes?

TEXT BY HANNA-KAISA TORKKELI, VASILEIOS TSIFOUTIS

ECHA will launch revamped IT tools this spring. The applications will be much more intuitive and easier to use. What are the new features of the tools?

IUCLID 6

Installing IUCLID 6 on a desktop computer will be much easier as no additional software is required. Help on different functionalities, such as dossier creation, will be available in your own language.

OECD harmonised templates

The updates to the harmonised templates (OHT) will help you to report your information in a clear and consistent way, improving the quality of your registration dossier.

Better structured information also makes evaluating, publishing and searching for data more effective.

The updated OHTs include:

- **Revised templates for hazard information.** The *Administrative data* section will be enhanced with a clearer field organisation and standard phrases to justify reliability scores for studies and data-waiving cases. The test material used in the studies can be defined in a separate object, which can be linked in the *Materials and methods* section of all study records where the same material was used.
- **New templates on use and exposure information of the substance.** You can report each use as a separate record which includes both the use description and the information related to the exposure assessment.
- **Extension of the use description** allows you to provide additional information on the type and conditions of use, making more transparent for the authorities and the public how the risks are controlled.
- **Dedicated fields to report information on the intermediate status** (chemical reaction, reaction products) and the application of strictly controlled conditions of the substance are also available.

Substance identity profile

If you are a lead registrant, IUCLID 6 will allow you to include information on the substance identity profile (SIP). The SIP describes the collectively agreed scope of the joint submission by defining the compositions and forms of the substance that are covered by the jointly submitted data, i.e. the hazard information and classification.

SIP compositions included in the IUCLID 6 lead dossier will be visible on the REACH-IT joint submission page to all members of the joint submission, so they can make sure that their substance is covered. It will also help connect potential registrants with the appropriate joint registration during the inquiry process.

Revised completeness check

The completeness check that ECHA performs on each incoming registration will be revised. It will be adapted to the new IUCLID formats and changed information requirements: for example, the extended one-generation reproductive toxicity study (EOGRTS) is now the standard information requirement for reproductive toxicity under REACH.

As before, the IUCLID Validation Assistant will be updated so that you can check your dossiers before submitting them to ECHA. The completeness check will be complemented by a manual verification of those elements that cannot be checked automatically.

***

A new test version of IUCLID 6 has been released on the IUCLID 6 website. Try it and familiarise yourself with some of the new features. Keep in mind, however, that test versions do not contain all the features of the official release.

IUCLID 6 will be launched before the release of REACH-IT to allow you to install it and migrate your IUCLID 5 database. Once the new REACH-IT is published, you will only be able to submit IUCLID 6 dossiers.

Information related to IUCLID 6 can be found on the IUCLID 6 website.
https://iuclid6.echa.europa.eu/

REACH-IT

User interface

Improved and simplified workflows will ease the submission of your dossier. You will also be able to see the upcoming deadlines and actions (e.g. submission of a requested update) at a glance. The contact management and the search function will be optimised and accessing already submitted information will be easier.

Online registrations

If you are a member of a joint submission, you will be able to build and submit your IUCLID 6 member dossier online in REACH-IT, through

a simplified interface. However, you can only create your dossier online if you report standard information requirements, have only one composition and you fully rely on the hazard information provided by the lead.

If these conditions do not apply, you need to use the standard IUCLID application to build your dossier.

One substance, one registration

There has always been a requirement in REACH for 'one substance, one registration'. However, following the *Implementing Regulation on joint submission of data and data sharing*, REACH-IT has been updated to make sure that dossiers for the same substance cannot be submitted outside of a joint registration. Individual registrations already in REACH-IT can only be updated under specific conditions.

! If you need to submit an initial dossier or an update (e.g. requested update related to compliance check) after the release of the new REACH-IT, you need to make sure that you are using IUCLID 6.

REACH-IT

***

For IUCLID and REACH-IT, the user support will be integrated into the tools. For REACH-IT it will be translated into 22 EU languages. ECHA will also simplify the user manuals, which will remain available in 23 EU languages on its website.

CHESAR 3

Chesar 3 will exchange data with IUCLID more effectively than before. It will also enable better assessment of complex substances, such as multi-constituents or UVCBs, or substances transforming during use or in the environment.

You will also be in a better position to report to the authorities how you have carried out your safety assessments.

In addition, Chesar 3 includes additional functionalities both for the environmental and human health assessments, for example, the possibility to edit several contributing scenarios at the same time when the same changes apply to all of them. The help text has also been integrated in the application and generating your chemical safety report (CSR) will also be easier.

Any assessments you have carried out with Chesar 2 will automatically be migrated to Chesar 3.

More information can be found on the Chesar website.
https://chesar.echa.europa.eu

chesar

***

Training and support on the new IT tools is currently under planning and will be announced soon on ECHA's website.

Further information:

ECHA clarifies criteria for 'one substance, one registration', News alert 27 January 2016
http://echa.europa.eu/view-article/-/journal_content/title/reach-it-is-back-up-echa-clarifies-criteria-for-one-substance-one-registration

Registrants of the same substance must be part of the same registration, News alert 25 January 2016
http://echa.europa.eu/view-article/-/journal_content/title/registrants-of-the-same-substance-must-be-part-of-the-same-registration

REACH data-sharing principles clarified, News Alert 07 January 2016
http://echa.europa.eu/view-article/-/journal_content/title/reach-data-sharing-principles-clarified

Information session on the new registration process, 4 Nov 2015
http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/information-session-on-new-registration-process

Completeness check to enhance availability of information, Newsletter 4/2015
http://newsletter.echa.europa.eu/home/-/newsletter/4/2015

Prepare for IUCLID 6, News item 24 June 2015
http://echa.europa.eu/view-article/-/journal_content/title/prepare-for-iuclid-6

REACH 2018 - step-by-step advice
http://echa.europa.eu/reach-2018

Terminology - in 23 languages
http://echa-term.echa.europa.eu/

TIMING OF THE LAUNCHES

The updated IUCLID used to create registrations and Chesar to prepare chemical safety assessments will be published on the **last week of April**, followed by an update of the submission tool REACH-IT **at the end of May.**

Perspectives of two big companies

How to prepare for the new IT tools

TEXT BY HANNA-KAISA TORKKELI

Are you managing your substance data on IUCLID installed on your company's own servers? If so, you should start preparing your IT infrastructure for the new tools soon. We asked Clariant's Head of Global Regulatory Compliance, *Dr Michael Hartmann* and Evonik's Senior Expert of Product Stewardship, *Mr Thomas Becher* how their companies are getting ready.

Clariant and Evonik are the biggest IUCLID users in terms of number of registrations. Dr Hartmann and Mr Becher have both been involved in the testing and development of IUCLID 6 and Chesar 3 through the European Chemical Industry Council's (Cefic) working groups.

