REACH 2018 - things for SMEs to think about

The last registration deadline concerns companies that manufacture or import substances in low volumes. Many of these companies are small and medium-sized enterprises. We spoke with Ms Janet Greenwood of the UK Chemical Regulations Self Help Group, to understand SME challenges.

REACH restrictions underway for lead and tattoo inks – where are we?

Restricting means limiting or banning the manufacture, placing on the market or use of a substance. We share with you the latest developments with the most topical restriction proposals.

“What we need now is courage”

Over 200 professionals came together at ECHA in April to discuss how new approach methods can be used to improve chemical safety. The benefits of these methods are clear – they contribute to better toxicology, lower the demand for animal testing and raise competitiveness.

Product treated with a biocide? Don’t forget 1 September 2016

If you place products on the EU market that are treated with a biocide, you need to make sure that you comply with the law by 1 September 2016.

Confidence in compliance

How does ECHA make sure that the information provided by companies on substances is complete and good quality? The main way is by evaluating registration dossiers. The formal requests for further information significantly contribute to the improvement of the data. This, in turn, improves confidence in the legal compliance of registrations and in the companies submitting them.

Confidence in compliance is very relevant to all of you who are preparing your registrations for the last registration deadline. Good quality information is not only fundamental for the protection of human health and the environment – it is crucial for your company to enable appropriate communication on safe use in the supply chain, all the way down to workers and consumers. Without reliable information, it is not possible to put the necessary operational conditions and risk management measures in place. A good quality dossier also makes your life easier after registration: you are less likely to receive ECHA’s requests for further information. At the end of the day, your registration is part of your business reputation – it is an important asset.

We have shared our concerns about the quality of data in our annual evaluation reports. Before you start preparing or updating your dossier, please read the recommendations of the reports. They highlight the most common shortcomings we have encountered and give you a chance to avoid the mistakes.

Steps to successful registration

The next step to be highlighted comes in July. It is about assessing hazard and risk and is the most extensive of all the steps. To help you in your tasks, we are preparing practical support on the information requirements and on how to avoid testing substances on animals. We will also publish a new practical guide to help managers of small and medium-sized enterprises (SMEs). A webinar on assessing hazard and risk will be on 20 July.
The updated IT tools (IUCLID 6, Chesar and REACH-IT) will also all be published by the end of June. Their new structures and features will help you to report your data in a more complete and comprehensive way.

**Proposals to test on animals**

In the meanwhile, 1 June 2016 is our deadline for producing draft decisions on all proposals to test on animals, which were submitted for the 2013 deadline. Since September 2015, all registrants have been asked to detail the alternatives to the animal test they have proposed. We then publish their reasoning as part of the third party consultation. This follows the recent decision by the European Ombudsman about ECHA’s role in the examination of proposals to test on vertebrate animals and should help us to make sure that testing on animals is only done as a last resort.

**New approach methods to avoid animal testing**

In April, we held our third scientific workshop. The topic was new approach methods, which aim to reduce testing on animals. As one of our main objectives is to promote alternatives to animal testing we were happy to see over 200 international experts discuss how these new approaches can be more widely used. We are convinced that well-tailored new approach methods can contribute to better toxicology and, as a consequence, safer chemicals, a more competitive economy and fewer animal tests. However, honest discussion on the limitations, relevance and robustness of these methods is first needed. Have a look at the interviews we made during the event on page 20.

On a final note, I hope to see you at our stakeholders’ day on 25 May. The second session of the day will be dedicated to dossier quality. If you are not coming to Helsinki, you can still follow the event online.

I wish you all a sunny and relaxing summer.


**REACH 2018 phase 4: Assess hazard and risk**
The next step in preparing a successful registration dossier - step four - is about assessing the hazards and risks of your chemicals. For this, you need to collect all available information, compare that with the legal requirements, identify any potential data gaps and come up with ways of filling them. Your ultimate aim is to demonstrate the safe use of your substance, while making sure that testing it on animals is kept as a last resort.

The starting point for your information gathering is to analyse the current situation: what information have you got and what do you still need? These four steps will help you in your planning:

1. Gather and share existing information

Collect all the physicochemical, toxicological and ecotoxicological information that is relevant for your substance. There are five main types of information you need:

1. The substance identity information;
2. Physical and chemical characteristics of the substance;
3. Environmental properties of the substance;
4. Human health properties of the substance;
5. Uses and conditions of use of the substance from manufacture to waste.

You may get the information from a variety of sources: you may have it in your own company, get it from databases or other sources in literature or on the internet. Remember to check the identity of the test material and to respect the copyright of the data owners. You may need to pay the data owner for using their data.

You need to collect information on the current and potential future uses of your substance. You may get this from your downstream users, but also sector organisations are often able to give descriptions of the typical uses of substances used by their members.

When you gather your data, keep in mind that you also need to assess its relevance, reliability and completeness. Providing information of good quality and fulfilling the legal requirements make your life easier after registration: ECHA is less likely to request further information. Furthermore, as most of the information from your registration dossier will be made public on ECHA’s website, it will be a reputational asset for your business rather than a potential embarrassment.

Remember that you are not alone: You must share your data with other companies registering the same substance. In this way, you will have access to more information to fulfil your obligations and you and your co-registrants can avoid repeating tests.

2. Consider your information needs

You also need to know the requirements which are relevant for your registration. These depend on the volume of your manufacture or import. The bigger the volume, the more information is needed.

If you are registering at the lowest tonnage band (1 to 10 tonnes a year), you will need to provide data on up to 22 properties. However, some properties will not be applicable to your substance.

If you register for the next tonnage band (10 to 100 tonnes a year), you will need additional information on up to 13 properties.

If you register for the highest tonnage band (more than 1000 tonnes a year), you will need to provide data on 55 properties. You may get this from your own company, get it from databases or other sources in literature or on the internet. Remember that you are not alone: You must share your data with other companies registering the same substance.

3. Identify information gaps

By comparing the outcome of steps 1 and 2, you will be able to identify what new information you need for your registration. This new information must be generated together with the other registrants of the same substance.

4. Generate new information or propose a testing strategy

When you have identified a data gap, you need to find a way to fill it. Remember that testing on vertebrate animals is always the last resort.

Ask yourself the following questions before conducting a new test.

- Is testing technically possible? Testing for specific pieces of information can be avoided if it is technically not possible to conduct the study due to the properties of the substance. For example, if your substance is very volatile or highly reactive.

- Is it possible to use alternatives to animal testing to fill in the data gap? Examine whether you could use existing information from a structurally-similar substance (read-across), from a computer model (QSAR), from an in vitro test, or from multiple sources to build a conclusion on the property by predicting its effect (weight of evidence approach).
Recent legal changes to the REACH annexes mean that you can only provide information on skin corrosion, serious eye damage and skin sensitisation through in vitro studies.

