ECHA
EUROPEAN CHEMICALS AGENCY
2 NO May 2018

Newsletter

© ISTOCK/IN-FUTURE

Final push for the last REACH registration deadline

With the final registration deadline only a couple of weeks away, I want to **encourage companies to submit their dossiers on time**. The 31 May deadline is the last milestone of a journey that started a decade ago – to close the information gap on existing chemicals used in the EU. I take this opportunity to highlight some practical solutions if you are facing difficulties in registering. I also sum up what will happen after 31 May, as registration is just the first step in sound chemicals management.

To help registrants in exceptional situations, the Directors' Contact Group (DCG) offers four solutions on **dossier completeness**, **legal entity changes**, **dependency on the lead registrant**, and cases where **nobody is planning to register a substance**. You can apply for any of the solutions by providing evidence of your difficulties as soon as possible. Most solutions take into account that you may not have all the data you need by the deadline. You can see the requirements on our website. If your justification is appropriate, we will give you instructions on how to proceed.

If your DCG application is accepted, you will only get your registration number after submitting a complete dossier, which will most likely be a few months after the deadline. In the meantime, you will remain legally on the market and can use your submission number to prove you submitted your registration before the deadline.

A full picture of the 10-year journey will be available in September after we have checked all the dossiers, but we will publish a preliminary overview in early June. We also hope to publish the non-confidential information from the 1-100 tonne

registrations by the end of 2018, after assessing all the confidentiality claims. In addition, we will check the SME status of those companies claiming to be one. Later, evaluation and risk management processes will kick in. By law, ECHA has to check at least 5 % of dossiers for compliance. In substance evaluation, you may be asked for information beyond the standard requirements. You will hear from us if we need more information from you during these checks.

In 2019, there will be an EU-wide enforcement project on registration. Inspectors and customs authorities will check that companies have fulfilled their registration obligations and that the conditions are in place for registering a substance as an intermediate under strictly controlled conditions.

As you are responsible for the safe use of your chemicals, **you must keep your registration up to date**. To this end, we will publish support material for phase 7 of the REACH 2018 Roadmap in November. The issue of updates is also flagged in the recent REACH review and we are currently discussing with the Commission how to encourage updates. Keep in mind that a compliant, up-to-date dossier gives you a clear business advantage, as you are able to explain to your customers what risk management measures are needed to ensure safe use. In turn, your customers can be confident that the substance will be available to them. Here are my top tips for post-registration:

- Make a **plan for keeping your registration up to date**. Keep track of new data, potential new uses for your substance, and volumes produced or imported.
- Make sure you have **access to your REACH-IT account**, as we use this channel to communicate with you.
- Have a platform to **collaborate with your other co-registrants** to deal with new registrants and requests for more information from authorities.
- **Submit an inquiry for each new substance** you place on the market in quantities over one tonne per year.
- **Follow the authorities' work**. Check your portfolio for substances that are subject to regulatory action and see whether safer alternatives are available.

Christel Musset
Director of Registration

"I want to encourage companies to submit their dossiers on time."

In this issue:

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

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

ISSN: 1831-4953

Editor-in-chief: Maurizio Roncaccia
Editor: Paul Trouth

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

newsletter.echa.europa.eu
echanewsletter@echa.europa.eu
Follow @ EU_ECHA on Twitter
Like us on Facebook
Follow us on LinkedIn
Subscribe to our YouTube videos

Plastics, chemicals and regulation

TEXT BY NEDYU YASENOV

Plastics are important materials that are abundant in our daily lives. They make life easier in many ways, and are often lighter and less costly than alternative materials. However, some contain hazardous chemicals and when these end up in the environment, they can have a negative impact on nature and human health.

WHAT'S THE ISSUE?

Microplastics are very small pieces of plastic material, typically less than 5 mm in size. They can be unintentionally formed when larger pieces of plastic, including synthetic textiles, wear and tear. They can also be intentionally manufactured and added to products for specific purposes, for example, as exfoliating beads in facial or body scrubs.

An estimated **2 to 5 % of all plastics** end up in the oceans. Once released into the environment, they may be consumed by and accumulate in animals, and can even end up in the fish and shellfish we eat.

With such high levels of plastic entering our environment and considering the harmful effects this may cause, solutions have been sought to design biodegradable and compostable plastics. But most that are currently available and labelled as biodegradable only degrade under specific conditions that do not occur in nature, and can therefore still cause harm to ecosystems.

Although intentionally added microplastics may represent a comparatively small proportion of all of the plastic found in the oceans, they could also be accumulating upstream in our inland waters and soils. In response to this, several countries, including some EU Member States, have taken action to restrict their use. The cosmetics industry has also taken voluntary action to replace plastic microbeads with alternatives.

WHERE ARE THEY USED?

Intentionally added microplastic particles are used in a range of products placed on the EU market including:

- certain **cosmetics**;
- **personal care products**;
- **detergents** and **cleaning products**;
- **paints**;
- **products in the oil** and **gas industry**; and
- **media for abrasive blasting**.

In similar products, microplastic particles can function as an abrasive (e.g. exfoliating and polishing agents in cosmetics known as microbeads) but can also have other functions, such as controlling the viscosity, appearance and stability of a product.

Microplastic particles can be released into the environment through wastewater. So, for example, when you wash cosmetics from your face, the particles carried by the water run down into your sink and can end up as litter in the environment. In addition, they may pose a potential risk to human health. In the same way, certain products that intentionally release microplastics during their use, such as certain nutrient prills used in agriculture, are also a cause of similar concern for the environment.

WHAT IS ECHA DOING TO REGULATE THIS ISSUE?

Prompted by such concerns, several EU Member States including Belgium, France, Italy, Sweden and the United Kingdom have proposed national bans on the intentional use of microplastics in certain consumer products – principally uses of microbeads in rinse-off cosmetic products where they are used as exfoliating and cleansing agents.

Actions to ban the intentional use of microplastics in consumer products are also already in effect in the US, Canada and South Korea as well as in other countries.