"We used our experiences from the various test phases for IUCLID 6 to prepare ourselves for the launch. Our IT department mastered the installation and setup of IUCLID 6 including significant changes that came with the switch to a different application server (GlassFish) that had not been included in our IT infrastructure before. To do this, we needed to build up new expertise," says Dr Hartmann.

Evonik has also benefited from their testing experience. "Our IT department has focused on installing the test of the server version that runs in our own IT environment and on data migration. At present, we are integrating more end-users in the testing to make them familiar with the new functionalities and the modified data structure," Mr Becher explains.

Evonik currently operates seven productive IUCLID 5 installations and one training system. IUCLID 6 offers new features for controlling access to different installations.
"We are investigating if we can combine our different IUCLID 5 systems into one large Evonik IUCLID 6 installation with better control instruments for data access."

For Clariant, the testing work requires timely reservation of installation slots from the IT department. "To do the testing properly, we need the test versions at least 4-6 weeks before the actual test phase schedule," Dr Hartmann points out, and continues: "New training requirements will be a huge one-time effort for our organisation, but it will not affect our registration objectives for 2018."

'SIGNIFICANT IMPROVEMENTS'

Mr Becher expects that the new features of IUCLID 6 are designed to ease the experts' work with the database. "However, as IUCLID is quite a complex tool these features may also risk less experienced users getting lost in the system," he says.

For REACH-IT, he looks forward to significant improvements in the general workflows, messaging system as well as a better search and download of information. "But we only have limited information about the new version of REACH-IT and no hands-on experience so far", he adds.

"With the stricter implementation of the 'one substance, one registration' principle and the new rules for the completeness check, the changes made to the IT tools are the most extensive since REACH entered into force. We expect a permanent increase in workload and hope that the combination of all these changes will not delay us in submitting our dossiers to ECHA".

For Dr Hartmann the main thing is that all three applications work together without problems to ensure a smooth registration process. "We expect IUCLID 6 to have a more detailed user administration, stronger support for consistent data maintenance and a better help system and training material that allows easy access also for inexperienced users. As for Chesar, we are looking forward to, for example, better integration with IUCLID 6 to avoid duplicate maintenance of data."

Further information:

IUCLID 6 website
http://iuclid6.echa.europa.eu

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

REACH-IT
http://echa.europa.eu/support/dossier-submission-tools/reach-it

REACH 2018 - step-by-step advice
http://echa.europa.eu/reach-2018

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

TIPS FOR REACH 2018 REGISTRANTS

Mr Becher and Dr Hartmann share their tips on for companies registering for the first time for the 2018 deadline.

- **Get familiar** with the IT tools as soon as possible.
- **Check** whether the installation and operation of the IT tools require internal approval procedures – especially if you use the server version of IUCLID.
- **Build up** expertise. If you will download the server version, get to know GlassFish, which is the new IT platform for IUCLID.
- **Check** ECHA's website for information on the update schedule, training material and webinars for the new tools.

Do you know what the desktop and server versions of IUCLID are? Read the online version at
http://newsletter.echa.europa.eu

REACH 2018

How to get organised with your co-registrants

TEXT BY ANCA-MIRELA PETRISOR

Do you need to register a substance before 2018? Have you already found other companies that have registered or will register the same substance as you? The next step is to get organised with your co-registrants and work together to share data and its costs.

We interviewed two companies who have experience from the previous deadlines of working in a substance information exchange forum (SIEF), splitting the work and costs.

How did you start cooperating? Did you join an existing SIEF or form a new one?

Samantha Schiavon, KAO Chemicals:

We have experience of both. For substances already registered we joined an existing SIEF, got in contact with the lead registrant and after approximately six months received the information we needed to prepare our registration.

In other cases, my company has been the lead registrant. We have contacted other companies to identify potential co-registrants and get the available safety data.

Jörg Blumhoff, Organica:

To register a very important raw material, we joined an existing SIEF. The initial contact was very easy and the lead registrant replied very quickly. Along the way, communication was not very effective, but we succeeded in registering our critical substance together with six other companies.

Did you split the work between the members of the SIEF or did you rely on the lead registrant to do it all? Did you outsource any work?

Ms Schiavon:

For us, the most common practice is to manage everything as the lead registrant. It's better and easier to organise the work rather than to split it.

As for using external help, yes, we outsourced some of the work on assessing risks.

Dr Blumhoff:

We joined the SIEF as a member, so there was little work to be done. Basically, the information, the data and the letter of access (LoA) were provided by the lead registrant and we just had to pay for it.

To help with our registration tasks, we worked with consultants and laboratories.

How did you share the costs?

Ms Schiavon:

We shared all costs between the members of the SIEF for the new safety data that we needed, the administrative work and the work outsourced.

Dr Blumhoff:

In one SIEF costs were split equally in relation to the tonnage band registered. So, as a small company producing substances between 1 to 10 tonnes per year, our cost was, of course, cheaper than for the other companies.

At the end of the day, joining an existing SIEF and getting our substance registered was a good experience.

In view of the 2018 deadline, do you expect new members to join the SIEFs you are in?

Dr Blumhoff:

Yes, I expect new members to join the SIEFs we are in at the moment. Our resources do not allow us to be lead registrants in these SIEFs, so I do not think we have to prepare anything for the newcomers.

For some SIEFs, where there's no communication at present, but which will end up being very important for us, we will probably have to contact the other SIEF members to see if they really want to register the substance. If there is no reaction, we will have to register those substances by ourselves.

***

Read also **our top tips for the upcoming REACH 2018 deadline**, which is in many ways different from the previous registration milestones.

Further information:

REACH 2018 phase 3: Get organised with your co-registrants
http://echa.europa.eu/reach-2018/get-organised-with-your-co-registrants

Support web pages for registration
http://echa.europa.eu/support/registration

REACH 2018 - step-by-step advice
http://echa.europa.eu/reach-2018

Terminology - in 23 languages
http://echa-term.echa.europa.eu/

KAO CHEMICALS

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, for the 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 working full time on REACH.
http://www.kaochemicals-eu.com/
http://www.kao.com/jp/en/corp/

ORGANICA FEINCHEMIE GMBH WOLFEN

ORGANICA is a small fine chemical company, specialising in hazardous chemical reactions and focused on the exclusive synthesis of fine chemicals. The company offers customised synthesis of advanced organic intermediates for major pharmaceutical and industrial companies around the world.

http://www.organica.de/en/

ECHA'S TOP TEN TIPS FOR 2018 REGISTRANTS

A lot can be learnt from successful registrants. However, we expect that the 2018 registration deadline will be different: there are many inexperienced and/or small and medium-sized companies registering; the SIEFs will be smaller; and there is a lot of new data to be shared, generated and documented. The new I*mplementing Regulation on joint submission of data and data sharing* is expected to guide companies better on how to fulfil their REACH requirements. We share with you our top tips for REACH 2018 on how to get organised with your co-registrants:

1. **Get in touch** with your co-registrants through the pre-SIEF page of REACH-IT. Other registrants may have used other identifiers for the same substance, so widen your search by using the '*related substances*' option.