Remember that if you decide not to test or if you use an alternative approach, you will have to justify yourself in your registration and provide relevant documentation to support your approach.

If you conclude that a new test is needed, it must be performed according to one of the methods included in the European Commission’s Test Methods Regulation (or to an international test method recognised by the Commission or ECHA). Toxicological and ecotoxicological tests must be carried out in compliance with Good Laboratory Practice.

WORK TOGETHER

Generating new information is a joint task of companies registering the same substance. You will need to collectively decide and agree on what the next steps are: which tests to carry out and how, and how to share the costs.

You will also need to agree on the classification and labelling of your substance based on the hazard data. In some cases, different classifications are possible for the same substance because of different impurities influencing the classification.

All your hazard data and classifications should be recorded in the registration dossier. In addition, if you manufacture or import more than 10 tonnes a year, you need to carry out a chemical safety assessment (CSA) and record it in a chemical safety report (CSR). You and your co-registrants can agree that the lead registrant submits the CSR jointly on behalf of everybody or you can submit your own CSR separately.

ECHA’s top five tips for data gathering

- **Start now.** Gathering existing and creating new data takes time. Plan your time, activities and resources in phases over the coming two years.
- **Analyse your situation** and understand what new information you need. The information requirements are different depending on your manufacture/import volume. Understand that discussing within the SIEF may take quite some time.
- **Share data openly** with the other companies in the SIEF. Remember that all registrants of the same substance must be part of the same registration as it is not possible to submit a registration individually.
- **Testing on animals is the last option** – always consider alternative methods first. This is a legal obligation. Sharing data also reduces your own costs and helps to avoid unnecessary testing on animals.
- **Book a test laboratory** as soon as possible. Testing takes time and laboratory capacity is limited.

Further information:


Support for low volume, low risk chemicals http://echa.europa.eu/docu-

ments/10162/2621167/echa_annex_iii_strategy_en.pdf


**Upcoming in July**

New online content on information requirements and how to avoid testing on animals as well as a practical guide for managers of small and medium-sized enterprises (SMEs) will be published on 19 July. The webinar on assessing hazard and risk will be on 20 July.
“There are no shortcuts in safety assessment”

TEXT BY HANNA-KAISA TORKKELI

Putting information together for your registration dossier on the hazards and risks of your substance is the most extensive and time consuming part of the registration process. The basis for generating new data through testing is a comprehensive analysis of where you are and what you need to achieve.

RIGHT TEST FOR THE RIGHT SUBSTANCE

Analysing the current situation – reflecting the reality of your manufacturing process – is the starting point for your testing strategy. You also need to assess the relevance of your proposed testing.

“What you need is a scientific approach. Firstly, you need to test the real substance you are manufacturing (with all its impurities) and not a clean sample of it. Secondly, reflect on the nature of the product, its application and the possible exposure routes, and decide what testing strategy is going to work best. Thirdly, consider the applicability of the tools you are planning to use – are they fit for purpose?” says Dr Erwin Roggen, a Danish consultant, who actively promotes alternative methods when helping companies with their choices of testing.

FOCUS ON HUMAN SAFETY

The testing strategy you decide to go for should give you accurate and correct information about your chemical.

“Companies really need to understand what tests they can use for their compounds. The tests recommended in the test guidelines of ECHA or the OECD might not work for certain compounds, for example, because they belong to a different chemical group with different solubility or reactivity than the substances used for developing the guideline. In these cases, the test guideline should not be followed for the sake of it. You instead need an intelligent strategy to give you the right safety information about your substance. Too often, this possibility is discarded due to uncertainty about the costs and worries about the willingness of regulators to accept them.”

For Dr Roggen, animal-free methods are always the first choice. The animal-based methods can then be used to confirm the conclusions, address complexities that animal-free methods cannot solve or to satisfy regulatory authorities.

Companies come to me when they are facing a problem with their testing strategy. For example, one company looking to launch a new product on the market was testing on animals, according to the guidelines, for several years but failing to get the test right for human safety. I proposed an animal free testing strategy not only to assess safety but also to understand what was going wrong. It took just six months to figure out and confirm what was going wrong in their production process. That was an eye opener for this company: if they had done this thorough analysis of their compound earlier, they would not have wasted time and money on testing and would have been on the market earlier.”

USE EXTERNAL HELP

According to Dr Roggen, the challenge for the REACH 2018 registrants is resources. “Smaller companies are unlikely to be able to keep up with new guidance and really understand what it means for their products. They need external help to figure out, for example, how alternative methods can be used to improve confidence in the safety assessment of their chemicals and how to interpret the test data,” he says.

Assessing chemical safety is always a balance between speed and accuracy, business and chemistry. Toxicologists want to scrutinise everything, while the business side want to move on and get things done. But human safety should be the priority for all.

“At the end of the day, there are no shortcuts for determining the safe use of your chemical,” Dr Roggen concludes.

Further information:


**Tempus fugit, time flies**

*Tempus fugit* is a Latin phrase, usually translated into English as ‘time flies’. The expression comes from Virgil’s Georgics, where it appears as “fugit inreparabile tempus”: “it escapes, irretrievable time.” The phrase is used in both its Latin and English forms as a proverb that “time’s a-wasting.”

In just 24 months, the third deadline for the registration of phase-in substances under REACH will be over. This giant operation, ensuring the registration of a group with well over 20,000 substances under the European chemical registration regime, is currently running at full speed. While many companies are actively working on their compliance, even more companies have not yet started. For them, time is running out.

Completion of a registration dossier takes time. For substances with no or insufficient data, testing or finding alternative ways of data gathering (e.g. providing acceptable waiving statements and read across) is needed to complete the dossier. In most cases, the services of both contract research organisations (CROs) and/or consultants will be required. Vacant capacity versus available time is currently a challenge that many potential registrants seem to be unaware of. The reality is that demand and supply for these services is well out of balance.

Besides REACH, there are many other demands for these services. Strong demand from the pharmaceutical, biocide and agrochemical industries is also putting pressure on the availability of services for testing and dossier preparation support. CRO capacity is tight and not exclusively available for REACH testing.

There is also pressure from ‘internal competition’. For the May 2018 registration deadline, substances with volumes between 10-100 tonnes a year require a developmental and reproductive toxicology (DART) endpoint, obtained in most cases through an OECD 421 or OECD 422 test.

At the same time, ECHA is sending out (draft) decision letters approving the initiation of testing for further DART endpoints (mainly OECD 414 and OECD 443) proposed for completion of the registration dossiers from the previous milestones in 2010 and 2013. Both requirements make demands on the same DART capacity available at the CROs, causing a conflict.

As an example, for a substance in the volume range of 10-100 tonnes a year with a complex composition (UVCB) and no available data, the time involved in substance characterisation, SIEF communication, performing all required testing and the preparation of a lead registration dossier, including a required chemical safety assessment and safety report, may vary between 15 and 34 months.

