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There are now legally recognised alternative methods to test for skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and acute toxicity. Use them!

Three years of working with the Biocidal Products Regulation

1 September 2016 marked three years since the Biocidal Products Regulation (BPR) entered into force. This was an important milestone. It means that all biocidal active substances that are used in the European Union must have been either approved or be under evaluation. You can legally keep your biocidal product on the market until you receive the approval for your active substance as long as your application was made on time and the active substance is under evaluation for your product-type.

Since the regulation entered into force, we have worked hard with the European Commission and Member States to set up the processes and developed guidance and tools to manage its implementation. We are happy to see that industry is starting to use the new opportunities that the regulation offers. Union authorisation is a good example of something that is becoming day-to-day business for companies, ECHA and the evaluating competent authorities. Companies are preparing to use this new route to get their biocidal products authorised in one go throughout the entire EU.

1 September 2016 was also the last day to apply for approval for active substances used to treat articles. The same deadline applied for active substances contained in biocidal products that were not considered as such under the former Biocidal Products Directive. These deadlines were part of the transitional measures included in the new regulation to make the change from the directive easier to manage.

Although we are well on track with most of the requirements under the regulation, there are still new regulatory developments. One of these changes is the European Commission’s proposal of new criteria for endocrine disruptors. This is an important step for
everyone involved in safer chemicals. We expect the final criteria to be adopted in 2017 and we will then know the exact implication for our work on biocides.

We continue to work on improving the IT tools that you need for your daily work. Since July, R4BP 3 only accepts dossiers that are in the new IUCLID 6 format. For you, the update to IUCLID 6 is good news because it is easier to use and install. Don’t forget that you can now also manage your Review Programme-related tasks directly in R4BP 3. To help us to keep improving, we need your feedback and I invite you to provide this in particular through the IT users group. This group is open to all stakeholders and will have its next meeting in Brussels on 14 November 2016.

Lately, we have received many questions related to the data requirements for in situ generated active substances. We are discussing this together with the Member States and also with the working group of the Biocidal Products Committee. Our aim is to publish more information on this topic in the first half of next year.

Finally, 1 September was our fourth Biocides Stakeholders’ Day. Around 120 participants attended the conference in Helsinki and more than 500 watched online to catch up with the latest updates and advice. If you missed the event, you can watch the video recording and check out the presentations on our website.

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How ECHA is assessing glyphosate

TEXT BY NEDYU YASENOV

The criteria for classifying and labelling hazardous chemicals have been developed to protect human health and the environment. A topical example where the need for harmonised classification of a substance is being examined is glyphosate. ECHA’s Committee for Risk Assessment (RAC) is currently evaluating the proposal by Germany to revise its existing classification.

Classification and labelling is one of the ways of ensuring that the risks of hazardous chemicals are managed within the European Union. Substances that can burn the skin, are poisonous when swallowed, or are dangerous to inhale, for example, need to be classified and appropriately labelled. When the classification of a substance is harmonised, any product containing the substance must be appropriately labelled and packaged throughout the EU; this includes, where relevant, making sure that children cannot easily open the container or packaging.

EU Member States, manufacturers, importers and downstream users of chemicals may propose the harmonisation of the classification and labelling for a substance. If a harmonised classification already exists, a Member State can also propose to revise it.

Active substances in plant protection products generally have a harmonised classification. This is already the case with glyphosate, which is used as a weedkiller.

PROPOSAL TO REVISE THE EXISTING HARMONISED CLASSIFICATION FOR GLYPHOSATE

Glyphosate already has harmonised classifications because of its irreversible effects on the eye (Eye Dam. 1, H318) and toxicity to aquatic life with long-lasting effects (Aquatic Chronic 2, H411). The German Federal Institute for Occupational Safety and Health (BAuA) has reviewed these existing harmonised classifications and proposed to add a classification for specific organ toxicity after repeated exposure (known as STOT RE 2, H373).

ECHA’s Committee for Risk Assessment (RAC) will evaluate this proposal as well as the other potential health hazards of glyphosate such as carcinogenicity, germ cell mutagenicity and reproductive toxicity, and possible environmental hazards, which have been addressed in the dossier but for which Germany has not proposed a classification.

The approval to use glyphosate as an active substance in plant protection products expired at the end of June 2016. The European Commission decided to extend the approval for 18 months, by which time – under normal circumstances – RAC will have adopted its opinion on glyphosate’s harmonised classification.

PUBLIC CONSULTATION ON THE PROPOSAL

After receiving the proposal for harmonised classification, ECHA checked that it fulfilled all legal requirements. The next step was to launch a 45-day public consultation that welcomed comments on the classification proposal, including the endpoints for which no classification was proposed. The consultation ended on 18 July and all the comments received have been sent to the German authority for them to consider and respond to – they are also available on ECHA’s website (after any confidential content has been removed).

THE ROLE OF THE COMMITTEE FOR RISK ASSESSMENT

RAC’s task is to prepare an opinion on the need for additional harmonised classifications of glyphosate.
The committee considers the available data on the substance, including any scientifically relevant comments submitted during the public consultation. It then examines the available evidence and may consider whether another category other than that proposed would be more appropriate for the classification of the substance.

The classification is based solely on the hazardous properties of the substance. It does not take into account risk or exposure because the assessment does not evaluate the quantities used, nor the way in which it is used. Such aspects are considered later on, as part of further risk management measures when assessing if a certain use can be authorised. For example, the use of glyphosate as a pesticide is covered by the Plant Protection Products Regulation, which is managed by the European Food Safety Authority (EFSA).

**HARMONISED CLASSIFICATION IS IMPORTANT FOR THE SAFE USE OF GLYPHOSATE**

RAC’s final opinion will be published on ECHA’s website together with the background documents and responses to the comments received. In the course of next year, ECHA will forward RAC’s opinion, together with all the comments, to the European Commission. If the Commission finds that the proposed harmonised classification and labelling is appropriate, it will submit a draft decision concerning the inclusion of glyphosate on Annex VI to the CLP Regulation.

This means that all manufacturers, importers and users of the substance in the EU must classify it accordingly, enabling users to be better informed about it, its potential effects and how to use it safely.

**Further information:**

**WHAT IS GLYPHOSATE?**

\[N-(\text{Phosphonomethyl})\text{glycine (EC 213-997-4, CAS 1071-83-6), or glyphosate (ISO),}\] is one of the world’s most widely used active substances to prevent unwanted plant growth. These substances are referred to as herbicides or, more commonly, as “weedkillers”.

It is used in agriculture and horticulture to kill weeds before sowing. Some genetically modified plants have been developed to be resistant to glyphosate and in those cases, glyphosate is used to kill weeds once the crop has been sown. This practice however is not permitted in the European Union.

**Source:** BfR FAQ on the assessment of the health risk of glyphosate
http://www.bfr.bund.de

**Committee for Risk Assessment**

**Harmonised classification and labelling**

**ECHA’s Committee for Risk Assessment (RAC) is currently evaluating the proposal by Germany to revise the existing classification for glyphosate.**
The fifth step in preparing a successful REACH registration is to create your dossier in IUCLID. You need to structure the data you have on your substance so you are ready to submit it to ECHA.

Before you start working with IUCLID, it is important that you get familiar with how the registration information is structured and with the terminology used in the application. You can do this by trying out the tool with test data before creating a real dossier. You can also read the user manual: How to prepare registration and PPORD dossiers.