2. **Take the initiative** in SIEFs that are crucial for your business, especially when no other SIEF member seems to be willing to move ahead.

3. **Make sure** that you discuss substance sameness before you start sharing data. This way you will spend your time and money on the right substance from the very beginning.

4. **Focus your discussions** on getting things done in the SIEF – and if you cannot agree on how to distribute work among the SIEF members, consider hiring a consultant. Act in time and establish a timeline for your registration.

5. **Provide the information needed** to move on with the preparation of the joint registration dossier without unnecessary delays.

6. **Make use of the material and IT tools** that ECHA has developed to help you to comply. Bringing a dossier to an acceptable quality level only after it has been submitted may be inefficient and costly.

7. Sharing data is **not meant to create profit** for anyone, but to share the actual costs between all co-registrants. If you start to prepare a dossier for 2018, establish a robust cost sharing model. If you join an existing registration, request a breakdown of the costs and only pay for the data you need to satisfy the information requirements relevant for your registration.

8. **Keep track** of all communication between SIEF members.

9. **Treat the company/person** you are negotiating with as you would expect to be treated.

10. Remember that preparing a **registration is a shared and individual responsibility** of all co-registrants. If you are not the one doing the work, check regularly to make sure that it is really progressing.

Explaining REACH:

Want to know about... how a substance is selected for regulatory risk management?

TEXT BY NEDYU YASENOV

Ever wondered how your substance is selected for risk management?

We have chosen two substances as examples to show you how it works.

FROM SCREENING TO A PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

Dioctyltin dilaurate (EC 222-883-3) is an organometallic substance, which was registered ahead of the second REACH deadline in 2013. It is used in the production of polymers, masterbatches and compounds, additives and plastics. In the Classification and Labelling Inventory a significant proportion of manufacturers and importers classified it as toxic to reproduction. The inventory also contains notifications reporting specific toxicity to the thymus through repeated exposure.

Dioctyltin dilaurate was picked up by the automated IT screening performed annually to try to identify potential substances of very high concern (SVHCs) and consider them for regulatory risk management. It is done based on specific criteria developed by ECHA and the Member States. Dioctyltin dilaurate was identified as potentially hazardous based on the significant number of notifications with severe classifications. It was further prioritised for manual verification because of the wide range of uses and potential for exposure to humans and the environment.

Based on the screening, the Swedish Chemicals Agency examined the substance. It found that the concerns for reproductive and specific target organ toxicity were reasonable and valid. It then concluded that harmonised classification and labelling was the most appropriate Community-wide risk management option for this potential reproductive toxicant. In September 2015, it notified ECHA of its intention to prepare a dossier for the harmonised classification and labelling (CLH) of dioctyltin dilaurate.

The substance is listed in the Registry of Intentions (RoI), which is a list of the authorities' plans for future risk management measures. Being in the RoI gives an important signal for industry to ensure that their registration dossiers are up-to-date. It also gives industry and other stakeholders more time to prepare for commenting later in the process. At present, ECHA is waiting for Sweden to submit a dossier for CLH.

Once the proposal for CLH is successfully submitted, a public consultation will begin. During the consultation, all concerned parties can comment on the proposal. These comments are taken into account when the proposal is discussed in ECHA's Committee for Risk Assessment.

FROM RISK MANAGEMENT OPTION ANALYSIS TO THE CANDIDATE LIST

1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters (EC 271-094-0, 272-013-1) are mixed alkyl diesters used as plasticisers and lubricants in adhesives, coatings, building material, cable compounding, polymer foils, PVC compounds and artist supplies (such as modelling clay and finger paints). These uses can lead to exposure of both consumers and workers.

Both substances are also classified as toxic for reproduction (Repr. 1B) when they contain 0.3% or more of dihexyl phthalate (EC 201-559-5).

Based on these facts, the Swedish competent authority performed a risk management option analysis (RMOA) for these substances in 2014. The purpose of the RMOA is to help authorities decide whether further regulatory risk management activities are required and to identify the most appropriate instrument to address their concern.

The substance was listed in the Public Activities Coordination Tool (PACT). This is a list of all the substances for which an RMOA or an informal hazard assessment for specific properties is either under development or has been completed. This list also give forewarming to industry and stakeholders of the next steps.

Sweden concluded that inclusion in the Candidate List was the appropriate regulatory risk management measure. It also believed that it would encourage companies to start substituting the substance already before it is included in the Authorisation List (Annex XIV of REACH).

Placing a substance on the Candidate List would also make sure that information about the substance contained in articles is made available to consumers, workers and ECHA. Inclusion in the Authorisation List would require manufacturers and importers as well as users to consider replacing it with suitable safer alternatives.

In February 2015, the Swedish competent authority submitted a dossier to identify the mixed alkyl diesters as SVHCs because of their toxic for reproduction properties. In its meeting in May 2015, the Member State Committee unanimously agreed to the identification of the substances as SVHCs. This led to the substances being included in the Candidate List in June 2015.