With only 24 months remaining, those who have not yet started may miss the deadline. Therefore, carpe diem! Commit to your obligations under REACH. Start now and contact CROs and/or consultancy companies for support. Time flies – don’t waste it!

**Frank Visser**

*European Sales Director, WIL Research - A Charles River Company*

WIL Research is a contract research organisation (CRO), acquired in early April 2016 by and merged into the Charles River Company. It provides contract research and expert consultancy for the registration of chemicals, pharmaceutical products, biocides and agrochemicals worldwide.

https://wilresearch.com/
REACH 2018 - things for SMEs to think about

TEXT BY JULIA SIERRA

The REACH registration deadline of 31 May 2018 will see the highest number of registrations to date. It concerns substances manufactured or imported in low volumes, between 1–100 tonnes a year. Many of the companies affected are small and medium-sized enterprises (SMEs).

We spoke with Ms Janet Greenwood, Secretary of the UK Chemical Regulations Self Help Group that helps SMEs understand their obligations under REACH and CLP.

Time plays a crucial role for companies that have obligations for the REACH 2018 deadline, especially if they are lead registrants. “My worry is that there are many lead registrant SMEs who think they have plenty of time before the deadline. But if they leave it until mid-2017, they may find that there is no help out there, as most of the testing labs and experienced consultants will be fully booked,” Ms Greenwood says.

In her experience with the Self Help Group, it is mostly lead registrant SMEs who need help from a consultant, whereas member registrants can manage with support and training from their peers.

LETTER OF ACCESS AND COST SHARING

The letter of access plays a big role in sharing data and results from the core REACH principle of ‘one substance, one registration.’ The document, which allows third parties to access data owned by someone else, is also the primary concern for Ms Greenwood.

“Even where cost sharing is carried out as fairly as possible, the cost per kilo of REACH data is higher for lower tonnage bands than for higher tonnage bands. Most SMEs work with lower tonnage bands and are therefore affected by this imbalance. The Commission and ECHA seems to have recognised that this cost per kilo bias could also apply to REACH registration fees, which may be why they offer discounts for SMEs. It would be good to see SME discounts offered on data as well.”

This situation might lead to companies reducing their product ranges, changing their strategy to only manufacture or import substances below one tonne per year, or even closing their businesses. “Ultimately, it could reduce both the number of chemicals on the market and the number of suppliers,” she points out.

MISSING LEAD REGISTRANTS AND LIMITED LAB CAPACITY

Small companies’ registration tasks can be hampered by lead registrants who are not following the rules of REACH. In some cases, the lead registrant is not serious about registering the substance.

“SMEs suffer from these situations. In addition, there are cases where a lead registrant exists but cannot provide an estimate of costs for the letter of access;” Ms Greenwood explains.

The lack of lab capacity and costs for tests are also challenges that need to be dealt with. “For at least one standard test in the 10 – 100 tonne range, the lab capacity is limited. Issues could also arise for performing other tests as we approach the deadline. To add to that, the costs for testing substance sameness are very high, if you have a non-standard substance that requires extra tests.”

WHAT ECHA COULD DO

The Chemical Regulations Self Help Group say that ECHA could be more active in cost sharing and enforcing best practice rather than just waiting for appeals.

“Providing a standardised method of cost apportioning and cost shar-
JANET GREENWOOD’S TOP FIVE TIPS FOR SMES FOR REACH 2018

» **Start now** - regardless of whether you are a lead or member registrant. Prepare a list of all your REACH substances and understand what tonnage band you will register them in.

» **Contact your lead registrant** to discuss prices for the letter of access. If there is no lead registrant for a substance that is critical to your business, consider taking the role yourself.

» Member registrants: once you have your letter of access prices, **work out which substances you can afford to register**. If you disagree with the price, discuss it with the lead registrant and consider appealing to ECHA if you believe the price is not fair, transparent and non-discriminatory.

» Once you know which substances you will register, try to get your **substance sameness tests** carried out early.

» **Consider registering substances earlier** than 2018, as it will spread the cash flow burden, and it will be less stressful than trying to ‘beat the deadline’.

REACH for non-EU manufacturers

TEXT BY PAUL TROUTH

If you import substances into the EU above one tonne a year, you need to register them with ECHA. However, you can also appoint an EU-based ‘only representative’ to carry out the registration tasks on your behalf. We spoke to Dr Dieter Drohmann, President of the Only Representative Organisation (ORO), to gain an insight into the role of only representatives ahead of the REACH 2018 deadline.

**DOING THE WORK FOR YOU**

Using an only representative **reduces the responsibilities of importers**, as they will be regarded as downstream users. In many cases, it offers an easier option for non-EU manufacturers to gain access to the EU/EEA market.

Appointing an only representative also gives non-EU based manufacturers **direct control over the registration process**, without having their importers register. “Only representatives work as a neutral partner, which means that the non-EU manufacturers do not have to disclose their confidential data to their importers and the supply chain. This can provide a competitive advantage as there will be fewer bureaucratic hurdles,” Dr Drohmann says.

Only representatives **handle their non-EU manufacturers’ confidential information securely**, and can submit pre-registrations, inquiries, registrations, classification and labelling notifications, notifications for product and process-oriented research and development (PPORDs) and authorisation applications.

“For the range of services offered, keeping communication channels open is vital. The only representatives communicate directly with ECHA, enforcement authorities, substance information exchange forums, consortia and other actors in the supply chain, which can reduce the workload for the non-EU manufacturers and importers and allow them to dedicate more time to their core business activities,” Dr Drohmann tells.

“Also, since only representatives are able to represent several manufacturers, even if they produce the same substance, the manufacturers can
further benefit from the synergies of their only representatives having hands-on experience of registering the same substances,” he adds.

REACH EDUCATION

One of the greatest challenges faced by only representatives is educating their non-EU manufacturers about what needs to be done to register their substances.

“Often, non-EU manufacturers are not aware of what needs to be done to register a chemical. It would be helpful if ECHA could provide an official guideline summarising the steps for non-EU manufacturers needing to register chemicals. ORO would like to help by educating non-EU manufacturers and importers,” Dr Drohmann says.

Another challenge for only representatives is enforcement. They must record the substance and volume base for which importers are covered by their activities for the enforcement authorities. Therefore, it is essential to receive the correct volumes and details from non-EU manufacturers.

“Importers need to know that they should request written statements from their non-EU suppliers. Inspections and training for importers can help to raise this awareness and make them understand that they need written, volume-based coverage,” Dr Drohmann says and adds, “the different levels of enforcement across Member States, particularly on who is responsible for the content and quality of safety data sheets, is also an area that should be clarified.”