In addition, you should have all the data you need at hand. Advice on identifying your requirements and collecting data is available through step four of the REACH 2018 Roadmap: Assess hazards and risks of your substances.

**WHAT DO I NEED?**

If you are registering a substance that other companies are also registering, you need to work together with them and prepare a joint registration.

For a joint registration, two types of dossiers can be prepared:

- A lead registrant dossier, which includes the identity of the substance that has been agreed by all the registrants, the information on the properties of the substance and the company-specific information of the lead registrant; and

- Member dossiers, where all the other registrants include their company-specific information, like contact details, exact substance identification, the volumes produced or imported, and the uses made of the chemical by their customers.

To create the lead registrant dossier, you need to install the IUCLID software. Once you have completed your dossier, you need to export it and submit it to ECHA through REACH-IT.

If you are a member and are relying solely on the data provided by the lead registrant (you have nothing extra to add, nor do you dissent from anything included), you can prepare your IUCLID dossier either in IUCLID or directly in REACH-IT.

**THE MAIN STEPS TO FOLLOW**

1. **Download and install IUCLID**

   You can download IUCLID free-of-charge from https://iuclid6.echa.europa.eu/download. If you are the only person in your company working on the dossier, you will most likely find it convenient to work with the desktop version on your own computer. Alternatively, if you use the server version, several people in your company can access and work on the same IUCLID data at the same time.

2. **Create your substance dataset**

   The first thing to do in IUCLID is to create your substance dataset, which includes the administrative and scientific data for the substance you are registering. It is the basis for your registration and you need to include all the required information. You can edit the dataset at any time in the future, for example, if you find new information on your substance.

   If you have included any information in your substance dataset that is confidential and you do not want it published on ECHA’s website, you need to indicate this by using ‘confidentiality flags’. Each confidentiality claim needs to have a robust justification.

   Before going any further, check the completeness of your substance dataset by running the Validation Assistant plug-in of IUCLID. You can do this easily by right-clicking on the substance dataset in the Navigation panel, and selecting ‘Validate’. It will show if your dataset is complete or whether you need to improve it. The Validation Assistant marks the fields you need to take a closer look at. To successfully submit your dossier to ECHA, you need to address the weaknesses identified.

3. **Create your dossier**

   The file that you submit to ECHA to register your substance is called a dossier. A dossier is a read-only copy of your substance dataset, together with administrative information about the type of registration. By right-clicking on your substance dataset and choosing ‘Create Dossier’, you will launch the dossier creation wizard, which will guide you through the process. In addition, by pressing F1 anywhere inside the application, the online help system will appear and point you to relevant support.
While creating your registration dossier in IUCLID, pay attention to the following:

- **Submission type**: are you registering a substance for standard uses (your substance is used as it is, or in mixtures) and with standard information requirements? Does your registration cover a substance for intermediate uses only (your substance is used to make another substance)? Are you a lead registrant or a member? Choose the correct submission type in the dossier creation wizard.

- **Administrative information**: in this step, you can claim information, such as your tonnage band or registration number, confidential.

  If you register below 10 tonnes per year, you may be eligible for a reduced fee. You need to indicate it here by claiming a fee waiver.

- **Name your dossier**: under additional administrative information, you should give a name to your dossier, which enables you to easily identify it in your own system. Do not use confidential information in the name, as it will be seen by anyone you share the dossier with.

**Review your dossier**

After you have inserted all the information in your dossier, you can review it. Then, open the Validation Assistant and run it on your dossier one more time. Even if the Validation Assistant showed no failures when you ran it on the substance dataset, it is essential that you also run it on the final dossier – you may have added some information during dossier creation that can result in a different completeness outcome.

**Run the dissemination preview to see what will be published online**

Most parts of a registration dossier are made publicly available. With the Dissemination preview plug-in, you can see in advance what will be published. In addition, ECHA will check any confidentiality claims you may have placed in the dossier. If your claim is rejected, you will be given an opportunity to improve your reasoning. If a claim is not adequately justified, the information will be published.

**Export and submit your dossier**

Once you are satisfied with the data in your IUCLID dossier, export it and submit it to ECHA using REACH-IT.

**CREATING A DOSSIER IN REACH-IT**

If you are a member registrant and you agree with all the information submitted by the lead on your behalf, you can fully prepare your registration in REACH-IT. In this case, you do not have to install IUCLID.

The REACH-IT dossier creation wizard will guide you through the process and fields that you need to complete. You will need to provide the following:

- Substance identity and composition

**REACH 2018**
IUCLID is an international tool used to prepare, store, maintain and exchange data on chemicals. By law, REACH registrations have to be submitted to ECHA in IUCLID format. It can be downloaded free-of-charge from the IUCLID website: https://iuclid6.echa.europa.eu/download.

IUCLID 6 is available, News item 29 April 2016 https://echa.europa.eu/view-article/-/journal_content/title/iuclid-6-is-available

REACH-IT https://reach-it.echa.europa.eu/reach/

Multilingual explanations of terms https://echa-term.echa.europa.eu/

WHAT IS IUCLID?

- IUCLID is an international tool used to prepare, store, maintain and exchange data on chemicals.
- By law, REACH registrations have to be submitted to ECHA in IUCLID format.
- It is available in two versions:
  - The desktop version of IUCLID is easily installed on your computer or laptop. Any information you have in your workstation IUCLID is only available to you, not for any other users.
  - The server version runs on your company’s server. The data in this IUCLID version can, therefore, be worked on simultaneously by several users.
- ECHA develops the software together with the OECD.

REACH 2018

“Many companies will be able to prepare their registrations directly in REACH-IT”

INTERVIEW BY HANNA-KAISA TORKKELI

The new IUCLID 6 published in April 2016 is much more intuitive and simpler to use, which will help companies to prepare their registrations for the 2018 deadline. We asked Dr Peter Douben of consultancy REACH-Wise how exactly the new tool affects the REACH 2018 registrants.

“I see two major benefits of IUCLID 6: the possibility to prepare dossiers in REACH-IT and the fact that IUCLID, together with REACH-IT, is much firmer on the one substance, one registration principle,” he says.

Dr Douben believes that many companies will use the possibility to create their member dossier directly in the dossier submission tool REACH-IT – not having to download IUCLID. “Those who are registering one or two substances and are a bit behind in their preparations – I call them ‘late-realisers’ – will use it to prepare their registration on their own. They can get valuable help from ECHA’s Helpdesk of course.”

Making sure that companies registering the same substance are part of the same submission was reinforced by the European Commission’s Implementing Regulation on joint submission of data and data sharing, which came to force in January 2016. It means that companies will not be able to submit a registration dossier separately if a registration for the same substance already exists. According to Dr Douben, this is a positive development. “It will prevent free-riders entering the system and is fair to those registrants who do their job well.”

CONSISTENCY AND EASY ACCESS TO HELP

IUCLID 6 also provides a more consistent way to fill in the data. “For every section, you always begin with a right-click of the mouse. This will guide you in the right direction. Also, the structure is more consistent: you can more easily manage different legal entities from different manufacturing sites or the same substance for different legal entities,” Dr Douben points out.

Another plus is the help system, which has been completely revised and integrated into the application. “The online help guides you to...
the specific advice on the issues you are dealing with. I personally prefer reading complex matters in print, but nonetheless, it points me directly to the correct place in the manual,” he concludes.