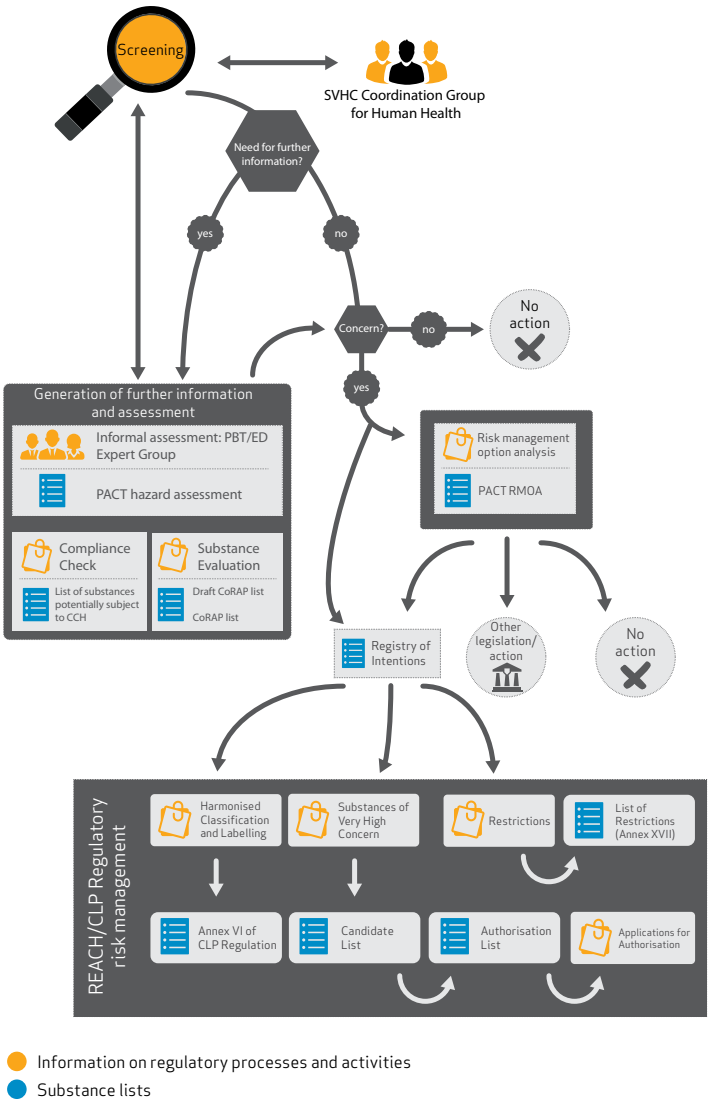
Further information:

Substances of potential concern
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

SVHC Roadmap to 2020
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

Terminology - in 23 languages
http://echa-term.echa.europa.eu/

Image on the right:
The potential routes to regulatory risk management, Interactive version available online at:
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern



WHAT YOU CAN DO

- Keep your dossier, including use and volume information, up-to-date with the best quality data you have. Poorly justified and completed dossiers will be more likely selected for scrutiny.
- Follow ECHA's news and website so that you know what is planned for your substance (e.g. PACT, CoRAP, Registry of Intentions)
- Provide your comments and further information timely through public consultations. The deadlines are tight and inflexible.

SCREENING SCENARIOS

Harmonised classification and labelling (CLH)
The aim of the CLH screening is to identify substances on the EU market that are not currently harmonised, but for which a harmonised classification and labelling is justified. Priority is given to substances with potential carcinogenic, mutagenic and toxic for reproduction (CMR) properties, or respiratory sensitising properties and with wide dispersive uses.

ECHA has developed scenarios that analyse the self-classifications from registrants and notifiers of substances with CMR and respiratory sensitisation properties. In addition, substances that are structurally similar to these are identified, as are substances with these properties that have been identified by external bodies (e.g. non-EU authorities).

Substance of very high concern (SVHC)
The SVHC screenings focus on substances with harmonised classifications such as CMR category 1A/1B and with PBT or endocrine disrupting properties at the level of the substance, its constituents or degradation products. Furthermore, the wide-dispersiveness of the uses is considered.

Explaining biocides:

Want to know about...the Review Programme?

TEXT BY VEERA SAARI

The Review Programme is the work programme to examine existing biocidal active substances which were already on the market on 14 May 2000. All biocidal products containing any of the active substance/product-type combinations included in the programme can remain on the market without an authorisation while waiting for the substance to be approved - subject to national law.

WHICH SUBSTANCES ARE IN THE REVIEW PROGRAMME?

More than 650 active substance/product-type combinations are included in the programme. The combinations are listed in Annex II of the Review Programme Regulation.

CAN SUBSTANCES STILL BE INCLUDED IN THE PROGRAMME?

Yes, in the following circumstances:

- A substance/product-type combination was previously not considered to be in the scope of the biocides legislation but now is following a change in guidance or legislation.
- The identity of a substance already present in the programme is redefined. In this case, you can add a substance that corresponds to the former identity.
- All previous participants (i.e. companies that have expressed an interest in getting a particular substance/product-type combination included in the programme) have withdrawn their interest. Other companies with an interest can take over the role of participant to keep the substance/product-type combination in the programme.

In 2016, there are two important deadlines:

1. Following the redefinition of *in situ* generated active substances in 2015, notify alternative precursors or systems for *in situ* generation by **27 April 2016**. By the same deadline, you can also notify an active substance that corresponds to the former identity of a substance which has been redefined as *in situ* generated. (*In situ* generated = active substance is generated from one or more precursors at the place of use.)
2. To include active substance/product-type combinations that were previously considered excluded from the scope of the biocides legislation based on the recently revoked Manual of Decisions, declare an interest to notify to ECHA by **30 October 2016**.

Besides these deadlines, there are currently **12** active substance/product-type combinations listed on the "Upcoming deadlines" page on ECHA's website which are considered eligible for inclusion in the programme, resulting from either the withdrawal of all the participants (interested companies) or redefinition of the substance. Check the deadlines to notify ECHA of your interest in these – next upcoming ones are in September and November 2016.

IS THERE A FEE FOR NOTIFYING?

The notification can be done for an active substance in one or more product types. There is a fee for the notification, but this will be deducted from the amount you have to pay when you later apply for approval of the active substance/product-type combinations.

WHEN WILL THE DECISIONS BE TAKEN FOR THE SUBSTANCES IN THE REVIEW PROGRAMME?

By 2024, all the active substances included in the programme should have been examined by a Member State and they should have received either an approval or non-approval decision. There are legal deadlines for Member States to evaluate the substances. The deadlines are listed per product type in Annex III to the Review Programme Regulation. The approval decisions will be given for a defined period of up to 10 years and are renewable.

***

Join us in Helsinki for our free **Biocides Stakeholders' Day** on 1 September 2016 in person or online to hear the latest updates, advice and experience. More information at http://www.echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/biocides-stakeholders-d-3

Further information:

Biocides legislation
http://echa.europa.eu/regulations/biocidal-products-regulation/legislation
Review Programme Regulation (EU) No 1062/2014 under Implementing and delegated acts

Upcoming deadlines
http://echa.europa.eu/regulations/biocidal-products-regulation/upcoming-deadlines

Biocides - state of play and challenges ahead

TEXT BY JULIA SIERRA

We spoke with Mr Michael Flüh, Head of Unit and Mr Pierre Choraine, Head of Sector from the European Commission's Health and Food Safety (SANTE) Directorate-General, to look at the next milestones for the biocides regulatory framework.

©EC

© ECHA

Mr Michael Flüh (left) and Mr Pierre Choraine from the European Commission's Health and Food Safety (SANTE) Directorate-General give their views on the current status of the biocides regulation and talk about the next milestones.

ON TRACK: BIOCIDES DEADLINES

By 1 September 2015, ECHA had received 158 applications from companies asking to be included on the list of active substances and suppliers, known as the Article 95 list.