NON-EU COMPANY: BE TRANSPARENT

To help only representatives prepare high quality registrations, non-EU companies need to be transparent and give information on what levels of activity the only representative should be involved, e.g. in SIEFs or consortia, and in which tonnage band the registration is planned. “Only representatives also need to know about data ownership and substance identification as well as have the correct information about the company size of the non-EU manufacturer,” Dr Drohmann highlights.

“Mutual trust between the only representative and the non-EU company is essential. It is very important that the non-EU company selects a professional and experienced only representative since the tasks are complex, specialised and REACH is still relatively new to everyone.”

“it is also good to remember that the only representative role does not stop with the registration of a substance. The service continues with dossier updates, safety data sheet supply tracking and importer and substance volume tracking each year,” Dr Drohmann concludes.

Further information:

ORO’S TOP TIPS FOR NON-EU COMPANIES

- Choose your only representative wisely and set up a detailed and fair contract for both parties. For advice, consult ORO.
- To prevent contractual disputes later on, remember to add a clause in your contract reflecting a possible change of your only representative.
- If you change your only representative, make sure that the substances in your REACH-IT account are transferred to the new only representative.
- Read and follow ECHA’s advice on data sharing. If you purchase a letter of access, make sure that it complies with the new implementing regulation on data sharing.

Q&As on only representatives:
http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/Only+Representative+of+non-EU+manufacturer

ONLY REPRESENTATIVE ORGANISATION (ORO)

ORO represents the majority of only representative service providers. It currently has 33 full members in 11 Member States and one associated member in Turkey.

ORO members represent more than 2 000 non-EU manufacturers, with the majority located in Asia. ORO members cover over 16 000 chemicals already registered or pre-registered and provide coverage for more than 20 000 EU importers located all over the EU/EEA. So far, around 3 200 REACH registrations have been submitted.

For the first and second REACH registration deadlines, only representatives conducted 20 % and 25 % of all registrations, respectively.

For the 2018 deadline, it is expected that more than 25 % of all registrations will be done by only representatives, mostly on behalf of small non-EU manufacturers.

http://www.onlyrepresentative.org
REACH restrictions underway for lead and tattoo inks – where are we?

TEXT BY NEDYU YASENOV

REACH restriction is a regulatory tool that is used when the risks from a substance are not controlled by other regulatory means and need to be addressed Union-wide. It means that the manufacture, placing on the market or use of a substance is limited or banned. We share with you the latest developments with the most topical restriction proposals.

OVERVIEW: LEAD AND ITS COMPOUNDS

Lead is highly regulated in the EU and worldwide. Restrictions or total bans for a range of uses in several sectors apply in the EU. For example, lead carbonates and lead sulphates have been restricted in paints for more than twenty years.

The hazards of lead are well known both to human health and the environment. It affects the blood, the nervous, immune, renal and cardiovascular systems as well as accumulates in soils and sediments. It is also toxic to plants, animals and micro-organisms.

The list of substances restricted under REACH (Annex XVII) already contains an entry for lead and its compounds. This entry covers the uses of lead and its compounds in jewellery and in some consumer goods, with parts that children can put in their mouths. The latter restriction applies from 1 June 2016. The costs and benefits of these two restrictions are shown in Table 1.

Lead and its various compounds also have harmonised classifications in the Classification, Labelling and Packaging (CLP) Regulation for their human health and environmental effects.

Different lead compounds have also been scrutinised under the SVHC Roadmap, where the best options for controlling the risks for substances are analysed through the risk management option analysis (RMOA). As a result, many lead compounds are already on the Candidate List of substances of very high concern (SVHCs). Some, for example lead chromate, have already ended up on the Authorisation List and now need permission before they can be used.

In addition, the European Commission has requested ECHA to prepare new restriction proposals for lead in shot and lead used as stabilisers in polyvinylchloride (PVC).

LEAD IN SHOT OVER WETLANDS

Lead in gun shot may pose a risk to human health and the environment, in particular to aquatic bird species. Several reports link the eating of spent shot with the deaths of ducks and all species of birds. Reports are also warning about possible risks to people who eat game meat, such as pheasants.

Many EU Member States already have national legislation in place to restrict the use of lead in shot. In addition, there is an International Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of the UN Environment Programme, to which the EU is a party.

To manage the risks, harmonise the conditions of use throughout the EU and adhere to the international

GUIDELINE FOR LEAD IN CONSUMER ARTICLES

To help manufacturers, importers, distributors and users of articles as well as Member State competent authorities, ECHA has prepared a guideline on the restriction for lead and its compounds in articles. The restriction will apply as of 1 June 2016.

The guide focuses on giving descriptions and examples of article types, which fall within or beyond the scope of the restriction. The document is endorsed by the Member States and will be published shortly.
agreement, the European Commission requested ECHA to assess the risk and the need for phasing out lead shot in wetlands.

The intention to prepare a restriction dossier was announced in April 2016. There is also a call for evidence to gather more information on the issue. In the coming months, ECHA will organise a workshop to inform its stakeholders of the restriction initiative and to gather further information on lead in shot.

Furthermore, the Agency is now collecting information for the assessment of the risk and the socio-economic impact for other uses of lead in ammunition. These include hunting in terrains other than wetlands, target shooting as well as using lead weights for fishing. In its assessment, ECHA will pay special attention to aspects related to animal welfare in hunting and preventing accidents to hunters and sport shooters. If the risk is demonstrated, this might lead to the preparation of a separate dossier for restriction.

LEAD IN PVC

Lead is used as a stabiliser in polyvinylchloride (PVC) plastics and is released when articles produced from PVC are used. The Commission has asked ECHA to assess the potential risk of lead in PVC plastics.

ECHA will consider issues like the concentration limits of lead in recycled PVC, the availability of analytical methods and the potential impact on humans exposed through the environment (including workers).

The intention to restrict lead in PVC has already been published in the registry of intentions. ECHA has already carried out a call for evidence to gather further information. The Annex XV restriction dossier is foreseen for submission in October 2016. The eventual restriction will complement a voluntary EU agreement to stop using lead stabilisers from 2015.

See more: http://www.vinylplus.eu/progress/13/68/Lead-Replacement

TATTOO INKS

Many reports show significant concerns for public health stemming from the composition of inks used for tattooing. The most severe concerns are allergies caused by the substances in the inks and possible carcinogenic, mutagenic or reproductive (CMR) toxic effects.

As tattoo inks are currently not subject to harmonised control in the EU, ECHA has been asked to assess the risks, the relevant socio-economic impacts and the need for Union-wide action by preparing a dossier for restriction. The potential restriction would not control risks from poor hygiene that may also be an issue with tattooing. The intention for a restriction dossier is likely to be published in July 2016 and is likely to be developed in cooperation with several Member States.