Furthermore, the European Commission recently published a study that provides further information on the intentional uses of microplastics in products and what risks

Microplastic particles can be typically released to the environment through wastewater. So, for example, when you wash cosmetics from your face, they run down into your sink contributing to litter in the environment.

they pose to human health and the environment.

The **European Food Safety Authority (EFSA)** also recently produced a statement that reviewed the available evidence on micro- and nanoplastics in food.

In line with REACH procedures for restricting substances that pose a risk to the environment or human health, the Commission has started the process of restricting the use of intentionally added microplastics by requesting ECHA to review the scientific basis for taking regulatory action at EU level.

The Commission has also asked ECHA to investigate the need for a restriction for **oxo-degradative plastics**. These contain additives that promote the oxidation of the plastic material so that it degrades more quickly under certain conditions. The concern over these is that they also degrade into microplastics.

ECHA'S INVESTIGATION

In January 2018, ECHA announced that it will examine the need for restrictions on oxo-degradative plastics and for intentionally added microplastic particles.

As part of this examination, the Agency undertook a call for evidence and information, which closed on **11 May 2018**. This call aimed to gather information on all possible intentional uses of microplastic particles in products.

The information gathered will be used to see whether these uses pose a risk at EU level and to assess the socio-economic impacts of any potential restriction. A separate call for evidence was also undertaken related to oxo-degradative plastics.

The initial scope of the investigation on microplastics was wide by design and not limited to intentional uses in consumer and professional products to ensure that the diversity of uses and the sectors within which intentionally added microplastics are used are fully understood. The scope of any proposed restriction will be based on the information received as the Agency's understanding of the risks and socio-economic impacts develops.

DID YOU KNOW?

Microplastics are synthetic, water-insoluble polymer items smaller than 5 mm in size, which are considered to be of particular concern for the aquatic environment. The potential impact of microplastics on the aquatic environment and human health has generated concerns in EU Member States and worldwide.

Oxo-degradative plastics or oxo-plastics contain additives that promote the oxidation of the material under certain conditions. They are used in applications such as agricultural films, rubbish and carrier bags, food packaging, and landfill covers. They can break down into very small particles, potentially contributing to environmental contamination by microplastics.

WHAT'S NEXT?

ECHA will submit its proposals to the Commission by mid-January 2019, after which discussions will continue in ECHA's scientific committees: the **Committee for Socio-economic Analysis (SEAC)** and the **Committee for Risk Assessment (RAC)**.

The restriction proposals will then be subject to a six-month public consultation where companies, trade unions, NGOs, individual citizens and public authorities worldwide can comment.

Based on the opinions of RAC and SEAC, the Commission will prepare a draft amendment to the **restriction list** (Annex XVII to REACH).

Any possible restrictions will come into force at the same time in all EU Member States and depending on the scope of the proposals, intentionally added microplastics and oxo-degradative plastics will not be allowed to be used, manufactured or imported freely anymore in the EU.

Further information:

ECHA to consider restrictions on the use of oxo-plastics and microplastics – News release – 17 January 2018
https://echa.europa.eu/-/echa-to-consider-restrictions-on-the-use-of-oxo-plastics-and-microplasti-1

European Commission's press release on plastic waste – 16 January 2018
http://europa.eu/rapid/press-release_IP-18-5_en.htm

European Commission's plastics strategy
http://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy.pdf

Intentionally added microplastics in products report
http://ec.europa.eu/environment/chemicals/reach/pdf/39168 Intentionally added microplastics - Final report 20171020.pdf

Study on the impact of the use of "oxo-degradable" plastic on the environment
https://publications.europa.eu/en/publication-detail/-/publication/ab9d2024-2fca-11e7-9412-01aa75ed71a1

Presence of microplastics and nanoplastics in food, with particular focus on seafood – scientific opinion of EFSA's Panel on Contaminants in the Food Chain (CONTAM)
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4501/abstract

Endocrine disruptors explained

TEXT BY NEDYU YASENOV AND VEERA SAARI

The EU has decided on criteria for identifying whether a substance used in a biocidal product has an impact on our endocrine system. The criteria will apply from 7 June 2018. We take a deeper look at what endocrine disruptors are, why they should be regulated and what the new criteria mean for companies.

WHAT ARE ENDOCRINE DISRUPTORS?

Our bodies have a network of glands and organs that produce, store and secrete hormones called the endocrine system. Many organs can produce and release hormones, but the standard endocrine organs include the brain, ovaries, testes, thyroid, pancreas and adrenal glands. The hormones travel around the body in blood and other bodily fluids, signalling any organ that has a receptor for that particular hormone.

When certain substances enter the body, they can trigger abnormal processes in the endocrine system, with potentially severe health consequences. Substances that act in this way are called **endocrine-disrupting chemicals (EDCs)**.

Some EDCs mimic the structure of a hormone and bind to the receptor instead, causing a similar effect or blocking the action of the natural hormone. Others may bind to transport proteins in the blood altering the amount of natural hormones, or may interfere with metabolic processes in the body affecting the synthesis or breakdown rates of natural hormones.

EDCs have been linked to health issues related to growth and development, immunity, metabolism, reproduction and behaviour and more, because hormones regulate nearly every process in the body.

WHERE ARE THEY FOUND?

A wide range of mainly man-made substances may cause endocrine disruption. EDCs can be difficult to identify because they may produce effects that vary depending on the substance, the species affected and its life stage. Sometimes, their effects may also only be seen long after exposure.

Exposure to EDCs may happen through different routes and come from contaminants in food, drinking water or in our environment and the different household and industrial products we are exposed to.