**Further information:**

Phase 5: Prepare your registration as a IUCLID dossier

Webinar 4 October 2016:

Registrants of the same substance must be part of the same registration. News alert 25 January 2016

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**DR DOUBEN’S TOP FIVE TIPS FOR SMES FOR REACH 2018**

1. **Know your substance and its details:** if you are a lead registrant, make sure you include a substance identity profile in your dossier. This will help other registrants to know if your joint registration is the correct one for them. If you are a member, make sure your substance fits the substance identity profile before joining the substance information exchange forum (SIEF).

2. **Find out what data you have and what you will need:** the requirements are different by production/import volume and substance type. Think about what you bring to the table in the joint registration.

3. **Know how your substance is used down the supply chain:** talk to your customers to make sure you cover all their uses in the registration. Use this information to, for example, reduce any risks.

4. **Lead registrant:** figure out what you will provide to the members of the joint registration – the full IUCLID file or a printout of the IUCLID data? **Member registrant:** know what you will get from the lead – this will affect the way you prepare your dossier. If you get a IUCLID dataset from the lead, you can directly use it as a basis for your own dossier and just add your own information. If you get a printout of the data, you will need to fill in all the required information in IUCLID.

5. **Make sure you are part of a joint registration:** ECHA is very firm on the one substance, one registration principle – make every effort to share data and submit a joint dossier. Discuss any issues early.

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**Global data sharing – steps away from reality?**

**INTERVIEW BY PÄIVI JOKINIEMI**

Companies making chemicals are increasingly marketing them worldwide. Taking into account different regulations and the need to create separate datasets for each market, requires both money and resources. Could there be an easier way? We spoke with representatives of chemical companies and regulators, to find out where we are with the global sharing of data on chemicals.

The aim of the global assessment of chemical datasets is to have consistent hazard and risk profiles for substances. To get there, all the existing data and the validated methods for risk assessment need to be taken into account. “When we speak about datasets of chemicals we are essentially speaking about their hazard and risk assessment,” explains Dr Adriana Jalba, Manager at the European Chemical Industry Council, Cefic.

Dr Brian Richards, Director of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) at the Australian Government’s Department of Health, agrees that the assessment and quality of data are key elements in global data sharing. “Success is dependent on being able to assess the strengths and weaknesses of different types of data and developing methods to share them appropriately. Regulators need to continue to be able to assess the quality of the information being shared with rigour and transparency”.

**BENEFITS FOR INDUSTRY, REGULATORS AND SOCIETY AS A WHOLE**

Dr Jalba points out that global data sharing would not only benefit industry, but also regulators and ultimately the whole of society.

Global data sharing has a key role in promoting innovation and competitiveness because it would, for example, allow companies to get their new, innovative products to market faster than they can today. “If you look around, you can see that supply chains today are worldwide
interconnected ecosystems, which means that we have a very complex economy,” Dr Jalba says and continues “the global economic environment is increasingly volatile and therefore, it is essential that companies are able to get to market very fast. If you can’t, you may lose your investment “.

It could also help to reduce the costs for compliance both for companies and regulators. Increased efficiency could also bring along other benefits. “By avoiding duplication of work, regulatory agencies can increase their efficiency and effectiveness. This would ultimately reduce the burden on industry and also enhance the public’s ability to access information on chemicals,” Dr Richards points out. As an example, he mentions that NICNAS’ chemicals assessment programme has extensively used international chemical databases to assess over 3 000 chemicals which are already in use in Australia but have not previously been assessed. These assessments can now in turn be used by other agencies and they can also be accessed by industry and the public anywhere in the world.

“Global data sharing could improve risk management decisions, which leads to better human health and brings positive environmental outcomes. It also provides an important way of avoiding unnecessary animal testing,” Dr Richards says. “For society as a whole, economic growth will be a direct benefit,” Dr Jalba adds.

IMPROVED REGULATORY COOPERATION NEEDED

There are tools that enable global data sharing. For example, in OECD countries, data can be reported using the OECD harmonised templates. This means that the data required are in a similar format to what has already been collected for other purposes. Also, technical hurdles are less of a problem. According to Dr Richards, developments in technological infrastructure have removed many of the traditional boundaries to sharing large amounts of data and it is now easier to communicate and collaborate with each other. “At NICNAS we are considering adopting IUCLID, in part to enable easier sharing of information, such as QSAR (quantitative structure-activity relationships) predictions,” Dr Richards says.

However, there are still issues that need to be solved before global data sharing can become a reality. For example, systematic regulatory cooperation is required so that data generated under one jurisdiction can be completely validated and acknowledged in another. “Data sharing itself has limited value if there is no cooperation between regulators to reduce the existing divergences. We are all aware of the divergences on the approaches we take and on the different regulatory systems. We need more integrated systems for rulemaking and implementation,” Dr Jalba points out.

WHAT ABOUT OWNERSHIP RIGHTS?

Perhaps the biggest issue in global data sharing is, however, the protection of the ownership rights of data, particularly for commercially sensitive and confidential information. According to Dr Jalba, companies are willing to share data but before they can do it there needs to be a clear global framework for data sharing and law governing the data, to ensure that ownership rights and intellectual property are protected.

Regulators are well aware of this challenge. “We as regulators need to remain aware of intellectual property ownership and have safeguards and protocols in place when sharing information,” Dr Richards says.

Dr Jalba mentions that there are interesting projects ongoing that could help regulators to identify possible solutions for the challenges of data sharing and data protection. “Korea is implementing a REACH-like regulation and there is a lot of convergence there. In this context, data sharing is extensively discussed with Korean industry. We could use that to understand how the global process for data sharing can be put into place. For me, that could be the pilot project to learn from.”

CALL FOR POLITICAL LEADERSHIP

Closer relations between peer regulatory agencies and the increasing harmonisation of data requirements between the regulatory frameworks can bring us closer to successful data sharing at the global level. There needs to be a common understanding of data and the related hazard and risk assessment. Ultimately, there must be an agreement that brings certainty to industry that their ownership rights are protected during the process.

Dr Jalba calls for political will and leadership to make global data sharing a reality. She emphasises that other regulators also need to be engaged with and support the idea. For example, questions of trade in general are central to understanding the bigger picture. “I think we have to go a long way to fix the practicalities in terms of data sharing, but I believe that it is possible and I hope it will happen in the near future,” she concludes.
Avoid a headache on 31 May 2018 - make sure your uses are covered

As the REACH 2018 deadline for registration approaches, manufacturers and importers of chemicals are preparing and intensifying their work to make sure that they comply. But it is not only those companies that are impacted – it also affects users further down the supply chain.

There are significantly more users than there are manufacturers of chemicals. There are also substantially more users of finished articles than there are producers of those articles. You could consider this as an inverted pyramid where the large and varied range of uses balances on a much smaller number of substance manufacturers and importers.

TRUST IN THE MARKET

Having discussed the 2018 registration deadline with users of chemicals and articles, many believe that the materials they use will remain in the supply chain simply because they have been using them for many years. They also have confidence in the registration process, probably because the two previous deadlines did not yield any nasty surprises or because users have not seen substances being removed from the market yet.

However, 2018 may change that because this deadline covers low volume tonnages between 1 to 100 tonnes. Reports suggest a much higher number of registrations than ever before and a large proportion of these may be made by SMEs – potentially with lower levels of resources and a greater reliance on external third party consultation.