OTHER ONGOING RESTRICTION WORK

Formaldehyde and formaldehyde releasers

The European Commission has requested ECHA to investigate formaldehyde releasers and their uses. The aim is to help the Commission consider whether there are grounds to request ECHA to prepare a restriction proposal on formaldehyde. Another aim is also to support the Member States (France and the Netherlands) in analysing formaldehyde under substance evaluation and the SVHC Roadmap.

Polycyclic aromatic hydrocarbons (PAHs) and other substances in synthetic sports pitches

The European Commission and the Member States clarified in March 2016 that the rubber crumb used as infill material on synthetic turf sports pitches does not fall within the scope of an existing restriction of PAH substances. Being a mixture, rubber crumb needs to fulfil the conditions under the restriction on CMRs.

The Commission is now expected to ask ECHA to assess the remaining risks posed to human health by synthetic turf to determine whether a further restriction is needed.

Further information:

Restriction under REACH

Current restriction intentions

List of substances restricted under REACH

Cost and benefit assessments in the REACH restriction dossiers

Lead info card

Terminology - in 23 languages

DID YOU KNOW?

- Denmark has a ban on the use and trade of lead shot.
- The Netherlands and the Flemish region of Belgium have banned all use of lead shot for hunting and sport shooting.
- 14 Member States have banned lead in shot (partially or fully) either on wetlands or for waterfowl hunting. In several other Member States, discussions are underway.

NEWS FROM ECHA
Joining forces to improve downstream users’ understanding of EU chemicals legislation

TEXT BY LAETITIA REYNAUD, CHEMI

CheMI represents the interests of EU downstream users whose main activity is to incorporate substances and mixtures into articles. It operates as a platform to share information on REACH-related developments and to express the voice of its members on common interests.

CheMI helps to make sure that European article producers are well informed about their role and obligations as downstream users under REACH. It supports them in their tasks to manage the safe use of chemicals in the workplace and to communicate relevant information to customers, including consumers.

EXCHANGING INFORMATION

The platform participates in several high level groups set up by the European Commission and ECHA, including the meeting of the Competent Authorities for REACH and CLP (CARACAL), the Directors’ Contact Group and the Exchange Network on Exposure Scenarios (ENES). It operates with a minimum of overhead and on a subscription-free basis, using load sharing to achieve its objectives.

The representation of CheMI in these groups helps members to stay aware of any ongoing EU debates and initiatives. The small and medium-sized enterprises (SMEs) particularly need all the relevant information to help them fulfil their responsibilities under REACH.

CheMI members meet face-to-face around three times a year. They exchange information on applying and interpreting the regulation.

Experts are frequently invited to these meetings to talk about specific issues.

One of the most recent discussions in the platform was on the European Court of Justice ruling from 10 September 2015 on substances of very high concern (SVHCs) in articles. A member of the group followed the issue and communicated the final decision to the rest of the group. CheMI members discussed the outcome and exchanged views on the interpretation for different articles manufactured by CheMI members.

As a result, all were better informed and had a better understanding of the ruling. It is then up to each sector to individually prepare appropriate communication to its membership, considering the specificities of the sector.

CheMI is now supporting ECHA as an active participant in the Partner Expert Group, which is updating the Guidance on requirements for substances in articles.

CheMI members have also participated in discussions organised by ECHA on possible ways to improve knowledge and communication through the supply chain about substances ending up in articles, such as a Materials Information Platform (MIP).

VOICING CONCERNS

CheMI’s presence in the high-level groups also enables regulators to stay up-to-date with industry.

Through these meetings, authorities get a better understanding of the specific issues of article producers, such as the communication obligations and consumers’ right to know about substances in articles (Article 33 of REACH). For the latter, CheMI has highlighted the challenges of supply chain communication for complex products - in particular when it involves long, global supply chains.

In addition, CheMI members have insisted on the need to ensure a consistent enforcement of the REACH obligations by EU producers and importers of articles. At present, certain processed chemicals, which are not allowed in the
EU, may not be identifiable in imported articles. This, unfortunately, puts EU production at a competitive disadvantage and could lead to further deindustrialisation in the EU, if not properly tackled. Overall, there can be unforeseen consequences of chemical legislation on the daily business of downstream users. It is vital that downstream users can voice their position both in the legislative process and later at the implementation phase of the EU legislation. CheMI is a facilitator to achieve this goal.

WORKPLACE SAFETY

The safe use of chemicals at the workplace is a key concern for CheMI companies. REACH has helped improve communication between companies, suppliers and users of chemicals.

However, the way workplace safety is currently addressed at European level should be reassessed. When substances are found to have risks limited to the workplace, the use of occupational health and safety legislation should be considered.

CheMI has recently joined the Cross Industry Initiative (CII) that promotes a better interaction between REACH and workplace legislation.

Further information:

European Court of Justice ruling from 10 September 2015 on substances of very high concern (SVHCs) in articles http://curia.europa.eu/juris/document/document.jsf?text=&docid=167286&pagelndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=122741


ChemI’s members are European trade associations, which represent a variety of manufacturing sectors, such as producers of tyres and rubber articles, textiles and clothing, toys, and packaging.
**Wanted: safer alternatives for bisphenol A**

Text by Irene Poza Latorre

Credit card slips, bank receipts, logistics labels, cash register receipts or fax paper have something in common: bisphenol A or BPA. In 2014, France proposed to restrict the use of BPA in thermal paper. This year, the European Commission is expected to take the final decision on that. In the meanwhile, companies are getting prepared by finding safer alternatives.

In 2015, ECHA’s Risk Assessment Committee backed the French proposal to restrict the placing on the market of thermal paper containing bisphenol A - on the grounds that it is an endocrine disruptor. With the proposal, the search for alternative substances or techniques started.

We spoke with Dr Aurélien Gouzy of INERIS, the French national competence centre for industrial safety and environmental protection, whose organisation is making the substitution of BPA a reality through a website that promotes safer alternatives.

“We have been very active on BPA in France since 2012, when our government published a national strategy on endocrine disruptors. In line with the strategy, the Minister of environment asked large distributors and banks to make a voluntary commitment to use bisphenol-free thermal paper. INERIS was asked to help develop a ‘BPA-free label’, which could be issued to every company with a BPA-free policy,” Dr Gouzy explains.

**PROACTIVE HELP**

The website ‘SNA-BPA’ was kicked off in 2012 as an early reaction to the potential restriction. The site provides operational support to companies interested in substituting bisphenols (BPA, BPS and BPF). It is available in French and English. In addition to finding alternatives to BPA in thermal paper, it helps companies to find safer alternatives for BPA in polycarbonate, epoxy resins, food containers and several other applications.

“Users of the website can exchange ideas and information with each other on bisphenols. We encourage industry to share information with us that is relevant to the topic,” Dr Gouzy says.