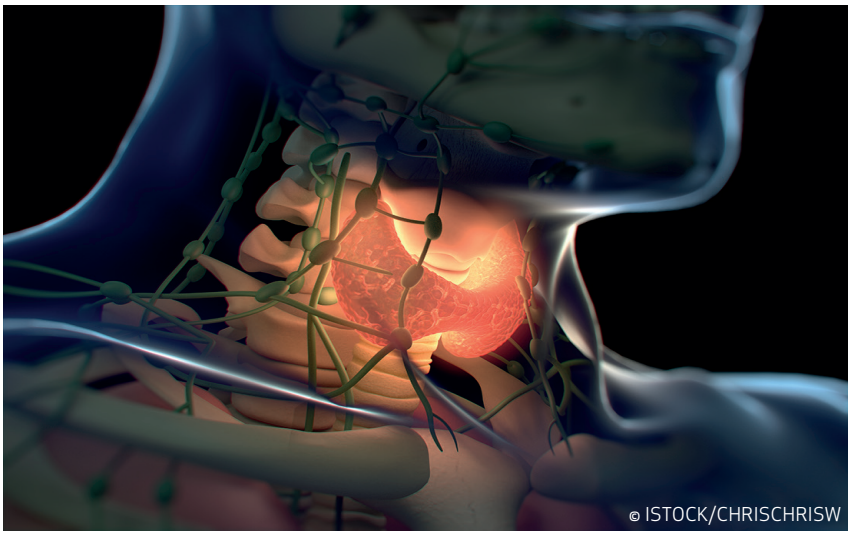
In wildlife, effects that are suggested as being related to endocrine disruption have been seen in molluscs, crustaceans, fish, reptiles, birds and mammals in various parts of the world. In some species, growth is altered, reproduction has been impaired and development has been delayed causing a decrease in populations.

DEFINING THE EDC CRITERIA

In June 2016, the European Commission presented draft criteria to identify endocrine disruptors in the fields of **plant protection products** and **biocidal products**. The criteria endorse the World Health Organisation's (WHO) definition of an endocrine disruptor as "an exogenous substance or mixture that alters functions of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations".

After scrutiny by the European Council and the European Parliament, the final criteria were officially published in the Official Journal in November 2017 and will apply from **7 June 2018**. According to the criteria, a substance is considered to have endocrine-disrupting properties if:

- it shows **an adverse effect in an intact organism or its offspring**, which changes the morphology, physiology, growth, development, reproduction or life span of the organism and impairs its functional capacity, its ability to compensate for stress or increases its susceptibility to other influences;
- it has the **potential to alter the functions of the endocrine system**; and



© ISTOCK/CHRISCHRISW

The growing concern in the EU about endocrine disruptors possibly causing negative human health and environmental impacts has led authorities to introduce specific legislative obligations to try to control the risks stemming from EDCs.

- there is a **biologically plausible link** between the adverse effect and the endocrine activity.

Conclusions on whether the criteria are met have to be drawn separately for humans and for non-target organisms.

WHY REGULATE THEM?

The growing concern in the EU about endocrine disruptors possibly causing negative human health and environmental impacts led authorities to introduce specific legislative obligations to try to control the risks stemming from EDCs.

For substances under approval as biocides or registered under REACH, the potential for endocrine disruption is a property considered in the assessment process.

Under **biocides legislation**, the ED criteria are either exclusion criteria (for effects on human health) or substitution criteria (for effects on the environment). Derogations exist, for example, if there are public health concerns, negligible exposure or disproportionate negative impacts on society.

Member State authorities are starting to evaluate biocidal active substances against the new criteria for EDCs. All substances that are currently under evaluation in the **review programme** will be looked at. For substances that have already been approved, the Commission and national authorities are in talks on whether and when these should also be assessed for endocrine disruption according to the new criteria.

It is expected that including this assessment for active substance approval will significantly increase the volume of work for authorities and ECHA's **endocrine disruptor expert group (EDEG)** and will delay the assessment of active substances this year and probably in the coming years. EDEG provides informal, scientific advice on questions related to identifying endocrine disrupting properties of chemicals, including biocides.

EDCs can also be considered on a case-by-case basis **under REACH** as an equivalent regulatory concern to substances of very high concern (SVHCs). This means that they can be identified alongside substances known to cause cancer, mutations and toxicity to reproduction as well as those that are persistent, bioaccumulative and toxic and very persistent, very bioaccumulative. The aim is to reduce their use and ultimately replace them with safer alternatives.

Under CLP, endocrine disruption is not a specific hazard class, but EDCs have a mode of action which may lead to classification for reproductive toxicity, carcinogenicity, or specific target organ toxicity. Adverse effects related to the environment and caused by an endocrine disruptive mode of action may also lead to classification.

GUIDANCE SOON AVAILABLE

The Commission requested ECHA and the **European Food Safety Authority (EFSA)**, with support from the **Joint Research Centre (JRC)**, to develop a common guidance for the identification of endocrine disruptors in the context of the Biocidal Products and the Plant Protection Products regulations.

The draft guidance was subject to a public consultation from December 2017 to January 2018. More than 2 000 comments were received. Since then, the document has undergone a further consultation with ECHA and EFSA's scientific bodies.

Currently, a final consultation is ongoing with the representatives of the Member State competent authorities for biocides and plant protection products.

The final guidance document will be published in June – by the time the endocrine disruptor criteria for biocides become applicable.

Further information:

Hot topics: Endocrine disruptors
https://echa.europa.eu/hot-topics/endocrine-disruptors

European Commission's web pages on endocrine disruptors
https://ec.europa.eu/health/endocrine_disruptors/next_steps_en

Commission's press release presenting criteria to identify EDCs in the pesticides and biocides areas – 15 June 2016
http://europa.eu/rapid/press-release_IP-16-2152_en.htm

HOW COMPANIES PLACING BIOCIDES ON THE MARKET CAN PREPARE

- **Review** the active substances in your products and portfolio in light of the new criteria.
- **Be prepared** to provide more information on the possible endocrine-disrupting properties of your active substance in your application.
- **Consult** the national authority responsible for the evaluation of your active substance before starting to test it to support the identification and assessment of possible endocrine disrupting properties.
- **If your substance has already been approved** at EU-level, note that the European Commission and national authorities are in talks on whether and on what level already approved substances should undergo assessment for endocrine-disrupting properties.
- **Note** that the criteria will also apply to co-formulants, not only active substances.
- **Stay up-to-date** - talk to your national industry association and follow ECHA's news

REACH review: safer chemicals, but still work to be done

INTERVIEWS BY TIIU BRÄUTIGAM

In March 2018, the European Commission's second REACH review was published. It concluded that the regulation is effective, but there is still room for improvement. We spoke with *Ms Cristina de Avila*, Head of Unit for Sustainable Chemicals at DG Environment and *Mr Michael Flüh*, Head of Unit for REACH at DG Growth – Internal Market, Industry, Entrepreneurship and SMEs to ask about the main achievements and challenges ahead – as well as potential new tasks for ECHA.