MAKING A BUSINESS DECISION

Registering smaller volume materials may bring some difficult commercial decisions when companies balance the costs of registration with the financial return on a low tonnage material. However, those small tonnage materials may be the key ingredient in a product, defining a final product’s character in a similar way that a small touch of vanilla or lemon defines the flavour of our favourite cakes. For these reasons, companies further down the supply chain need to be aware of the upstream commitment to register by their suppliers.

WILL YOUR SUBSTANCE BE REGISTERED?

The first step towards successful registration is to understand your portfolio. Companies purchasing but not directly producing or importing the substances they use, typically rely on their upstream suppliers to comply with the necessary registration obligations. However, under REACH, they have no guarantees that their supplier will successfully complete their registration.

Therefore, companies that are relying on those upstream should reassess their materials portfolio. My advice is to start discussing with your suppliers now, to find out if they intend to register the substance that you are using. Confirmation for substance registration may also be found by examining ECHA’s registration database. In many cases, users will find that the materials they purchase are already registered or that there is a strong commitment and evidence showing that the necessary steps are being taken to ensure compliance. Such findings will give a positive message on the longevity of supply and ease decisions regarding future production, investment and targeted growth.

MAKE SURE YOUR USE IS COVERED

You need an eye for detail because errors made in a registration dossier could have a detrimental impact on the future of your business.
It is important that you act quickly and start discussing the registration plans with your suppliers. Not only will this help you to define your future strategy, it will also make sure that the registrations that are currently being prepared are more accurate because your supplier will better understand exactly how you use their substance.

Correct descriptions of how substances are used are vital for creating accurate registration dossiers and related safety advice. ECHA, together with its stakeholders, have created use maps to help communication between registrants and downstream users. These use maps can help you consider all the relevant aspects related to registration in a consistent manner.

If you are not familiar with the use maps, you can find more information on ECHA’s website or from your sector organisation.

TOP TIPS FOR DOWNSTREAM USERS

- Do not presume that the substances you source and rely on will automatically be registered by the manufacturer or importer.
- Reassess your material portfolio and get a clear picture of the substances you use that do not have a registration number (or confirmation that no number is needed because the substance is exempt).
- Where you don’t have a number, examine ECHA’s registration database and communicate with your supplier to ask the status of their registration. If there is no number, ask if they are going to register the substance by 31 May 2018.
- If you source a mixture or finished article from within the EU, ask for a formal statement ensuring that all the substances used in its manufacture are registered where necessary, or ask for a commitment from your EU supplier for continued REACH compliance.
- If you have doubts about the continued supply of a key substance, check if it can be sourced elsewhere from a supplier who has already registered or is committed to registering. Consider also your options regarding sourcing, importing, self-registration or even replacing the substance with something else.
- Alert ECHA or your national helpdesk if you identify a key substance that may disappear from the market because there does not appear to be anyone planning to register it.
- Act quickly – communicating sooner will improve the level of awareness and allow business strategy decisions to be made with greater confidence and reduced pressure.
- If you intend to register by yourself, external support and testing may be required. This could be time consuming and its availability may reduce as the deadline approaches, so act now.

Remember, positive communication will provide improved security for your business’ future as well as a safer Europe.

Further information:

- ECHA’s registration database
  http://echa.europa.eu/information-on-chemicals/registered-substances
- Use maps
- REACH registration and downstream users
- REACH 2018
  https://echa.europa.eu/reach-2018
- National competent authority helpdesks
  http://echa.europa.eu/support/helpdesks

WEST AND SENIOR

West and Senior Limited (UK) is a market leader in the supply of pigment and additive systems and is an SME. Whilst not manufacturing base chemicals, they source around 250 substances to create over 20,000 formulations.

The company is reliant on their upstream suppliers for REACH registration compliance. They have taken an active role in the positive promotion of REACH awareness and compliance, including discussions with government authorities, the European Commission and ECHA. The company has communicated its needs with suppliers and, through trade associations, supports active, open and early communication throughout the supply chain.

West and Senior Limited also take part in a multiple discipline consortium – Cross Sector UK – covering many areas of the manufacturing industry and trade associations examining the process of REACH and supporting increased levels of understanding and compliance guidance.

http://westsenior.co.uk/
Phasing out dangerous substances – how can we speed up?

INTERVIEW BY PÄIVI JOKINENI, JULIA SIERRA

REACH is one of the main reasons why companies identify hazardous substances and find safer alternatives to substances of very high concern in the EU. But, how can we speed that process up? By devoting more time and money to it and by coordinating our efforts. It is also important to bring authorities, researchers and industry together. ECHA Newsletter spoke with Dr Joel Tickner and Ms Molly Jacobs about the main findings of their study on substitution.

“There is a clear interest in substitution in Europe. With greater capacity and enhanced collaboration, there are great opportunities to increase substitution,” says Dr Joel Tickner from the University of Massachusetts, Lowell Centre for Sustainable Production. Dr Tickner and Ms Jacobs have carried out a study for ECHA, to explore how finding safer alternatives could be accelerated and what the main obstacles are. The study finds that there is a clear pressure for substitution in Europe and that the REACH Regulation is a dominant driver for it. This differs clearly from the situation in the United States where substitution is mainly a market driven activity, with less pressure from authorities. Many Member States are active in investigating safer chemicals but they do not always share information with each other. Therefore, he is calling for better coordination of the ongoing substitution programmes.

“Given the limited resources, there is no reason why similar efforts should be undertaken by multiple authorities. So, collaboration – between authorities, through the supply chain and with stakeholders – is critical to developing expertise, sharing knowledge and ensuring successful substitution activities,” Dr Tickner states.

LACK OF RESEARCH FUNDING FOR INNOVATION

Innovation requires research and research requires money. Therefore, the funding of research becomes a key issue. “In our survey and interviews, we often heard about the need for research funds to really support innovation and identify alternatives,” Ms Jacobs says. There are several research funding programmes that could support identifying alternatives but they are not always easy to find or linked to regulatory priorities. “The next step has to be to map what the innovation funds are for. Many are targeted in a very specific direction and with a quick look, substitution is not mentioned as a grant priority. It does not mean that if they received a proposal related to substitution that it would be rejected but these should be explored further,” Ms Jacobs explains.

According to Dr Tickner, a significant portion of the materials-related research money from the European Commission is currently going to the circular economy. This is an important area of research and identifying safer alternatives would fit perfectly into this discussion. “If you deal with a dangerous chemical and it is in a circular economy, this means that you will just keep circulating it and bringing it back around. That is not a good solution.”

In addition to funding, it is important to bring together the researchers and the companies who are looking for safer alternatives. “We have identified a large and growing research base in sustainable and green chemistry,” Ms Jacobs explains and continues, “however, researchers are often completely
There is a large and growing research base in sustainable and green chemistry.

IMPROVING TECHNICAL FEASIBILITY AND ALTERNATIVES ASSESSMENT

One of the biggest risks in substitution is that the alternative substance may not work out as hoped. Sometimes the uncertainty around the feasibility of the safer alternative can stop the substitution. “It is important to find ways to enhance collaboration around technical feasibility, for example, through industry sector groups,” Dr Tickner emphasises.

He gives an example of the collaboration in Massachusetts between the university and small companies using problematic solvents in degreasing. Regulations and liability concerns were driving the companies to consider changing from these hazardous substances to safer alternatives. But the companies were hesitant to do so because of a lack of resources to test the alternative and concerns about reduced performance. To help out, the university set up a laboratory to help companies to do proper performance testing, to eliminate the technical risk of substitution.