"Companies are aware of their obligations under the Biocidal Products Regulation (BPR). Now it is the national authorities' responsibility to make sure they comply with the legislation," says Mr Flüh.

In the first phase of enforcement, Member States check the documentation sent by the companies and verify whether it is compliant with the legislation or not. However, there may still be products placed on the market without the authorities' knowledge.

"Therefore, there needs to be a second phase when authorities must go from paper checks to supermarkets or factories to verify whether a product is compliant or not. This will be a major challenge for enforcement authorities in the future", he adds.

Mr Choraine stresses that the European Commission now expects the national authorities to enforce the obligation. "We recognise though that this is a complex matter and that Member States will have to use their sensible judgement and take proportionate actions. There might, for instance, be cases where non-compliance could be the result of difficult data-sharing negotiations.

In addition, the Review Programme is now on track with an average of 50 assessments concluded each year. "ECHA is achieving the planned output," says Mr Flüh. The programme is expected to be finalised by 2024. "Only then, will the mission be achieved", he points out.

You can read more about what the Review Programme is on page 10.

HIGH EXPECTATIONS FOR UNION AUTHORISATION

Union authorisation (UA) enables companies to get authorisation for their biocidal products at Union level with just one application. This allows quick and easy access to the whole EU market and reduces the administrative burden on applicants. After more than a year in place, companies are now starting to explore this new possibility.

"In the beginning, the number of applications received for Union authorisation was quite low. Now, the trend has changed and the number is continuing to rise. We hope that this is not a one-off event and that it becomes a stable and predictable trend," Mr Flüh remarks.

"We see this EU-wide authorisation offering a lot of benefits for industry so our expectations are high," he says and continues: "The legislation is still quite new and it can take some time before the market is fully aware of the benefits they can get out of it".

NEW STUDY ON FEES

Last year, the European Commission launched a study to evaluate the fees companies need to pay for biocides applications. It was triggered by the fact that initial expectations for fees from Union authorisation were not being met.

"Our concern is that our assumptions, such as fee-based income for ECHA, are not going to materialise to the same amounts as anticipated a few years ago," Mr Choraine explains.

Some companies have also complained that the fees are too high. "In this case, the fees are an obstacle for the market to submit applications".

The outcome of the study is expected shortly. "Based on the results, we will see whether some of the assumptions made at the start of the BPR have to be reconsidered and whether the amount of fees has to be adjusted".

RAC AND THE BPC: A GOOD INTERACTION IS VERY IMPORTANT

Mr Flüh and Mr Choraine both highlight the importance of a good interaction between the Committee for Risk Assessment (RAC) and the Biocidal Products Committee (BPC) for the decision-making of the European Commission.

The Commission approves or rejects an application for an active substance based on the opinion of the BPC. When the substance is carcinogenic, mutagenic and reprotoxic (CMR), both the BPC and the Commission need have the opinion of the RAC on the classification of the substance. This information comes from the RAC. Therefore, a good synchronisation of both RAC and BPC opinions make the work easier.

"It is very important that when the BPC delivers its opinion on an active substance, that we have the RAC opinion on the classification of the substance. This is crucial for the smooth functioning of the BPC's work," they say.

ENFORCEMENT GROUP

At present, biocides are not part of ECHA's Enforcement Forum, which deals with enforcement issues throughout Europe. But ECHA and the Commission have recently established a Biocides Enforcement Group.

"The idea is to meet back-to-back with ECHA's Forum to benefit from the experts present at that moment," Mr Choraine explains.

The group will discuss how to best use the resources and exchange views and priorities on enforcement.

"The idea is that the group will eventually be integrated into the Forum, although for the moment it is a separate entity," Mr Flüh concludes.

NEXT MILESTONES

» **Improving the IT tool:** The Commission wants ECHA to improve the biocides IT tool R4BP.

"The underlining idea is to give industry and applicants a powerful tool to enable them to fulfil their legal requirements. The users are still encountering problems when making use of R4BP," Mr Flüh says.

» **Treated articles:**
To place articles treated with a biocidal product on the EU market, the active substance needs to be approved or under evaluation. For those active substances that are not yet in the approval process, companies need to submit an application for the active substance by 1 September 2016 to continue to be legally on the market.

"Treated articles (Article 94) are very relevant for the import of articles into the EU. The legislation says that articles can only be treated with substances under assessment in the EU. This is an issue for international trade and we have informed third countries. It will also be an issue for enforcement in the future, and we have to continue making efforts to inform our trading partners," Mr Flüh says.

» **Maximum residue limit (MRL):** MRL is the highest level of a pesticide residue that is legally accepted by the EU in or on food or feed. The amounts of residue found in food must be safe for consumers and must be as low as possible. Biocides may also end up in the food chain and can present a health risk.

"At the moment, we are still discussing the right approach with the Member States and are proposing to focus on identifying the substances of greatest concern. Afterwards, we need to make sure that the controls really focus on these substances," Mr Choraine explains.

» **Rodenticides:** Substances used as rodenticides will be reviewed in 2016 under the Review Programme. In 2017, there will be major work on the comparative assessment of all products containing rodenticides.

Further information:

DG SANTE, biocides
http://ec.europa.eu/health/biocides/policy/index_en.htm

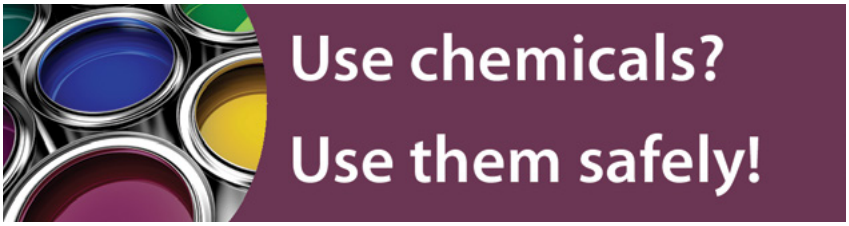
ECHA's biocides web pages:
http://echa.europa.eu/regulations/biocidal-products-regulation

Biocides terminology in 23 languages
http://echa-term.echa.europa.eu/

Supply chain communication - help yourself, use the tools

TEXT BY HANNA-KAISA TORKKELI

ECHA, sector associations and EU Member States have worked for two years to develop tools and templates to improve communication on safe use in the supply chain. The work has got off to a promising start: new tools, that help both registrants and downstream users have already been published and many more are in the pipeline.



WIN-WIN

Divina Gómez, Regulatory Affairs Manager at the Association of the European Adhesive and Sealant Industry (FEICA), says that the sector-specific harmonised use maps benefit all actors in the REACH chain.