THE REVIEW CONCLUDES POSITIVELY ABOUT THE IMPACT OF THE EU'S MAIN CHEMICALS LEGISLATION. WHERE DO YOU SEE THE MAIN BENEFITS OF REACH?

Cristina de Avila, Head of Unit for Sustainable Chemicals, DG ENV:

We now have studies that show that the benefits of REACH are vast. Out of the many benefits listed by the REACH review, I think that **improved risk management** is one of the main achievements of the legislation. We are now considerably more capable of introducing risk management measures and able to better address the risks posed by chemicals to human health and the environment. There is a fundamental link between the information gathering done by companies and the capacity of authorities to take risk management measures based on this information.

For the general public, **improved access to information** on chemicals, freely available on ECHA's website, is a great benefit.

Michael Flüh, Head of Unit for REACH, DG GROW:

REACH has enabled us to generate very comprehensive data about the safety of chemical substances, which is also beneficial for the industry – they now have much **better knowledge** about the safe use of their substances. Industry is also responsible for passing on this information throughout their supply chains, which leads to better transparency. This increases knowledge on the safe use of substances and also brings **benefits to workers, the environment and consumers**.

We know that REACH is a significant investment for industry, but in the long term, we expect that it will pay off. We can see the advantages, for example, clear signs of substitution to safer chemicals in the EU. Gathering data on chemicals can be a **driver for innovation** and investing in safer substances.

Also consumers are starting to show more confidence in the safety of chemical products produced in the EU. The recent Eurobarometer study confirms this.

THERE ARE ALSO MANY AREAS WHERE IMPROVEMENTS ARE NEEDED. WHAT ARE THE MAIN CHALLENGES?

Cristina de Avila:

The review lists many challenges. One example of this is related to **substances in articles**. But most importantly, I would highlight **compliance with registration obligations**, as the registration data impacts all other REACH processes: communication in the supply chain, evaluation, restrictions and authorisation.

The registration information is vital for helping companies identify risk management measures and recommend them to those using the substances, but it is also important for enabling authorities to screen substances and address those of most concern. Improving this area is fundamental for making REACH work better.

Michael Flüh:

One core issue is **authorisation**, which is not yet working ideally.

From left: Michael Flüh and Cristina de Avila.

The process should be more efficient: more predictable for industry and more manageable for ECHA, Member States and the Commission. In the long run, it will foster competitiveness and innovation, but we need to make sure that the investments for companies are feasible, manageable and cost-efficient.

We also need to ensure a **level playing field** exists between EU-based companies and those in third countries, so that products from third countries also comply with EU standards and meet the same safety requirements. Enforcement and controls of imported products play a key role here. A further challenge is to **support small and medium-sized enterprises** to meet their REACH obligations for the registration deadline and also beyond.

HOW DO YOU SEE ECHA BECOMING A "EUROPEAN AND GLOBAL REFERENCE CENTRE FOR THE SUSTAINABLE MANAGEMENT OF CHEMICALS"?

Michael Flüh:

ECHA is already now a recognised authority in the field of chemical safety. Its future tasks could relate, for example, to **occupational safety and health or waste legislation**. New tasks would require a careful assessment of staff and resources necessary, which should be mindful of the budgetary constraints in the current context.

The large database on chemicals could be used even more by industry to look for alternatives to substitute hazardous substances. The data on chemicals should also be explored for other areas, such as **circular economy**.

Cristina de Avila:

ECHA could use its expertise on chemicals to **give scientific advice on chemical substances** for occupational safety and health-related topics and for further environmental legislation, such as on water, waste or fertilisers. There are areas of environmental legislation with proposed restrictions for certain substances – for example, the substances in end-of-life vehicles or electric and electronic equipment. ECHA could play a role here as a scientific assessment provider.

★ ★ ★ ★ ★

Bjorn Hansen, ECHA Executive Director:

The main message for ECHA is to continue the ongoing work to **gain efficiencies** – across the board in our activities. We have done a lot to improve the speed and resource intensity of our processes. These efforts need to continue, but there is also more to be done on the content of what we do.

We now have 10 years of implementation experience. Drawing the lessons from this can help us better focus on what really matters to take decisions or make useful opinions.

Looking at the deadlines, most of the actions are urgent. We need to improve on our implementation of **evaluation**, **restrictions** and **authorisation**. But we must also prepare for the next Multi-annual Financial Framework. Beyond 'efficiency gains', this means **recalibrating the Agency to the work after the 2018 registration deadline**.

ECHA has built up competences on **advising industry**, **managing data**, **assessing chemicals**, **managing risks**, **assessing societal and economic consequences of risks and risk management decisions** and **operating an agency**. These competences are needed when implementing any chemicals legislation. So ECHA could help the EU to be more efficient and consistent by taking on more chemicals legislation and by helping countries build capacities to implement it.

Further information:

REACH review
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

THE REACH REVIEW

The REACH review highlights the main results of this legislation, such as:

- **information on more than 17 000 substances in 65 000 registration dossiers** of the main chemicals manufactured and used in the EU. This has improved risk management, communication and transparency in the supply chain, allowing Europe to better address risks;
- further **harmonisation of the internal market** for chemicals;
- **progress in restricting or banning the use of certain chemicals** that may be harmful to human health or the environment and driving their replacement by safer alternatives; and
- **promoting alternative, non-animal methods** for the hazard assessment of chemicals, reducing the need for tests on animals.

The report proposes many actions to improve the quality of registration dossiers submitted by companies, to simplify the overall authorisation process and to ensure a level playing field between EU and non-EU companies through effective restrictions and enforcement. The Commission wants to further support SMEs in their compliance and enhance enforcement by national authorities. The Commission also wishes to improve the coherence of REACH with worker protection and waste legislation.