In addition to resource challenges, when assessing the technical feasibility of an alternative, there is often a lack of information in supply chains due to confidentiality issues. This is an example of a bottleneck that could be unblocked by better collaboration, exchange of knowledge and more open communication.

Since the assessment of alternatives is crucial to identify safer substances and assess their implementation, the staff working on this have to be properly trained to ensure quality. “Both the applications for authorisation and restriction proposals that we have reviewed vary significantly in quality,” Dr Tickner says and continues, “there is a need for training and education and this applies to industry and industry groups but also for the staff in Member States and in ECHA and its committees, so that they can understand what makes a high-quality assessment.”

“TIME IS CRITICAL”

According to Dr Tickner, even the simplest substitution can take one to two years to implement. Therefore, his message to companies is to start evaluating alternatives as early as possible. “Supply chain and sectoral collaboration is critical in this. The earlier you start looking for alternatives and working with research institutes, your own trade institutes and the government authorities, the better the position you will be in to substitute.”

Further information:

REACH is the dominant driver for substitution - more action is needed, Press release 5 September 2016
https://echa.europa.eu/view-article/-/journal_content/title/reach-is-the-dominant-driver-for-substitution-more-action-is-needed

RESEARCH FUNDING

The study mentions some funding programmes that could be useful for research on safer alternatives.

- COSME – the EU programme for the competitiveness of small and medium-sized enterprises.

- LIFE – EU’s financial instrument supporting environmental, nature conservation and climate action projects.
  http://ec.europa.eu/environment/life/

- Programmes under Horizon 2020 - the biggest EU research and innovation programme.
  https://ec.europa.eu/programmes/horizon2020/

- Funding through the European Investment Bank.
  http://www.eib.org/

- Eco-innovation programme – part of the EU’s Entrepreneurship and innovation programme that supports innovation among SMEs.

Also, many EU Member States have their own funding programmes.
In January 2016, ECHA commissioned a study to look at the process of substituting dangerous chemicals in the EU. The aim of the study was to find practical ways of promoting innovation and substitution in the EU. The study was led by Dr Joel Tickner, Director and Associate Professor of Environmental Health, and Ms Molly Jacobs, Senior Research Associate and Project Manager from the University of Massachusetts, Lowell Centre for Sustainable Production. Dr Tickner and Ms Jacobs carried out surveys and interviews with representatives of the Member State competent authorities, non-governmental organisations, industry and research centres.

Lost at SEA...?

INTERVIEW BY PAUL TROUTH

Socio-economic analysis (SEA) weighs up the pros and cons of an action, for example, how society would be affected by the continued use of a chemical. As part of socio-economic analysis, cost-benefit analysis is used to quantify the benefits of chemicals management in social and monetary terms so that they can be directly compared to the costs.

The practice was discussed at an OECD workshop hosted by ECHA during the summer. We talked to Alan Krupnick and Michael Donohue, two experts in the field.

AVOIDING NEGATIVE IMPACTS FOR HUMAN HEALTH AND THE ENVIRONMENT

Risk assessors and economists need to work together to make an economic valuation that helps governments and institutions regulate chemicals in the best possible way. This cooperation makes sure that the wants of the public and the risks of hazardous chemicals are identified properly and that all the nuances are taken into account.

“Economists use real-world behaviour to figure out these values. Consumer preferences for avoiding the negative impacts of chemicals are used to turn the health and environmental impacts into monetary values. The values are not just plucked from thin air; they are grounded in consumer behaviour and thinking,” explains Alan Krupnick, Co-Director of the Center for Energy and Climate Economics at the US-based thinktank Resources for the Future.

“If the cost-benefit analysis results in the reduced use of toxic chemicals, either through restriction or substitution, then public health and the environment will be affected positively. However, the cost-benefit analysis should be the force driving the decision making. What shouldn’t happen is for the cost-benefit analysis to be done just to justify a decision that has already been made,” Mr Krupnick points out.

HOW DO WE KNOW WHAT THE PUBLIC WANTS?

There are two ways we can try to understand what the public wants. We can ask them directly or we can observe them. To come up with a useful economic assessment of different options, however, it is important not only to know if the public is positive or negative about certain chemicals, but how much so.

“The first group that needs to understand consumer behaviour are the economists. They are the ones who will be conducting the surveys and the statistical analyses,” says
Socio-economic analysis is used, like air quality for example. Air quality has the goal of making the air clean, but the picture is not so straightforward for chemicals. Once chemicals are part of a product, then you also have to think about how well the product works and how removing the chemical would affect this, which is much more challenging to assess," Mr Krupnick explains.

The analysis should go beyond just looking at the chemical in question and also look at possible substitutes. This wider scope makes the socio-economic analysis of chemicals more complicated.

“Ideally, you would also think about the availability of the substitute in the analysis, but we don’t fully know about the availability of substitutes, let alone their potential toxicity. Since agencies do not have the authority to force industry to choose particular substitutes, there remains a lot of uncertainty in terms of the substitutes chosen by industry and whether they are, in fact, any safer,” he remarks.

Mr Krupnick and continues, “once the peer-reviewed information is published, this is when regulatory agencies have a duty to keep up with the most relevant data and most recent literature to really understand the desires of the public before taking any decisions.”

Michael Donohue, Manager of the Economic Health and Analysis Division of Health Canada, points out that we also need to know how the public values their own use of substances. “Say, for example, that you have an itchy skin rash and your doctor prescribes you some lotion that has a possible side-effect of causing an upset stomach. Would you use the lotion knowing that it would upset your stomach?”

How the public answers a series of these kinds of question gives an indication of how they prioritise their use of substances. “The difficulty with this approach is that the consumers don’t always know what chemicals are in the products they use, so although you can see what they are doing, the observation doesn’t help you fully understand why they make the choices they do. To understand this, you need huge amounts of statistical data from a large sample of people to isolate the key variables that appear to drive people’s decisions,” Mr Donohue explains.

CHEMICALS CAN BE TRICKY

Socio-economic analysis is never easy, but with chemicals, things get very difficult to assess. For example, there are chemicals like biocides, which need to destroy some forms of life, so they need to have a certain level of toxicity for them to work.

“There are risk-risk trade-offs for chemicals, that you wouldn’t find in other areas where socio-economic analysis is used, like air quality for example. Air quality has the goal of making the air clean, but the picture is not so straightforward for chemicals. Once chemicals are part of a product, then you also have to think about how well the product works and how removing the chemical would affect this, which is much more challenging to assess,” Mr Krupnick explains.

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DID YOU KNOW?

Socio-economic analysis

Socio-economic analysis assesses the impact of a regulatory action compared to what would happen if no action was taken or compared to an alternative course of action. For chemicals, this could mean assessing whether to continue using a substance or phasing it out.

Cost-benefit analysis

Cost-benefit analysis is one method that can be used under socio-economic analysis. It converts all of the impacts into monetary units so that the costs and benefits can be directly compared. The conversion is based on valuation techniques that estimate how willing consumers are to pay to avoid a certain risk to health or damage to the environment. The goal is to assess the overall impact that a proposed management action will have on the public, in terms of their quality of life. It is, therefore, critical when monetising costs or benefits for the monetary units to be chosen in a way that accurately reflects the true social impacts, or quality of life impacts, of different outcomes.
LEARNING FROM EACH OTHER

Chemicals management differs throughout the world, but there are lots of opportunities to learn from each other.