"They help registrants to prepare more realistic chemical safety assessments for their REACH registrations. In turn, we downstream users, receive better quality information in the exposure scenarios from the registrants. They will also be more comprehensive. With more realistic exposure scenarios, our members can provide consistent safe use information to their customers much more easily", she says.

Clariant's *Erika Kunz*, who chairs the Chemical safety report/Exposure scenario (CSR/ES) Roadmap working groups of the European Chemical Industry Council (Cefic) and the German industry association VCI says that the tools developed enable the information to be delivered in a more harmonised way. "Harmonisation is likely to enhance the quality of industry's risk assessments and exposure scenarios", she mentions.

Harmonised and structured information also minimises the unnecessary back and forth communication in the supply chain, which saves time and resources.

The use maps help downstream users to make sure their uses are covered in the registration dossier of a substance.

"It will also be easier for our members to check the compliance of their activity - whether their uses are covered in the information received by their suppliers", Ms Gómez points out.

Also authorities benefit from the standardisation. "We expect that through the different tools the information in the dossiers will increase. This will help authorities to make the right decisions on substances that potentially need further scrutiny. More comprehensive and accurate information about the substance and its uses may also remove a potential concern", says ECHA's *Andrew Murray*.

Downstream users are very important as they play a key role in improving the safe use of chemicals in workplaces and in communicating safe use information both up to their suppliers as well as down to their customers.

IMPROVING THE CONTENT

The CSR/ES Roadmap focuses on is the harmonisation of format and on improving the actual content, meaning how uses are described.

Ms Gómez thinks that the consistency of information on the use of chemicals (use description, use conditions) will be improved when all downstream user sectors provide such information on the same

template, using the same terminology.

"The information registrants receive will be more representative of the uses in the supply chain. Also the fact that the templates will be IT compatible, will help the registrants' and downstream users' tasks and ensure consistency", she explains.

ECHA's Andrew Murray agrees. "Through the use maps, registrants know where to look for information; they get the same information and are able to use that in their assessment. Downstream users can then put the information they receive from their supplier to their customers in a language that the particular sector can understand. They should also be able to identify more easily the content of the exposure scenarios and how they relate to their activities and workplace settings on-site."

"The uses need to be better expressed, that's one thing. But we also need to work on the exposure assessment side in terms of what parameters go into an exposure assessment", Andrew Murray says.

GETTING EVERYONE ON BOARD

The work done under the CSR/ES Roadmap is responding to industry's demands for good quality information in the supply chain.

"All of the products which we have been working on under the roadmap are designed to meet those needs. The hope is that through using the products, the information in the dossiers will improve", Mr Murray explains.

The work still needs time to materialise. However, Ms Gómez believes that in the future, the communication in the supply chain will be on another level. "We are going in the right direction. Not all sectors are yet involved, but I hope more and more will come. Having meaningful and structured information throughout the supply chain will eventually improve communication on safe uses and make complex risk assessments more transparent to the users of chemicals."

Dr Kunz also encourages all actors in the supply chain to get active.'

"We have to realise that the benefits of the roadmap work will only come after the tools and methods are actually implemented. Many of them are already there and now we need to start using them."

Further information:

CSR/ES Roadmap
http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

Contact ECHA to get active in the roadmap work:
http://echa.europa.eu/csr-es-roadmap/contact-form

Downstream users
http://echa.europa.eu/regulations/reach/downstream-users
EsCom catalogue
http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

Exposure scenarios
http://echa.europa.eu/regulations/reach/downstream-users/exposure-scenarios

Safety data sheets eGuide
http://view.pagetiger.com/ECHAe-Guide1-1/Issue1

Approaches to generating safe use information for mixtures
http://echa.europa.eu/regulations/reach/downstream-users/communication-with-customers/approaches-to-generating-safe-use-information-for-mixtures

Safe use of mixtures (SUMI), DUCC
http://www.ducc.eu/News.aspx#news5

Specific consumer exposure determinants, A.I.S.E. news
https://www.aise.eu/newsroom/newsroom/aise-publishes-new-tool-for-consumer-safety-exposure-assessments-reach-specific-consumer-exposure-determinants-sceds.aspx

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

HELP FOR SUPPLY CHAIN COMMUNICATION

Online now:

- Template: Specific consumer exposure determinants (SCEDs), April 2014
- Template: Exposure scenario, August 2014
- Format: Structured short titles (STT) for the exposure scenarios, November 2014
- IT exchange format: ESCom v.2.0 package, July 2015
- Standard phrases: ESCom v.2.0 package, July 2015
- Method and template: Safe Use of Mixtures Information template (SUMI), December 2015

Upcoming:

- Template: Sector use map, February 2016
- Template: Sector-specific worker exposure description (SWED) , February 2016
- Template: Specific environmental exposure categories (SpERC), spring 2016

Alternatives to animal testing – what's new in 2016?

TEXT BY TIIU BRÄUTIGAM

Many of ECHA's activities help to avoid unnecessary testing on animals. What will the new developments be in 2016?

ADVICE ON ALTERNATIVES TO ANIMAL TESTING

This year, the focus is on promoting alternative methods and approaches that are relevant for the information requirements of the 2018 registration deadline.

ECHA will publish advice on using the new OECD test guidelines related to serious eye damage/eye irritation and skin corrosion/irritation. For skin corrosion/irritation, the new *in vitro* tests can, in many cases, fully replace *in vivo* studies when used either alone or in combination. For serious eye damage/eye irritation, combinations of several alternative test methods may be used to replace *in vivo* testing.

In mid-2016, the Agency plans to publish an update to the *guidance on information requirements* (Endpoint specific guidance, (Chapter R.7a) to reflect both the scientific changes and the recent regulatory amendments in the REACH annexes. The updates concern the data requirements for skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and acute toxicity.

For skin sensitisation, there will be advice in using newly developed non-animal testing methods within a weight of evidence approach, which may be used to avoid in vivo testing. For acute toxicity, there will also be advice on using a weight of evidence approach, which can lead to avoidance of certain *in vivo* tests.

© FOTOLIA

Throughout 2016 there will be new developments in alternative methods as well as updates on ECHA's guidance and website. The focus will be on promoting the alternative methods and approaches that are relevant for the information requirements of the 2018 deadline.

These updates favour the use of *in vitro* methods over the in vivo tests, reinforcing one of the pillars of REACH: animal testing should be used as a last resort. Additional information for registrants is published in the *Practical guide: How to avoid unnecessary animal testing*.

HELP FOR 2018 REGISTRANTS

To support registrants ahead of the 2018 deadline, ECHA has developed a roadmap with seven phases. A webinar and web pages for the third phase: '*Get organised with your co-registrants*' will be launched in March 2016, providing tips on how to share existing data with registrants of the same substance. Sharing data is an obligation under REACH which helps to avoid unnecessary animal testing.