The voice of the Member States in ECHA

INTERVIEW BY NEDYU YASENOV

Under REACH, ECHA has to provide EU Member States and institutions with the best possible scientific and technical advice on chemicals. The role of the Member State Committee (MSC) is to resolve the different views of Member States on evaluation draft decisions or on proposals to identify substances of very high concern (SVHCs). We spoke to the MSC's Chairman, *Dr Watze de Wolf*, to ask about the work of the committee and its future role.

THE WORK OF THE MSC

ECHA's **Member State Committee (MSC)** meets several times a year to discuss and seek agreements on complex and sensitive matters related to the safety of substances and their effects on human health and the environment.

The committee's involvement is triggered by diverging views of Member States on:

- **dossier evaluation**;
- **substance evaluation**; and
- when comments are received on human health and environmental effects during public consultations for **identifying substances of very high concern (SVHCs)**.

But the committee is also regularly involved in:

- **updates of the Community rolling action plan (CoRAP)**, which specifies the substances that will be evaluated by Member States over a three-year period; and
- recommendations for **including priority substances on the Authorisation List**.

In February 2018, the committee reached a landmark of **1 000 agreements and opinions** on these processes.

"The key to this success has been close and constructive collaboration between all the actors involved in decision making. The achievement represents 10 years of hard work, multiplied by 10 for the efforts of ECHA, multiplied by 10 for the resources invested by the Member States," Dr de Wolf tells.

"The decisions significantly contribute to the generation of knowledge on the safe use of chemicals and show the general public and registrants they can be confident that the scientific content of the decisions taken by ECHA are carefully scrutinised by its peers," he adds.

PREPARING AND SUBMITTING DOSSIERS

Under REACH, companies have to submit registration dossiers to ECHA. The dossiers have to provide information on the properties and uses of substances they produce or import in quantities of one tonne or more a year. The higher the tonnage, the more information a company needs to submit.

REACH lists **standard information requirements** and possibilities to adapt them. If a company wants to use an adaptation, they have to provide a detailed scientific justification with documentation.

If they identify a data gap and cannot fulfil the information requirements, they have to submit **testing proposals** to ECHA.

Once companies have submitted their dossiers to ECHA, the Agency carries out **compliance checks** on at least 5 % of dossiers in each tonnage band to make sure they comply with legal requirements under REACH.

Watze de Wolf.

DOSSIER EVALUATION

If ECHA concludes that further testing or information is required, it sends draft decisions to concerned companies for their comments. The draft decisions can be modified based on the comments.

The draft decisions are then sent to the Member States, which can propose amendments to them.

If a Member State proposes an amendment to ECHA's draft decisions on testing proposals and compliance checks, the case is referred to the MSC to try to reach a unanimous agreement.

"One of the main challenges is to always keep lines of communication open with all actors from ECHA and the Member States. To reach an agreement, we need to understand who is saying what and to also spot unspoken things or implicit assumptions to find a mutually agreeable solution," Dr de Wolf explains.

If the MSC unanimously agrees on a draft decision, either during the meeting or in written procedure, ECHA finalises the decision and sends it to the registrants concerned.

If no agreement is reached, the draft decision and all relevant documents are referred to the European Commission.

SUBSTANCE EVALUATION

Member States evaluate certain substances to clarify whether their use poses a risk to human health or the environment.

The objective is to request further information from companies if a concern is suspected.

Together with the Member States, ECHA defines risk-based criteria and then selects substances that are to be evaluated.

In this regard, the MSC provides opinions on the draft Community rolling action plan (CoRAP) prepared by ECHA.

"The CoRAP informs companies and stakeholders which substances will be evaluated by which Member States and what the initial grounds for concern are. The MSC provides an opinion on any Member State proposals to add substances to the CoRAP outside of the annual updates and also looks to find agreements if two or more Member States express an interest in evaluating the same substance," Dr de Wolf explains.

Based on the MSC's opinions, ECHA adopts the final CoRAP for substance evaluation.

The Member State then evaluates all registration dossiers for the substance as a whole and, where needed, proposes additional tests to generate missing data that should address the identified concern.

If ECHA or a Member State proposes an amendment to a draft decision on substance evaluation, the MSC tries to reach a unanimous agreement.

IDENTIFYING SVHCS AND RECOMMENDING SUBSTANCES FOR INCLUSION IN THE AUTHORISATION LIST

Authorisation aims to ensure that SVHCs are progressively replaced by less hazardous substances or technologies where technically and economically feasible alternatives are available.

The Member States or ECHA (following a Commission request) can propose a substance to be identified as an SVHC based on its hazard properties. These can be:

- **carcinogenic, mutagenic, toxic for reproduction (CMRs)**;
- **persistent, bioaccumulative and toxic (PBT)**;
- **very persistent and very bioaccumulative (vPvB)**; or
- substances, on a case-by-case basis, that cause an **equivalent level of concern** as CMR or PBT/vPvB substances.

Proposals to identify SVHCs undergo a 45-day public consultation. If no comments challenging the hazard identification proposal are received, the substance is added directly to the **Candidate List**. But if new information is provided or challenging comments are received, the proposal, the comments received and the dossier submitter's responses to them are referred to the MSC. The MSC then seeks an agreement on identification as an SVHC.

"If a unanimous agreement is reached, the substance is added to the Candidate List. But if not, we specify our scientific agreements and disagreements, after which an MSC opinion is prepared and we refer the matter to the Commission," Dr de Wolf explains.

In a consequent step, ECHA looks at the substances on the Candidate List to decide which ones should be added to the **Authorisation List** as a priority.

ECHA prepares a draft recommendation of which substances to include in the Authorisation List and consults this with the MSC.

"For the recommendation process, the MSC forms an opinion, taking the comments received during public consultation into account. ECHA then uses the opinion to finalise its recommendation on which substances to include on the Authorisation List as a priority," Dr de Wolf says.