“If a chemical issue is important to Canadians, then I believe there is a pretty good chance that it will be important for Europeans too. Studies conducted to find economic valuations can often be very big, very costly and can also take a long time to conduct, so it would be beneficial for Europe and the rest of the world to learn from each other’s results to save costs and resources,” Mr Donohue says and continues, “but the lessons to learn are not just about the results of studies. We should also learn about the techniques used”.

On 22 June 2016, United States’ President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updates the Toxic Substances Control Act (TSCA). According to Mr Krupnick, the update will make TSCA similar to REACH, giving the US Environmental Protection Agency much more authority to get data from industry.

“There is a very lively research environment on chemicals in Europe, which helps make it easier to estimate the benefits of using less toxic chemicals. There are a lot of studies on benefit valuation whereas in the US, these have become less common. In the US, we have much more to learn from European studies, although we hope to see an increased focus on research with the updated TSCA,” Mr Krupnick tells.

“Once the research picks up and the body of literature begins to build, regulatory agencies will need to do more to check what other agencies throughout the world are doing to protect their own consumers from the particular health effects of certain chemicals and learn from each other,” he concludes.

SOCIO-ECONOMIC ANALYSIS AND REACH

Under REACH and other chemicals regulations, socio-economic analysis plays an important role, for example, in restricting the use of a substance or in requiring authorisation before a dangerous substance can be used. Proposals to restrict a substance need to describe the risks posed by the substance as well as the costs for industry. They also need to consider the benefits that the restriction would bring for human health and the environment. Companies applying for authorisation to continue using a dangerous substance may also include socio-economic analysis as part of their applications.

Further information:
- Socio-economic analysis under REACH
- Willingness to pay to avoid selected human health outcomes due to exposure to chemicals
- Health utility metrics in chemicals impact assessment
- Valuing selected health impacts of chemicals
- The Frank R. Lautenberg Chemical Safety for the 21st Century Act
- The US Code version of TSCA as recently amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act
  http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim
- Cost and benefit assessments in the REACH restriction dossiers

HEALTH CANADA & RESOURCES FOR THE FUTURE

Health Canada is the Federal department responsible for helping Canadians to maintain and improve their health. It is committed to improving the lives of all of Canada’s people and to making Canada’s population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public healthcare system.
http://www.hc-sc.gc.ca/

Resources for the Future (RFF) is an independent, non-partisan organisation, conducting rigorous economic research and analysis to help leaders make better decisions and craft smarter policies about natural resources and the environment. RFF was the first thinktank devoted exclusively to natural resource and environmental issues and helped create the field of environmental and natural resource economics.
http://www.rff.org/

Sources: Health Canada and Resources for the Future.
Want to know about...the completeness check and how it affects every dossier?

TEXT BY HANNA-KAISA TORKKELI, ANNIKA MÄLKIÄ

Complete and meaningful information on chemicals is the basic requirement for identifying – and managing – harmful chemicals. It also makes sure that the appropriate information on how to use them safely is communicated in the supply chain. To ensure that the data in a dossier is complete, ECHA performs a check on every dossier. What is this check about and how has it recently changed? ECHA Newsletter explains.

COMPLETENESS CHECK OF INCOMING REGISTRATION DOSSIERS

Each time a registration dossier is submitted, ECHA checks to make sure that it contains the information required by REACH. The check is done on new registrations and updates of existing ones. If the dossier is incomplete, ECHA informs the registrant and requests the missing information. The registrant can then update their information within a certain deadline, to make the dossier complete.

Because of continuing concerns about the quality of information in REACH registration dossiers, ECHA has been looking for every opportunity to improve the data. The revised completeness check process introduced in June 2016 is part of that. The revision introduced the following changes:

- Update of the existing, IT-based completeness check to include the new IUCLID formats, latest regulatory changes and more targeted checks to make sure key information is present;
- A new manual check of elements that cannot be checked automatically.

In addition, ECHA has also started to check the completeness of existing registrations in its database to make sure that they actually contain all elements required for a complete registration.

MANUAL VERIFICATION

This means that the dossiers are stopped at the completeness check step and ECHA staff review their contents.

The manual check focuses on data fields where the registrant should justify why they deviate from or adapt a standard requirement. The main areas are:

- substance identification information;
- the standard information requirements listed in Annexes VII-X; and
- the chemical safety report.

ECHA will also verify that companies have considered alternative methods for generating data if they are proposing a test on vertebrate animals. The manual check is always done in the same way so that the outcomes are consistent.

The aim is to make sure that registrants have provided relevant information and a meaningful justification if they deviate from the required information or propose an animal test.

Due to this extra step in the completeness check process, companies may experience short delays in receiving the result of the check - compared to the previous, fully automated one.

FIRST EXPERIENCES OF THE MANUAL CHECK

So far, ECHA has selected around 30 per cent of the incoming dossiers for manual verification based on IT-screening. Of these, about 30 per cent have failed the manual check. The main reason for failure was that they lacked a justification for waiving data and had an unclear substance identity. In particular, dossiers with an incomplete description of the manufacturing process of UVCB substances – a key identifier for these substances of unknown or variable composition – have failed the check.

Companies have, in most cases, been able to provide the requested information. In only two cases, the second submission was also not complete and was, therefore, rejected. They were registrations for UVCB substances which lacked sufficient information about the composition.
CHECKING EXISTING REGISTRATIONS

ECHA is now also checking existing registrations in its database. This project was set in full speed after the decision of the Board of Appeal in March 2016, which clarifies that ECHA can reopen the completeness check of an already registered substance and request the missing information.

It was also confirmed that this situation may eventually result in the revocation of the registration decision if the requested information is not given within a specific deadline set by the Agency.

A first set of requests for missing information in existing registrations were sent out in June. The main focus was on registrations where companies had indicated that they would submit study information but have not done so.

The revised completeness check process is expected to improve the data available to the authorities and the general public through the online chemicals database.

Further information:

New generation of IT tools coming soon, News alert 13 April 2016

ECHA to review completeness of registrations, News alert 8 April 2016

Information on manual verification at completeness check

Registration support: What information you need?
https://echa.europa.eu/support/registration/what-information-you-need

DATA – STILL NEEDS TO GET BETTER

Despite the amount of information now available, a significant proportion of registration dossiers contain data that is not of a sufficient quality. Without good quality data, the risk management of substances is delayed and the safe use of chemicals is not possible. It is vital that companies proactively update and improve their registration dossiers and safety data sheets on their substances. The good news is that when ECHA notifies companies of the need to improve their data, the vast majority of them respond constructively and make their dossier compliant with the law.

REACH and CLP: what’s working, what’s not?

TEXT BY TIIU BRÄUTIGAM

REACH and CLP have been in force since 2007 and 2009 respectively. How are things going? ECHA Newsletter had a look at two recent reports by ECHA to give some answers.

MORE INFORMATION ON CHEMICALS

There is now a wealth of information on chemicals freely available on ECHA’s website. So far, nearly 10 000 companies have registered chemicals; ECHA has received more than 54 000 registration dossiers for 14 000 substances.

In addition, over 10 000 companies have informed ECHA of their substance’s classification. This increased knowledge of chemical properties leads to improved chemicals management, and ultimately to safer products and the phasing out of the most dangerous substances.