**ONE STOP SHOP**

With over 1 000 visits a month from around the world, the site offers the latest news about the substitution of BPA, technical documents, frequently asked questions and reports, as well as information on the current regulatory framework.

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**TOP 5 countries**

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<tr>
<th>Country</th>
<th>Percentage of visits per month (total &gt; 1 000)</th>
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<tbody>
<tr>
<td>France</td>
<td>37 %</td>
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<tr>
<td>United states</td>
<td>16 %</td>
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<tr>
<td>Russia</td>
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<td>Germany</td>
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<td>UK</td>
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Table 1. Visits to the ‘SNA-BPA’ website. Although the target audience is mainly European industry, 21% of the traffic comes from non-European countries such as the United States, China, Chile and Morocco.
Users can also find resources relating to other bisphenols, such as BPS.

“The FAQ page is regularly updated and reflects the key points that emerge from the information exchange on BPA alternatives. We keep track of the most frequently asked questions and post the answers given by our experts. If needed, third parties help us to draft the answers,” Dr Gouzy points out.

**PLANS FOR THE FUTURE:** PHTHALATES

INERIS’s efforts to help companies substitute dangerous chemicals do not stop with bisphenol.

“In 2017, we will launch a similar site on one of the substances from the phthalate family,” Dr Gouzy mentions.

“We hope that our ambitious and innovative initiative will be useful for companies worldwide and will foster substitution. Our website could be taken as an example and the idea used for other substances as well – all for the benefit of European competitiveness and innovation.”

**Further information:**

French National Guidance Service on the Substitution of Bisphenol A
http://www.ineris.fr/substitution-bpa/en

Adopted opinions on BPA restriction proposal

BPA info card
http://echa.europa.eu/substance-information/-/substanceinfo/100.001.133

**DID YOU KNOW?**

**2014**


- ECHA’s Committee for Risk Assessment (RAC) adopted an opinion to strengthen the existing harmonised classification and labelling (CLH) of BPA from a category 2 reproductive toxicant to a category 1B reproductive toxicant concerning the adverse effects on sexual function and fertility.

**2015**

- RAC concluded that the risk for unborn children of female workers, for example, cashiers handling thermal paper, is not adequately controlled.

- ECHA’s Committee for Socio-economic Assessment (SEAC) concluded that the socio-economic benefits of restricting BPA in thermal paper are unlikely to be higher than the costs.

**2016**

- RAC and SEAC sent their opinions to the European Commission. The Commission now needs to decide whether to add BPA onto the List of restrictions.

- France has notified ECHA of its intention to propose BPA also as a substance of very high concern (SVHC) for its carcinogenic, mutagenic, reprotoxic (CMR) and endocrine disrupting properties.

**SUBSCRIBE TO INERIS’S NEWSLETTER**

If you are interested in receiving information on BPA alternatives directly to your inbox, you can subscribe to the SNA-BPA newsletter at:

The newsletter informs about the current state of knowledge on BPA substitution. The next issue will be dedicated to the substitution of BPF and BPS.

ECHA’s substitution web pages:

Painting a safer Europe:
https://www.youtube.com/watch?v=Zs8oPSXdUSU

Webinar recording: Why opt for substitution:

Terminology – in 23 languages
Take a tour around Hanna’s House of Hidden Hazards

Did you ever wonder whether your kids learn about hazardous household chemicals at school? After new Nordic online teaching material was introduced, the chances have increased in some countries. The website educates the youngest school children about what hazardous chemicals they can find at home and the new hazard pictograms.

When was the first time you realised that household products under the kitchen sink contain hazardous chemicals? It’s probably hard to remember, but it could have been in your class at primary school – at least that will be the case for thousands of school children from second to sixth grade in the Nordic countries.

They are now taught about hazardous chemicals and pictograms through a website called ‘Hanna’s House of Hidden Hazards’. The project is a joint effort by the five Nordic countries: Denmark, Finland, Iceland, Norway and Sweden, and supported by the Nordic Council of Ministers.

Fun Way to Learn

The website introduces school children to the new hazard pictograms that are used for hazard labelling of chemicals. The classification and labelling system (the CLP Regulation) in the European Union is in line with the United Nations’ Globally Harmonised System. The aim is for hazard labelling to become globally recognisable.

The website takes the child through ‘Hanna’s House’ and lets them experience different everyday situations where detergents and other products labelled with the CLP pictograms, from dishwasher tablets and toilet cleaners to grill lighter fluids, are used. By choosing from multiple options, the child is guided to the correct meaning of the pictograms, on which products they can be found and what precautions they should take when using the products.

Raising Public Awareness

“We wanted to raise public awareness of the new pictograms for hazardous chemicals. Consumers are obviously a difficult and very diverse group to target, so we decided to focus our efforts on school children and inform the future generation. They are not affected by old habits and the old labelling system, which makes it easier to create simple and clear educational material,” explains the project manager Trine Thorup Andersen from the Danish Environmental Protection Agency.

“Our aim is to get the website included in the national student portal, which would raise awareness of the material among more teachers in Denmark,” she adds.

Positive Feedback

Sari Tuhkunen, a Senior Officer at the Finnish Safety and Chemicals Agency, also took part in the development of the project.

“We hope that pupils get familiar with the pictograms and share their knowledge with their families as well.”

The school children found the online chemical hazard tour interesting and informative. “We have received very positive feedback from teachers and children in the schools we visited in Finland. The children found the website entertaining and they understood the concept and the pictograms.”
new pictograms for serious health hazards and gas under pressure were a bit too difficult though. They took photos of labels in their homes and we discussed the hazards and the labels in the class.”

She mentions that the working group would like to expand the possibilities of the website.

“The online material is targeted at school children from second to sixth grade but the plan is to develop it further. We could add more features for older pupils, but how we will do this is not yet decided.”

FILLING A GAP

Ann Kristin Larsen from the Norwegian Environment Agency says that they would like to develop the website with some more functions.

“However, we are still waiting for results from a survey we are conducting among teachers who have used the material.”

A lot of work has been put into distributing the website in Norway trying to get the message out to teachers.

“We have produced 500 packages containing posters and rulers with printed pictograms for Norwegian school classes. The feedback has been extremely positive. The message from the teachers is that this project is filling a gap with teaching material that did not previously exist.”

Further information:

Hanna’s House website (in English) http://english.hannashus.dk/

Chemicals in our life http://echa.europa.eu/chemicals-in-our-life


CLP quiz http://echa.europa.eu/clp-quiz

The teaching material is structured as a website. Through different examples, the pupils can learn about the hazard pictograms on household chemicals and why it is important to handle and store them correctly.
“What we need now is courage”

Over 200 regulators, scientists and industry hazard assessors came together at ECHA in April to discuss how new approach methods can be used to improve chemical safety. The benefits of these methods are clear – they contribute to better toxicology, lower the demand for animal testing and raise competitiveness as companies will be better able to predict the hazard potential of their products.