MSC AGREEMENTS AND OPINIONS ON...	NUMBER
ECHA's draft decisions on referred dossier evaluation cases (testing proposals and compliance checks)	734
ECHA's Community rolling action plan and its annual updates (CoRAP)	8
ECHA's draft decisions on referred substance evaluation cases	129
SVHC identification proposals	135
• Agreements to identify SVHCs	127
• Other agreements on SVHC proposals	8
ECHA's draft recommendation for inclusion of priority substances in the Authorisation List (Annex XIV) (RECOM)	8
A request by ECHA's Executive Director under Article 77(3)c	1
TOTAL	**1 015**

In February 2018, the Member State Committee (MSC) reached a landmark of 1 000 agreements and opinions. This number has now been surpassed.

OTHER TASKS

The MSC also issues opinions related to human health, the environment or other safety aspects of substances if **ECHA's Executive Director requests** them to do so.

"We are lucky to have people with extensive scientific expertise in many different areas. The committee's work also offers scientific support to improve cooperation between Member States, international organisations and third countries on substance safety," Dr de Wolf adds.

ACHIEVEMENTS IN THE PAST 10 YEARS

"In the past decade, the committee has continually looked for ways to improve, taking into account lessons learnt from appeals, and feedback received from our members, from accredited stakeholders and from previous scientific discussions during cases," Dr de Wolf explains.

These efforts have:

- **increased opportunities for companies to be heard** during evaluation decision-making processes;
- identified areas and endpoints that could benefit from **further harmonisation**; and
- helped **develop harmonised scientific approaches** for certain endpoints.

The committee plays a key role in preventing unnecessary animal testing. For example, when the MSC concludes that a current dataset appears to be enough for regulatory risk management measures under harmonised classification and labelling or SVHC identification.

"We were also the first regulatory body in Europe to take substance-specific decisions on regulating endocrine disruptors and several respiratory sensitisers by identifying them as SVHCs and imposing legal obligations on the manufacturers of products containing such substances," he tells.

WHAT THE FUTURE HOLDS

"I expect that the committee's involvement in dossier evaluation may reduce in the coming years, but issues for substance evaluation and identifying SVHCs are likely to increase in complexity," Dr de Wolf says.

"What is clear is that the role of the MSC will largely remain the same, that is, to continue to resolve diverging views between ECHA and the Member States," he concludes.

HOW THE MEMBER STATE COMMITTEE IS COMPOSED

The **Member State Committee** (MSC) has 29 regular members appointed for a three-year renewable mandate by each of the 28 EU Member States, as well as Norway. In addition, 25 Member States decided to appoint alternate members to replace their regular members when needed.

All members possess **specific regulatory or scientific expertise** in the areas of ECHA's work that require the MSC's involvement.

In their routine committee tasks, they are often supported by advisors and invited experts for targeted discussions on specific scientific, technical or regulatory matters.

Representatives of the Commission and accredited stakeholder organisations are also invited to **participate as observers** to the committee's work.

The MSC is chaired by Dr Watze de Wolf.

Further information:

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

Evaluation under REACH
https://echa.europa.eu/regulations/reach/evaluation

Authorisation under REACH
https://echa.europa.eu/substances-of-very-high-concern-identification-explained

Compliance checks
https://echa.europa.eu/regulations/reach/evaluation/compliance-checks

Community rolling action plan (CoRAP)
https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Testing proposals
https://echa.europa.eu/regulations/reach/evaluation/examination-of-testing-proposals

Opinions of the MSC adopted under specific ECHA Executive Director requests
https://echa.europa.eu/about-us/who-we-are/member-state-committee/opinions-of-the-msc-adopted-under-specific-echa-s-executive-director-requests

Standard information requirements
https://echa.europa.eu/regulations/reach/registration/information-requirements

Candidate List
https://echa.europa.eu/candidate-list-table

Authorisation List
https://echa.europa.eu/authorisation-list

Healthy workplaces – knowing and controlling the risks of dangerous substances

INTERVIEW BY NERIJA JUKNIUTE

How healthy is your workplace? Are you familiar with the risks of the substances you handle and are they being properly managed? To make workers and employers aware about the relevant risks at their workplaces, the European Agency for Safety and Health at work (EU-OSHA) recently launched a "Healthy Workplaces" campaign on managing dangerous substances. We talked to *Ms Elke Schneider*, a Senior Project Manager in the Prevention and Research Unit at EU-OSHA, to find out more.

According to the EU Roadmap on carcinogens, nearly 80 000 cancer deaths are attributed to work-related exposure to carcinogenic substances in the EU each year. Many of these deaths could be avoided by properly assessing the risks and controlling the substances.

WHAT IS THE CAMPAIGN ABOUT?

The campaign aims to raise awareness of the importance of protecting workers from risks due to exposure to dangerous substances and eliminate, or if this is not possible, manage the risks. It is the second such campaign on this topic organised by EU-OSHA.

In many businesses, in particular SMEs, there are misconceptions that they do not use dangerous substances, that they are not affected by them and therefore there is no risk to their workers. However, experience shows that chemicals may be present at almost every workplace and there is a need to promote a preventive culture in companies.

According to Ms Schneider, about half of the diseases in the **European schedule of occupational diseases** are linked to exposure to dangerous substances.

In the campaign, a dangerous substance is considered to be any substance that poses a risk to workers' safety and health.

It can be in a gas, liquid or solid form, including aerosols, fumes and vapours and can include manufactured and process-generated substances, such as diesel exhaust or silica dust, and natural substances like crude oil or flour dust.

"Our campaign aims to raise awareness on how important it is to protect workers from dangerous substances and highlights the need to manage risks, providing information on good practices, guidance and tools. We should remember that a healthy workplace is not only good for workers, but also good for business," says Ms Schneider.

WHICH SECTORS ARE MOST AFFECTED?

Almost every sector is affected as the campaign looks at all dangerous substances, not only manufactured chemicals.

The scope of the campaign includes process-generated substances such as dusts or fumes, or substances of natural origin.

In sectors with well-known exposures, such as agriculture, construction and manufacturing, more guidance is available.

"The aim of the campaign is to also raise awareness in those sectors where awareness is lower – many of which are service sectors. I am talking about hairdressing, cleaning, maintenance or the healthcare sectors. The campaign particularly aims to reach out to these sectors and help employers assess the relevant risks and prevent them," Ms Schneider explains.