The most dangerous chemicals are being phased out and many are replaced by safer alternatives. Examples of chemicals being phased out are musk xylene, a fragrance which is very persistent and very bio-accumulative, and MDA (4,4’-Diaminodiphenylmethane), which is used in polymers, lubricants and greases, and is carcinogenic.

So far, 31 substances of very high concern (SVHCs) have been placed on the Authorisation List and cannot be used without prior authorisation. In fact, relatively few companies have applied for an authorisation to use them, indicating that they have been phased out.

In addition, 20 restrictions proposed or made under REACH, limit
the use and reduce the risks of hazardous chemicals, for example, lead in jewellery and consumer articles, and chromium VI in leather products. 200 opinions on harmonised classification and labelling have in turn triggered further risk management actions.

**BOOST FOR INNOVATION?**

Almost 1 500 new substances have been registered since 2006, with an increasing annual trend. With REACH, companies can benefit from reduced information requirements for chemicals that are being used for research and development. This has been widely used, mainly by large companies.

European companies are also increasingly taking innovative approaches to finding safer alternatives to the most hazardous substances. More can still be done, but the pressure for safer chemicals from downstream users, retailers and consumers should not be underestimated. With increased awareness of substances of very high concern, consumer demand and the drive towards circular economy, innovative solutions will become more attractive.

**MORE CLARITY FOR CONSUMERS**

For consumers, there is still too little information about substances of very high concern in articles - especially in those imported into the EU. Companies are required to inform ECHA of substances of very high concern in products, but very few have done this so far. Importers especially need to take their responsibilities seriously and notify ECHA about the effects their products could potentially have on consumers. Additional awareness-raising amongst importers and stronger enforcement are the key to making this happen. Also, consumers need to be more aware of their right to ask if the products they buy contain SVHCs. So far, this right is not widely used.

**IMPROVE SUBSTANCE CLASSIFICATION**

The Classification, Labelling and Packaging Regulation requires companies to classify their substances. Many substances have a harmonised classification throughout Europe to ensure adequate risk management – in those cases, companies tend to comply. However, the challenge lies where companies are making their own self-classification for substances. There are still considerable variations between self-classifications from different companies for the same substance, which is confusing for downstream users and consumers. Therefore, ECHA proposes that the European Commission consider amending the CLP Regulation to require companies to share data and agree on the classification.

**RESTRICTIONS: BENEFITS OUTWEIGH THE COSTS**

ECHA has recently looked into the balance of benefits and costs of restrictions made under REACH so far and drawn a positive conclusion. For 16 restrictions, the costs were estimated at almost €300 million per year. However, their health benefits were estimated to be over double that, at €700 million per year. For example, restricting Chromium VI in leather articles is estimated to save more than €350 million per year in medical costs across Europe.

Another benefit from restrictions was emission reduction: around 190 tonnes of substances of concern, for example, mercury, were not released as a result of restrictions.

**DID YOU KNOW?**

ECHA’s second report on the implementation of REACH and CLP was published in May 2016. It describes the main achievements and challenges of the ground breaking EU chemicals legislation.

In April 2016, ECHA published a report on Cost and Benefit Assessments in the REACH restriction proposals. It summarises information on the costs and benefits to human health and environment. The report is based on the restriction proposals and opinions of the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).
20 restrictions proposed or made under REACH limit the use and reduce the risks of hazardous chemicals, for example, lead in jewellery and other consumer articles.

Further information:
We currently discard the majority of material we use in the EU. This is something that has to change. The objective of a circular economy is to retain material for as long as possible, minimising waste and the need for additional resources. This requires sustainable materials management and new, innovative approaches to producing materials with a longer life. **Bjørn Hansen** from the European Commission explains why the legislation on chemicals plays such an important role in a circular economy.

Chemicals are fundamental to the circular economy - they are used in products and will either be recycled or discarded as waste. A circular economy cannot be discussed without looking into the legislation on chemicals and what is happening with hazardous substances in the entire chain of events.

At the end of 2015, the European Commission adopted a package of measures to stimulate Europe’s transition towards a circular economy. Boosting global competitiveness, fostering sustainable economic growth and generating new jobs are some of the benefits that the package is expected to deliver.

**RECYCLE OR DISCARD?**

Our planet’s resources are limited. Achieving the goals of a circular economy, which relies heavily on greater recycling and reuse, will reduce the strain on natural resources and reduce the EU’s dependency on natural resource imports.

Although everyone is in favour of a higher degree of recycling, there are controversial aspects. For example, REACH has increased the number of chemical substances that are identified as being of concern for health or the environment. What should happen to those chemicals that are already circulating? Many of them will have been recycled and reused long before the current legislation came into force. Some of them may have a long lifetime and therefore stay on the market for decades.

According to Mr Hansen, Head of Unit of Sustainable Chemicals in the Directorate-General for Environment, the raw materials on the market today can be divided into three categories. The first is material that is harmless and is as good as new. This can clearly be recycled without restriction and used to produce new articles.

The second includes material which is so “dirty” that it cannot be put back on the market. “This material must be burned, incinerated with energy recovery or landfilled. Persistent organic pollutants (POPs) are a good example of this group of substances that should not be recycled,” Mr Hansen says.

Material in the third category falls somewhere in between. There is a question mark related over it. It can be physically recycled, but it may include harmful chemicals and, therefore, its use should be controlled and tracked.

It is mainly this third category that complicates the situation. “On one hand, you could say that there are so many unknowns in the future, that precaution tells us to get rid of as many substances as possible as soon as possible, to clean up the waste stream. This means that we would not let these substances be recycled and re-enter the production process. On the other hand, you could put more weight on the importance and value of the material and less on the potential dangerousness of the chemicals it contains,” Mr Hansen explains.

**THINKING AHEAD**

The question is, how to get rid of unwanted substances in recycled material without destroying the material and its function. “Most materials have a desired functionality. And there will be chemicals that are...
essential for that functionality. The tricky thing is to make sure that the value of the material is maintained for as long as possible, at the same time realising that it may also contain substances that you want to get rid of,” Mr Hansen explains.

Technology can offer some solutions. To find out what the material that goes into recycling actually contains, we need a system to trace chemicals. This is particularly important since the requirements in chemicals legislation today are higher than ever before. “This is something that we need to have anyway,” Mr Hansen says and continues, “if we ever want to enforce the law which says that dangerous substances present in articles have to be notified to ECHA, we have to be able to take, for example, a toy coming from outside the EU and test it. It means that something that is needed for current enforcement purposes can also be used in future to track chemicals”.

However, tracing all substances would have a huge cost, which means that in practice only the most important ones, both societally and technically, can be traced.

Mr Hansen also mentions 3D printing as an opportunity that could lead to cleaner materials in the future. “If people who are producing 3D printers and inks today, would think sustainably about materials now, in 50 years we could be on the right track,” Mr Hansen says. He points out that with 3D printing, once we stop using a product, it can be sent to the 3D printed material recycling plant and out will come the liquid that can be re-used to print the next item. But to actually get there, we need to act now. “If we do this in 20 years, it will be too late. People by then will have invested in the technology, the machines and in the direction of resource and development. They will be much less able to change.”

INVESTING IN SOMETHING POSITIVE

According to Mr Hansen, European industry should now be investing in innovation and moving towards a circular economy. It is the best way to secure Europe’s competitiveness on the global market. “We should be at the forefront of innovation and this applies also to the chemical sector. If a company has a line of chemistry that is predicted to be unsustainable, they have to invest in getting out of it. At the same time, they are actually investing in getting into something better,” Mr Hansen points out.