In July 2016, new material related to the fourth phase '*Assessing hazard and risk*' will be launched. A webinar and new web pages on how to fulfil the REACH information requirements with alternative methodologies will be available. A new practical guide on information requirements for low-tonnage chemicals, targeted especially at small and medium-sized companies and business managers, will give further advice.

PROMOTING READ-ACROSS

Read-across is another methodology used to reduce testing on animals. Widely used by REACH registrants, it allows them to use existing information from substances to predict the properties of similar substances where information might be missing. *An illustrative example* of how to use read-across is available on ECHA's website.

To promote a consistent and correct scientific use of read-across, in 2015 ECHA published a *read-across assessment framework* (RAAF) targeting human health endpoints. The RAAF explains how ECHA evaluates read-across in registration dossiers. A version covering environmental endpoints will be published in 2017.

MAKING SURE THAT ALTERNATIVES ARE CONSIDERED FIRST

Before testing on animals (higher tier studies), registrants must first submit a proposal to ECHA. Since September 2015, ECHA has been asking registrants what alternative methods they have considered before

submitting their testing proposals. Then the testing proposals and these considerations are published in a public consultation.

During public consultations, everyone can submit relevant information that could be used to avoid tests on vertebrate animals. Registrants can then consider the feedback received to fulfil their REACH information requirements.

SEARCH FOR DATA

In January 2016, ECHA revamped its *database on chemicals*. Users can now access information on chemicals and their properties in three levels: through a simple infocard, a more detailed brief profile and the full source data.

The website also offers access to the *OECD's eChemPortal*, where registrants can check whether information on animal tests is already available from other authorities.

USING THE QSAR TOOLBOX

In cooperation with the OECD, ECHA develops and manages the *QSAR Toolbox*, a software for grouping chemicals into categories and filling gaps in (eco)toxicity data. In 2016, ECHA will publish more illustrative examples on the use of QSAR toolbox.

SCIENTIFIC WORKSHOP ON NEW METHODOLOGIES

To support the development of new alternative methods, ECHA is organising a *workshop on new approach methodologies* in April 2016.

The possible regulatory impacts of the latest scientific developments will be discussed among academics, regulators, industry and other stakeholders.

The new approach methodologies aim to reduce the need for animal testing. To be valid in the regulatory context, the methods should generate information that is reliable enough for risk assessment and classification to protect human health and the environment.

ECHA promotes the use of alternative methods in many ways.

Further information:

OECD test guidelines
http://echa.europa.eu/support/oecd-eu-test-guidelines

Guidance on information requirements
http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Practical Guide: How to avoid unecessary animal testing
http://echa.europa.eu/documents/10162/13655/pg_avoid_animal_testing_en.pdf

REACH 2018, phase 3
http://echa.europa.eu/reach-2018/get-organised-with-your-co-registrants

REACH 2018, phase 4
http://echa.europa.eu/reach-2018/assess-hazard-and-risk

Grouping of substances and read-across
http://echa.europa.eu/support/grouping-of-substances-and-read-across

Public consultations on testing proposals
http://echa.europa.eu/information-on-chemicals/testing-proposals/current

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

eChem-portal
http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en

QSAR Toolbox
http://echa.europa.eu/support/oecd-qsar-toolbox

Workshop on New Approach Methodologies in Regulatory Science
http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/topical-scientific-workshop-new-approach-methodologies-in-regulatory-science

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

Guest column | Philipp Meister, adidas Group

Innovation, transparency and collaboration

The adidas Group has a long history in chemical management. Already in 1998, we were one of the first companies in the industry to implement a Restricted Substance List (RSL) applicable for all our products.

Our programme has constantly evolved based on emerging scientific knowledge and feedback from our stakeholders. For instance, chemical input has become a matter of concern in our industry and as a consequence we have focused on inputting chemical management by nominating chemicals to be used in our production processes.

Additionally, we have started to phase out chemicals of concern such as perfluorinated chemicals (PFCs). We aim to phase out PFCs for 99 % of all of our products by the end of 2017.

For a consumer-oriented, high performance, sporting goods company, this is a very ambitious goal. To achieve it, we drive for innovation and pioneer new methods to make sure that any alternative substances are environmentally-sound and technically feasible – without compromising on the performance and quality of our products.

To further improve our chemical management system, in 2014 we entered a partnership with bluesign® technologies – a leading chemical evaluation system provider – and implemented their chemical positive database 'bluefinder' into our apparel material supply chain.

We set targets for the use of bluesign® approved and therefore environmentally sound chemical formulations. Already in the first year of implementation in 2015, we achieved a high level of adoption. 65 % of dyestuffs and 25 % of auxiliaries are now bluesign® approved. We will continue to increase these targets on an annual basis.

Our approach to sustainability is driven by collaboration. We are a founding member of the Zero Discharge of Hazardous Chemicals group (ZDHC), an industry group of leading brands with the goal of promoting the adoption of more sustainable chemistry and practices. The ZDHC publically releases voluntary standards and tools such as the first industry-wide Manufacturing Restricted Substance List (MRSL).

The MRSL restricts the use of toxic input chemicals. The ZDHC MRSL has been adopted not only by the ZDHC member brands, but also by several governments and industry associations globally. It creates one harmonised direction for the global supply chain.

© ADIDAS

Philipp Meister.

Finally, we drive for transparency in our supply chain. We are working with the Institute of Public and Environmental Affairs (IPE) in China and requesting our key suppliers to disclose their wastewater data publically on the IPE platform. In 2015, the suppliers making up half of our global material volume across apparel, footwear and accessories disclosed their data on the IPE internet platform.

With the focus on innovation, collaboration and transparency, our programme is unique and recognised as a leader within the industry.