"We have just discussed plans with our national partners who help us implement the campaign, the national focal points and their networks, and will include industries that may have a regional relevance, for example ceramics, leather, or aquaculture," she adds.

EU-OSHA's "Healthy Workplaces" campaign on managing dangerous substances was launched on 24 April 2018 and will help to raise awareness among workers and employers about relevant risks to their health in the workplace.

WHICH GROUPS OF WORKERS ARE AT THE HIGHEST RISK?

The campaign not only focuses on specific sectors, but also on specific groups who lack knowledge and experience such as young workers and migrants, who may not understand the language of relevant training or instructions. Every profession has its specific risks related to chemical exposure, but some groups of workers may need specific support and protection.

"Young workers and women may be more vulnerable physiologically. And sub-contracted or maintenance workers may be at high risk, since they may be forgotten in risk assessments and working without tailored instructions. They may also be at risk as they have constantly changing workplaces, due to the nature of their tasks. We need to ensure they are considered and covered by preventive services, risk assessment, training and instruction, and protective measures," Ms Schneider tells.

"We are cooperating closely with our national focal points, providing a range of information materials, and sharing tools and instruments to address these risks. For example, we developed an **online interactive risk assessment (OIRA) tool**, which helps SMEs carry out a workplace risk assessment and implement appropriate preventive measures," she adds.

CAN EXPOSURE TO SEEMINGLY INNOCENT SUBSTANCES LIKE FLOUR DUST CAUSE SERIOUS SICKNESS TO WORKERS?

Just because a product has natural constituents does not necessarily mean it is safe or without any risks. All kinds of substances can be hazardous – for example, asbestos is a natural mineral but is known to cause serious lung diseases and lung cancer. A seemingly safe substance, such as flour dust, can also cause serious health issues.

STOP PRINCIPLE

There is a **hierarchy of control measures** set out in the occupational safety and health (OSH) directives, which means that prevention measures should be taken in a certain order. The **primary measure is the elimination of risk**, for example, by designing a new work process and avoiding the use of a substance. If elimination is not possible, follow the STOP principle.

- **S - substitution** – replacement of harmful substances with a safer alternative (either a process or a different substance).
- **T - technical measures** – minimising exposure to the substance, for example, by using a closed system, eliminating the substance at the source, using a closed system or local exhaust ventilation or enhanced ventilation, in this order of priority.
- **O - organisational measures** – minimising the time of exposure, duration, intensity and the number of workers exposed.
- **P - personal protective equipment** – protective clothing or equipment, from eye and respiratory protection to full body protection, skin protection, gloves or other means. When other measures are not enough, personal protection measures may be needed in addition.

"In our multilingual campaign guide, we have included a case example of a baker who developed serious asthma and a permanent work disability due to exposure to a high concentration of flour dust in a confined space. Flour dust is one of the main causes of respiratory disease in some Member States. While asthma is severe, there are also other symptoms affecting workers that may become chronic, such as rhinitis," Ms Schneider describes.

Many EU countries have developed guidance on how to effectively prevent bakers' asthma and they have run inspections and awareness-raising campaigns. This involves dust-avoiding work techniques, adequate local exhaust ventilation for some machinery and proper cleaning techniques, as well as innovative dust-avoiding flour mixtures.

WHAT ARE THE MAIN STEPS FOR MANAGING DANGEROUS SUBSTANCES AT WORK?

Employers need to carry out a workplace risk assessment and know which substances are used. As part of this, they should:

- **make an inventory of substances**, including the process-generated substances;
- **identify the hazards** using different information sources, CLP labels, safety data sheets, sectoral guidance, or risk assessment tools;
- **assess the exposure** (the intensity, frequency and duration, and who is affected, for how long, and how often; taking into account any combined effects); and
- **set measures according to the hierarchy of prevention** (including an action plan setting out who will implement the measure, by when and any necessary maintenance or repair work for incidents). This needs to take into account any workers that may be particularly at risk as well as any training needs.

The workplace risk assessment would need to be regularly updated and, in any case, whenever an incident occurs or a health issue is reported.

"Employers must carry out a workplace risk assessment, consulting

and keeping workers informed about what they may be exposed to and how to protect themselves. Sectoral guidance and a number of risk assessment tools have been developed, especially for SMEs, both by us at EU-OSHA, but also at a national level. Our **interactive eTool** helps to manage the risks and identify practical measures to prevent them and will be adapted to the national context in several countries," Ms Schneider informs.

WHAT IS THE ROLE OF REACH AND CLP IN MAKING WORKPLACES SAFER?

REACH and CLP provide important information for workplace risk assessment through the information on health effects and recommended risk management measures. More detailed information is provided in the safety data sheets and new classification and labelling requirements are in place.

REACH and CLP also cover restriction and authorisation for uses of certain substances. At workplaces, mostly mixtures are used and all the other circumstances of work also have to be assessed, for example, safety risks, or the machinery that people work with. In addition, employers have to respect the **hierarchy of prevention** when setting measures at workplaces.

"Another important aspect is the obligation for suppliers and manufacturers to provide information along the supply chain. This helps employers carry out risk assessments and is a sign of how REACH and CLP have strengthened the link between those who use chemicals and those who produce them," she adds.

ARE WORKPLACES IN THE EU HEALTHIER TODAY COMPARED TO 10 YEARS AGO?

According to Ms Schneider, the situation has improved a lot during the last years, but the landscape of health and safety is one that is constantly changing and presenting new challenges.

"We continue to share guidance and tools to improve worker safety, but there are sectors, such as the green jobs sector, waste management or recycling, which are growing rapidly and where new risks are emerging. Traditional risks can also come in different combinations and, therefore, new measures are needed," Ms Schneider says.

"The use of chemicals is not diminishing, but is actually growing. For instance, nanomaterials is an area where guidance on worker protection has been developed and we are currently updating our existing information on this to keep up with developments," she tells.