We spoke with some of the participants of the workshop to get an insight into the current and future use of these methods.

Why is developing new approach methods important?

Dr Thomas Hartung, Johns Hopkins University

“They are cheaper and faster and allow us to take advantage of the knowledge of the past. REACH has created the largest toxicological database on industrial chemicals in the world and with the new approach methods, we can take full advantage of this data to reduce the need for testing in the future.”

Professor Bob van de Water, Leiden University

“From the science perspective, we have to develop methods that are more appropriate for the human situation. These can be, for example, stem cell-derived methods where we more closely mimic the human situation. As for regulatory affairs, the main issue is to prove that these methods can better predict the human situation.”

Dr Elisabet Berggren, Joint Research Centre, European Commission

“Compared to traditional animal studies, new approach methods are based on the science and knowledge of how a chemical enters the body, reacts in it and interacts with the biological system. They save animal lives, but they also give a more robust scientific understanding, and can save costs and time. For authorities, screening for chemicals of concern is easier. New approach methods can also speed up the finding of less toxic alternatives.”

Dr Anette Mehling, BASF

“We are starting to understand the modes of action induced by chemicals when they react with biological systems. Registrants will be able to read-across better, group their substances and categorise them correctly. This will lead to regulators having more confidence in the data submitted by companies.”

Dr Bennard van Ravenzwaay, BASF

“Additional methodologies will improve the quality of read across cases, which the regulators will appreciate. The registrants, on the other hand, will know more surely where they stand if they do their job right.”

Dr Russell Thomas, US EPA

“In the US, we intend to use new approaches to more efficiently and quickly evaluate chemicals for safety. New approaches will also help us better understand how chemicals interact with important biological processes and cause toxicity. When we understand how chemicals interact with these processes, we can make better judgements about their relevance to human health.”

How can they reduce animal testing?

Dr Hartung

“The first step is to analyse the REACH database to know the limitations of the animal-based methods. If you think that animal studies are perfect, you will never use new methods. From the data, we know that some of the animal experiments cannot be reliably duplicated. For example, if you retest a substance that is a severe
eye irritant, you have a 20% chance that it comes out as a mild irritant and 10% chance for a non-irritant result. This shows that the assay is not perfect.

The next step is to compare chemicals with similar properties. We can analyse 15 000 substances in the REACH database and see what the neighbouring chemicals are and conclude on the most probable property. This is a very big step forward and can be even better than doing the animal experiment."

Prof. van de Water

"It all depends on case studies, which need to be developed and validated. If from 20-40 case studies done with alternative models, we get the same conclusion in 95% of the cases, we will have sufficient confidence on the alternative method and its ability to predict an in vivo situation.

What we also have to realise is that animals do not fully predict the human situation. According to knowledge from the pharmaceutical industry, 70% of human adversities are predicted in in vivo models. If we can get to 80% with in vitro models, we are doing a better job for human safety. We have to remember, of course, that it’s all based on animal studies."

Dr van Ravenzwaay

“Any accepted read across case will reduce testing on animals. If alternative approaches help to increase the likelihood of acceptance, they will contribute to reducing animal testing.”

What are the next steps – when can these methods be more widely used?

Dr Hartung

“The most important thing is access to the data. People should be able to mine the data and use computational tools to set priorities. I applaud ECHA for making this data available.”

Prof. van de Water

“There are already methods that can be used to identify hazards and to check whether hazards identified with in vitro are relevant for in vivo situations. However, there is no overall strategy to replace the animal studies. Hopefully, with the case studies, some of the new methods can be integrated to the strategies for safety testing in the coming years.”

Dr Mehling

“The regulatory acceptance or the confidence in using the approaches is not yet there. As soon as people are comfortable with the predictions these tests make, they will become more popular.”

Dr van Ravenzwaay

“What we need now is courage. Courage from registrants to do these studies and courage from the authorities to accept them. We need a few success cases, which will entice registrants to do more studies. This will, in turn, lead to increases in data, better read-across cases and more likely acceptance by authorities.”

“1 know that chemical similarity is important for the authorities. However, I appeal to the authorities: open up a little and let the biological data speak for itself. If the biology is right, the read across is right. By increased acceptance of biology-based approaches for read across, there are great opportunities to reduce testing on animals.”

Dr Thomas

“These methods are already being used in the US, particularly in the evaluation of chemicals affecting the endocrine system. We are using these methods to identify the chemicals we are most concerned about. There are also proposals by our government to start using these alternative methods instead of traditional methods for evaluating chemicals potentially disrupting the estrogenic system.

It’s important that both sides of the Atlantic are using these methods in a harmonised way. We need to continue discussions for a more harmonised approach.”

Further information:

Workshop presentations and case studies

Video reportage:
https://www.youtube.com/watch?v=gsAJwu2Cwr8&feature=youtu.be

What about animal testing?

Terminology – in 23 languages
Spotlight on science | Dr Thomas Jakl

Entropy, epigenetics and efficiency – the pillars for chemicals policy beyond 2020

The upcoming Helsinki Chemicals Forum gives us all a chance to look at chemicals policy in a broader context as we hear about successes towards sustainability. I am looking forward to hearing about safer and more effective new substances, new processes and new manufacturing technologies, but I sometimes wonder whether we need to challenge ourselves to think even further ‘outside the box’ if we are to make bigger leaps forward in safer chemicals beyond 2020.

It is sometimes said that what you measure is what you get and for that reason, I would like us to start thinking about qualitative measures that we can consider when thinking about chemicals. What about things like the conservation of molecular structures throughout a process? Or the renewability of raw materials needed in a manufacturing process? Both of these issues are really important because we need to be resource efficient and therefore reduce waste and all kinds of ‘losses’ during a process. These are core elements for sustainable chemistry. However, they are difficult to address with our current toolbox of indicators. I think that the concept of entropy helps us to get nearer to the essence of sustainability.

ENTROPY – A WAY OF ADDRESSING QUALITATIVE ASPECTS WITHIN A COST/BENEFIT ANALYSIS

Thinking about entropy gives us a way of evaluating processes and products that cannot be achieved by conventional approaches. Conventional approaches can describe and explain the effects of a substance, and make them consistent and comparable by monetising them, but they are very limited when describing more qualitative aspects, or the basic principles of a process.

I’m talking about qualitative aspects like the impact on civil society caused by loss of species diversity; the consolidation and controllability of material flows; energy usage and information contained in chemical structures. These can be taken account of and described much more clearly using the concept of entropy, and this would add an important dimension to the current methodology of cost/benefit analysis.

For this to work, entropy must be used in a way that is both expedient and consistent with its original meaning, and not reduced to a measure of disorder. So, what do I mean by entropy? Well, if you take a look at what all the approaches to entropy have in common, increases in entropy always involve a loss – of useful energy, of structure, of information and, ultimately, of quality. It is a hard concept to grasp and describe however.