Philipp Meister, Director Strategy, Social and Environmental Affairs, adidas Group

The adidas Group is a global leader in the sporting goods industry, offering a broad portfolio of footwear, apparel and hardware for sport and lifestyle around the core brands adidas, Reebok, TaylorMade and Reebok-CCM Hockey. Headquartered in Herzogenaurach, Germany, the Group employs more than 55 000 people across the globe and generated sales of around € 17 billion in 2015.
www.adidas-group.com

Roadmap to zero discharge of hazardous chemicals
http://www.roadmaptozero.com/

***

ECHA's substitution web pages:
http://echa.europa.eu/regulations/substituting-hazardous-chemicals

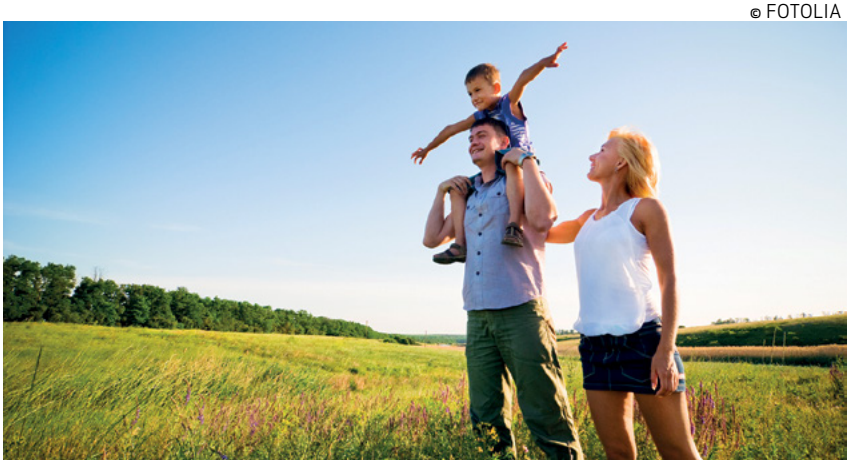
Painting a safer Europe:
https://www.youtube.com/watch?v=Zs8oPSXdU5U

Webinar: Why opt for substitution:
http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/why-opt-for-substitution

Sustainable development for a safer world

TEXT BY HANNA-KAISA TORKKELI

Healthy chemicals management calls for information about the properties, hazards, exposure and uses of chemicals. Increasing this knowledge and being able to make informed decisions about chemical production and safe use are one of the ways of meeting the goals set for 2020 by the World Summit on Sustainable development (WSSD).



The WSSD goal for 2020 is to that 'chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment'.

With regulations such as REACH, CLP, biocides and pesticides, Europe has one of the most developed and sophisticated environmental policies in the world. It is clear that our chemicals legislation is a great contributor to the 2020 goals.

"We can be proud because we have taken the protection of human health and the environment very seriously. 95 out of 100 citizens support the EU's policy on environment. Nine out of ten believe that the environment is important and that by protecting it we are bringing added quality of life. Europe has a good story to tell and we need to project our success to the rest of the world", says the European Commission's Director-General of Environment, *Mr Daniel Calleja Crespo*.

Since 2011, ECHA has been publishing information from over 50 000 registration dossiers and up to 120 000 substances on its website. A more user-friendly version of this database was just launched at the end of January.

"A lot of information on chemicals has already been made available. There are still important gaps to be filled, but this vast chemicals database will provide benefits also beyond the EU", says *Ninja Reineke*, Senior Policy Officer at a UK charity CHEM Trust.

Erwin Annys, Director at the European Chemical Industry Council (Cefic), adds that more information is still needed. "The REACH 2018 registration deadline is not the end - the process will continue and companies will look at how they can improve the quality of their dossiers where it is needed and how to come to a safer environment in general."

NEW CHALLENGES

On the road to 2020, Europe is also facing new challenges. In December 2015, the European Commission launched its initiative on the circular economy. "This will create a new kind of thinking of how we should engage with our businesses and what will be the influence on classical business models", says Dr Annys.

Ninja Reineke would like to see a stricter focus on the 'no data – no market' provision, to make sure that safe use is really achieved. "We would also like to see better synergies with other legislation to maximise the effectiveness of these laws as well as better and quicker regulation on substances of very high concern. We are very concerned about hormone-disrupting chemicals. For years, scientists have been alarming us that these chemicals can be contributing to an increase in cancer rates as well as infertility problems. These need to be addressed urgently."

In addition, balancing the protection of human health and the environment with economic interests is not always straight forward.

Studies have shown that the chemicals sector – and especially small and medium-sized companies (SMEs) is very important for jobs and growth in Europe, but that the strict regulations bite the hardest on the smallest players.

Director-General Calleja Crespo remains positive. "REACH has shown that it is possible to reconcile competitiveness and growth with a better knowledge of chemicals and their impact on health and with a better protection of the environment", he says and continues, "Of course, you still need to continue taking SMEs into account in terms of streamlining, simplification and lower fees."

Dr Reineke believes that protective regulations can trigger innovation. "What is bad for human health and the environment cannot be good for the economy in the long run. All the costs, for example, on health care or environmental remedy costs, are huge burdens on economies", she says.

To inspire innovation, she would like to see a stronger emphasis on substitution. "There is currently too little focus on rewarding those companies who are investing in safer alternatives. Instead, we are facing authorisations of DEHP in PVC for consumer products or lead pigments although there are safer alternatives. We need a clear regulatory signal where companies that replace harmful chemicals have the advantage and not those who continue with business as usual."

On the other hand, complying with legal obligations shows on the bottom line. "Our legislation costs money and it's a cost they don't have outside Europe. However, REACH has made companies look at their product portfolio and their position on the market and improved communication down the supply chain", says Dr Annys.

© ECHA

© ECHA

© CHEMTRUST

Director-General Calleja Crespo, Dr Erwin Annys and Dr Ninja Reineke.

"Whenever I have a choice, I choose products which are made in Europe. As European citizens we also have the responsibility to support European industry."

Director-General Calleja Crespo trusts companies and the regulatory framework to protect European citizens. "We have a first class chemical industry in Europe, and at the same time, first class regulation to make sure that the substances on the market are safe", he concludes.

Further information:

Workshop on REACH(ing) the WSSD 2020 goals
http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/workshop-on-reaching-the-wssd-2020-goals

Video interviews
https://www.youtube.com/watch?v=XNc4AdGz_sA

ECHA's substitution web pages:
http://echa.europa.eu/regulations/substituting-hazardous-chemicals

Painting a safer Europe:
https://www.youtube.com/watch?v=Zs8oPSXdU5U

CONSUMER PROTECTION

Consumers who buy products should be sure that they are safe – without being chemical experts. However, products on the shelves are not always up to standards.

"Recent media reports have revealed perfluorinated chemicals in outdoor clothing and endocrine disrupting chemicals in children's products or even food packaging. These are problems that have to be tackled urgently", Dr Reineke explains.

Dr Annys says that products made in Europe are a safer bet for consumers.

WORLD SUMMIT ON SUSTAINABLE DEVELOPMENT (WSSD)

In 2002, the international community made a commitment to the sound management of chemicals at the Johannesburg World Summit of Sustainable Development (WSSD). The aim is "to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment."

Since 2002, the European Union has made considerable progress in implementing legislation such as REACH and CLP to address that goal.

From 27 to 28 January, ECHA held a workshop in Helsinki to investigate how the current REACH and CLP processes can still be improved to increase their overall contribution to the WSSD 2020 goals. The presentations and recommendations from the workshop will soon be available on ECHA's website.

World Health Organisation, WSSD
http://www.who.int/trade/glossary/story097/en/