As soon as it is decided that contaminated materials will no longer be recycled, it immediately creates a market for innovation and replacements. Clear decisions and predictable, long-term actions give industry the stability that they need to be able to start planning alternatives. “Ideally, we should decide today if we want to ban something in 15 years, because then it will stimulate the markets,” he says and continues, “if we don’t address the problem, in 10 year’s time, not only will we have the same problem, but we will also have contaminated a lot of very valuable, clean material with the hazardous chemical,” Mr Hansen states.

IN THE END, EVERYTHING TURNS INTO WASTE

Mr Hansen reminds that for the time being, a circular economy is not going to solve the waste problem on its own, it is simply slowing down the time before a material becomes waste. We need to keep in mind that eventually, all material ends up as waste and cannot be recycled anymore.

“It hardly any material really maintains its full quality after multiple episodes of being recycled. So, we still need to make sure that we have sustainable waste management,” he emphasises. “It is important that we invest in prevention and make sure that every product is planned so that it contains clean material that, in the end, can be incinerated or otherwise safely disposed;” he concludes.

Further information:

The European Commission’s Circular Economy Strategy

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

As soon as it is decided that contaminated materials will no longer be recycled, it immediately creates a market for innovation and replacements.
Making non-animal test methods the default
TEXT BY NEDYU YASENOV

A lot of research is being done to develop test methods and strategies to assess the potential effects of chemicals on humans and the environment that can refine, reduce or replace the use of animals. These approaches are called ‘alternative methods’ to the traditional testing on animals that have been in place for decades. There are now legally recognised alternative methods to test for skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation and acute toxicity.

Legal changes to the REACH Regulation came into force on 20 June 2016 which set out the conditions under which animal testing is no longer required. This means that alternatives replacing some of the most frequently conducted animal studies are now the default requirement within Europe.

SKIN CORROSION/IRRITATION

Skin irritation and corrosion are effects that can occur both in the workplace and at home. They are categorised as local effects, which means that they occur at the point of contact between the skin and substance.

A step-wise approach to testing is required when assessing irritation and corrosion. If you get a negative result from a validated in vitro skin corrosion study, you will then need to perform a validated in vitro skin irritation test to further assess skin irritation.

If you then obtain a negative result from a validated in vitro skin irritation study, you will not need to do further tests, as it can be concluded that the substance does not need to be classified for corrosion or irritation.

SERIOUS EYE DAMAGE/EYE IRRITATION

Serious eye damage and eye irritation are effects that can occur both in the workplace and at home and they are also categorised as local effects. The front parts of the eye, i.e. the conjunctiva, iris and cornea, are usually assessed for irritation and corrosive effects as a result of direct contact with a substance.

The current validated in vitro studies can only detect substances which cause serious eye damage (CLP/GHS category 1) or which do not need to be classified for eye irritation (no category CLP/GHS). However, they cannot detect chemicals which are classified as eye irritants category 2 under CLP/GHS.

Here also a step-wise approach is recommended: for serious eye damage/eye irritation effects, the first study you should conduct is a validated in vitro study that can detect substances causing serious eye damage but can also indicate substances that do not irritate the eyes. If a conclusion on classification cannot be made, additional in vitro studies should be considered.

However, if the conclusion is neither “no classification” or “serious eye damage”, then you will need to use in vivo models to further assess the potential to irritate the eye and to conclude on classification and risk assessment.

ACUTE DERMAL AND ORAL TOXICITY

Acute toxicity means adverse effects which may occur within 24 hours of exposure to large amounts of a substance, either through skin contact, ingestion or inhalation. For example, an accidental spillage in the workplace could cause acute toxicity. The symptoms are generally rapid in their onset and affect various organs.

The test for contact with the skin can now be omitted if you can show that the substance does not need to be classified after the test related to oral toxicity. In addition, a validated in vitro test is available and can be used in combination with other information to show a lack of oral toxicity.

SKIN SENSITISATION

Skin sensitisation is an allergic reaction on the skin when it is exposed to a chemical for a second or more times. It is an immunological response.

From autumn 2016, alternatives (in vitro and in chemico methods) to animal testing are the default as a first step for generating new information to assess skin sensitisation potential as described in the REACH Regulation.

You can only test on animals if the alternatives for this endpoint are not suitable for your substance or if the results of the alternative tests
do not provide the information required for classification and risk assessment.

**HOW ARE REGISTRANTS AFFECTED?**

You must take these changed requirements into account when you submit information to ECHA.

If you have already registered your substance and submitted studies based on the previous requirements, you do not need to modify your registration dossier immediately. However, when updating your dossier, you will need to follow the new requirements, for example, registrants who met the previous requirements with an *in vivo* study do not need to carry out additional *in vitro* studies. However, when you update your dossier, you will need to explain why you did not submit an *in vitro* study.

To help you, ECHA is currently updating its guidance on information requirements. Advice on the use of OECD test guidelines related to skin and eye irritation have already been updated and published on ECHA’s website.

**Further information:**


Advice on skin and eye irritation testing helps reduce animal tests, News alert 5 July 2016 [https://echa.europa.eu/view-article/-/journal/content/title/advice-on-skin-and-eye-irritation-testing-helps-reduce-animal-tests](https://echa.europa.eu/view-article/-/journal/content/title/advice-on-skin-and-eye-irritation-testing-helps-reduce-animal-tests)

Registrants to use alternative test methods for skin sensitisation, News item 5 July 2016 [https://echa.europa.eu/view-article/-/journal/content/title/registrants-to-use-alternative-test-methods-for-skin-sensitisation](https://echa.europa.eu/view-article/-/journal/content/title/registrants-to-use-alternative-test-methods-for-skin-sensitisation)


Practical Guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes per year [https://echa.europa.eu/practical-guides](https://echa.europa.eu/practical-guides)

How to use alternatives to animal testing to fulfil your information requirements for REACH registration [https://echa.europa.eu/practical-guides](https://echa.europa.eu/practical-guides)


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**GLOSSARY**

- **Irritants** - cause a localised, reversible inflammatory reaction.
- **Corrosives** - cause burns at the point of contact.
- **Sensitisers** - give rise to an allergic reaction.
- **Acute toxicity** - lead to various symptoms, ranging from discomfort to death, and arising from a short duration of exposure to a relatively large amount of a chemical
- **Toxic(ological) endpoints** - endpoints that are used to define the properties of a substance, which may result in adverse effects in humans.
- **Acute vs chronic endpoints** - acute studies generally last no longer than a week and examine endpoints such as mortality and behaviour. With acute studies, a common endpoint is the dose of a compound required to kill half of the organisms in the study. Chronic studies are longer in duration (more than a week) and include endpoints such as reproduction, long-term survival and growth.
- **In vitro vs in vivo** - *in vitro* studies are conducted in test tubes, i.e. outside the living organism, using cell or tissue cultures. *In vivo* studies are conducted within the living organisms as surrogates for humans, for example, rats and mice.
- **Ex vivo** - studies where living cells/tissues or even organs are removed from a living organism and then used in a toxicity study to determine the effects of chemical exposure.
- **In chemico** - the use of non-animal or *in vitro* measurement of the reactivity or other physicochemical properties of compounds.