So, I recommend that we take a two-step approach. First, I would like to look at how entropy has been used in other situations to see how we could make best use of it when describing the sustainability of chemicals. That should lead to developing an approach to entropy based on scientific findings. Secondly, this approach should then be used as a basis for applying entropy as an indicator that can be understood and used by companies and the authorities working for the safe and sustainable use of chemicals.

It seems to me that by adopting this kind of approach, entropy can help us evaluate processes and products to determine their suitability as part of a viable economic system in the long term. This would be a far richer picture than a simple cost/benefit approach.

EPIGENETICS – UNDERSTANDING THE COMMUNICATION BETWEEN CHEMICALS AND THE LIVING

‘How’ and ‘when’ external factors interact with biological systems will certainly be the way in which we judge them in the future.

Epigenetics is redefining biological understanding about the relationship between living organisms and their environment. External factors – such as chemicals – can alter how genetic information in our DNA is (de-)activated and transformed without changing the genetic code itself. These activity patterns may be reversible, or they may also be passed on to subsequent generations.

Epigenetic changes are associated with serious adverse health effects, including cancer and endocrine
disruption. A number of effects related to epigenetic regulation are already considered relevant for risk assessment— in particular:

1. Effects caused by substances that directly affect the way the genome is activated or deactivated, for example, by DNA methylation, and may induce changes in regulatory pathways.
2. Epigenetic modes of action of chemicals that are known to be hazardous (e.g. endocrine disruptors, carcinogens), specifically those leading to irreversible changes in the organism.
3. Effects that pass on to subsequent generations.

But epigenetic effects may also differ in substantial ways from the other effects/adverse outcome pathways that we currently consider in risk assessment. The time lapse between exposure and adverse outcomes, for example, may differ significantly from the 'classical' toxic effects when epigenetic mechanisms are involved.

For us to be able to fully understand the epigenetic effects of chemicals, we will need to know much more about the pathways of epigenetic regulation, the links between the disruption of endocrine and epigenetic systems and the adverse outcome pathways relevant for risk assessment. We'll also need to know whether the effects of environmental stressors on epigenetic pathways are larger than any underlying physiological variability.

In my view, it is only a matter of time before risk assessment methodologies will have to understand this new language about the interaction between the living world and its surroundings.

**RESOURCE EFFICIENCY – SERVICES INSTEAD OF BARRELS**

Finally, there is one further quality aspect which will increasingly shape the way we look at chemicals’ use.

The focus for chemicals’ management will widen from assessing hazards and risks towards monitoring and continuously optimising how they are applied and used— thereby making resource efficiency a goal for future chemicals policy.

In short, we are moving from ‘using the right chemicals’ to ‘using chemicals right’. This is where service-based concepts, such as chemical leasing, are key. For example, this is the only current business model where the economically-driven goal for the manufacturer or producer is to use less.

When manufacturers are paid for their chemical’s performance rather than their quantity, it will be in their best interest to focus on performance rather than volumes sold. If manufacturers are paid per unit, their prime economic interest will be that the product is used as efficiently as possible.

How could this fit into the REACH philosophy? In my view, goals for resource efficiency should be required by the legal framework and could subsequently be fine-tuned and agreed upon on a case-by-case basis between the authorities and companies. Detailing resource efficiency as part of applications for authorisation to use substances of very high concern, or as part of a new requirement for continuous optimisation to be documented in the chemical safety report, could be monitored by ECHA.

Together with the Member States, ECHA could compile and evaluate data gathered by companies to demonstrate the appropriate use of chemicals to check whether the envisaged effect does in fact materialise.

I can clearly see that entropy, epigenetics and efficiency will frame the mind set for chemicals’ policy beyond 2020, because they help us to focus on quality: of design, of effects and of applications.

*Dr Thomas Jakl*

*Deputy Director General, Ministry of Environment, Austria; Member of ECHAs Management Board*

**Further information:**

Chemical leasing - the way forward? Newsletter 4/2015
Product treated with a biocide? Don’t forget 1 September 2016

TEXT BY VEERA SAARI

If you place products on the EU market that are treated with a biocide, you need to make sure that you comply with the law by 1 September 2016. Put simply, the active substance in the biocide needs to be approved within the EU (or be in the process of being approved) for the kind of use you are making of it.

As of 1 September 2013, products in the EU can only be treated with active substances that have been approved for the specific way you are using them. These uses belong to categories that are called ‘product-types’ and include for example disinfectants, preservatives and pest control products. To give companies time to comply with this change in the law, a transitional time was agreed – but that period runs out on 1 September 2016.

If you have not taken action so far, you need to:

1. **Make sure** you know which active biocidal substances are used to protect your product.
2. **Check the status** of the active substances on ECHA’s website: they should be either approved or under assessment for your product-type and use.
3. If the active substance is not yet in the approval process for the product-type and use, make sure an application for its approval is made by 1 September 2016.

**WHAT TYPES OF ITEMS ARE AFFECTED?**

Items that are affected are those that have been treated by a biocide so as to protect them in some way from harmful organisms like pests, mould and bacteria. The law refers to them as ‘treated articles’. These include:

- **Mixtures**: for example, a paint that contains an in-can preservative.
- **Articles**: a sofa with wooden arms, which have been treated with preservatives, or a refrigerator that has been treated with substances to prevent mould and odour.
- **Articles that intentionally incorporate** a biocidal product: socks that contain silver fibre to prevent odour.

Products whose **main purpose** is to act against unwanted organisms are considered biocidal products – not treated articles. An anti-bacterial wipe, for example, is a biocidal product – not a treated article – because its sole purpose is to control bacteria.

If you are not sure whether your product is a treated article or not, turn to your national helpdesk for advice.

**CHANGES FOR IMPORTERS FROM OUTSIDE THE EU**

Exactly the same rule applies for importers. This is a significant change compared to the previous biocides law, whereby articles imported into the EU could be treated with substances that could not themselves be used in the EU – for example, sofas treated with dimethyl fumarate to protect them from mould.

**WHAT HAPPENS AFTER 1 SEPTEMBER 2016?**

Products that have been treated with an active substance that is not in the EU approval process can only stay on the market until 1 March 2017.

If you develop a new active substance, you can apply for its approval at any time. However, you cannot place an article treated with the substance on the EU market until it has been approved.

**Join us in Helsinki at our free Biocides Stakeholders’ Day on 1 September 2016. Register on ECHA’s website.**


**Further information:**

- Treated articles
- European Commission guidance
- List of active substances (approved or pending approval)
  http://echa.europa.eu/information-on-chemicals/biocidal-active-substances
- Approval of active substances
- Biocides terminology in 23 languages