TOOL	INFORMATION
EU-OSHA's e-tool (EU wide) https://eguides.osha.europa.eu/dangerous-substances	• Helps manage risks posed by dangerous substances in the workplace.
OIRA platform (EU wide) https://oiraproject.eu/en	• Platform with free access to interactive and sector-specific risk assessment tools.
COSHH Essentials and e-COSHH (The UK, but widely disseminated) http://www.hse.gov.uk/coshh/essentials/coshh-tool.htm	• Easy, stepped approach to risk assessment and the factors that identify a suitable control approach.
GISBAU and GISCHEM (Germany) http://wingisonline.de http://www.gischem.de/index.htm	• Database with product codes for substance groups in common usage for construction, chemicals, metals and other industries.
Stoffenmanager (The Netherlands) https://stoffenmanager.nl	• Structures relevant knowledge and information for different types of enterprises.

There are helpful tools available for risk assessment and prevention measures and many are listed in EU-OSHA's campaign guide.

A HEALTHIER AND SAFER WORKPLACE BENEFITS EMPLOYERS

According to Ms Schneider, studies conducted by the European Commission show that for every euro invested in safety and health at work, there is at least twice a saving on costs.

"Companies with good occupational health and safety management in the workplace may benefit from reduced costs in complying with environmental legislation, as they pollute less and may save costs on materials and more efficient work processes. So this pays back in the long term. There is also a reputational effect for companies," Ms Schneider points out.

"There are also wider positive effects, not only for the company but also for society as a whole. It is obvious that keeping workers healthy means there will be less human suffering and absences due to health problems and accidents. This not only increases productivity, but may also reduce social costs such as compensation payments," she ends.

Further information:

EU-OSHA web page
https://osha.europa.eu/en/healthy-workplaces-campaigns/dangerous-substances-18-19

Healthy Workplaces campaign page
https://healthy-workplaces.eu

Campaign guide
https://healthy-workplaces.eu/en/campaign-materials/campaign-guide

Swedish national product registry – increased information on nanomaterials

INTERVIEW BY ADAM ELWAN

The Swedish Chemicals Agency (Kemi) has set up a mandatory reporting scheme to obtain information on the quantities and types of nanomaterials used in Sweden. We interviewed *Mr Robert Johansson*, Head of the Chemical Statistics and Registries Unit at Kemi, about the types of information they will collect and how it will be used.

Gathering information about nanomaterials on the EU market is an ongoing effort. Nanomaterials have been around for decades, but information about how they are used and in what quantities is scarce.

Many Member States, such as France, Belgium, Denmark and most recently Sweden, have launched their own mandatory registries to which companies must provide information about the nanomaterials they use.

NEW REPORTING REQUIREMENT

There has been a long-standing requirement in Sweden for companies to annually register the content of their chemical products in Kemi's products registry. This reporting requirement applies when the manufactured or imported volume of a product is at least 100 kilograms per year.

"The new requirement for nanomaterials means that companies reporting chemical products to be included in the registry must also state whether these contain deliberately added nanomaterials, regardless of their concentration," says Mr Johansson.

The purpose is to obtain information on the quantities and types of nanomaterials used in Sweden.

"This information can then provide a basis for making changes to legislation or taking other measures regarding nanomaterials, in areas such as healthcare, the environment or workplace safety," Mr Johansson tells.

WHO SHOULD NOTIFY?

Several actors are required to notify in the registry if their products contain nanomaterials, including:

Robert Johansson.

- **professional manufacturers or importers** of chemical products and biotechnical organisms;
- **those who, in their own name, package, repackage or change the names** of chemical products or biotechnical organisms for further distribution;
- **those who make mixtures** of chemical products and biotechnical organisms for further distribution;
- **manufacturers or importers** of notifiable chemical pesticides; and
- **third parties** that report the products on behalf of the manufacturers or importers.

"To support SMEs, companies with turnovers of less than EUR 500 000 per year are also exempt from the reporting requirement," Mr Johansson explains.

UP TO A COUPLE OF THOUSAND NOTIFICATIONS EXPECTED

Kemi expects to receive between 900 and 2 600 notifications, taking into account some exemptions that have been granted to properly evaluate the new requirements.

WHAT INFORMATION TO REPORT IN THE REGISTRY

The information that companies have to report in the registry includes:

- the **classification** of the nanomaterial according to the CLP Regulation;
- the **function** of the nanomaterial in the specific product;
- **primary particle size** of the nanomaterial;
- the **average size of the agglomerate or aggregate** for nanomaterials usually found in a product in an agglomerated or aggregated state;
- the **shape** of the nanomaterial;
- **crystal structure**; and
- the **surface area** and **surface treatment** of the nanomaterial.

© ISTOCK/XTOCKIMAGES

The Swedish Chemicals Agency (Kemi) has launched its own mandatory registry to which companies must provide information about their use of nanomaterials when they register the content of the ir chemical products.

Some of these exemptions cover nanomaterials that occur naturally or are accidentally produced as well as nanomaterials used as pigments.

"These figures are uncertain. They are partly based on a study originally made at EU level, so they might change when applied here in Sweden," Mr Johansson adds.

If a company has not reported the nanomaterials that are present in their product, Kemi can decide to publish a **statement of non-compliance** and request the missing information.

TIPS FOR OTHER COUNTRIES PLANNING TO ESTABLISH A NATIONAL REGISTRY

When setting up a national registry, there has to be a clear purpose and concrete ideas about how it should be used. "The registry should be planned together with different stakeholders, taking into account their views and needs during the entire process," Mr Johansson suggests.

According to Mr Johansson, many companies have asked whether it would be possible for different registries in the Member States to have a similar design and to be synchronised for easier data access across the EU.

Further information:

SweNanoSafe – the Swedish national platform for nanosafety
http://swenanosafe.se/in-english

Kemi homepage
https://www.kemi.se

Swedish Chemicals Agency – impact assessment of expanded notification obligation for nanomaterials
http://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2017&num=227&iLang=EN

European Commission – study to assess the impact of possible legislation to increase transparency on nanomaterials on the market
https://publications.europa.eu/en/publication-detail/-/publication/d42fe639-b080-11e6-aab7-01aa75ed71a

European Union Observatory for Nanomaterials (EUON) – National reporting schemes
https://euon.echa.europa.eu/national-reporting-schemes

Kemi products registry (in Swedish)
https://www.kemi.se/hitta-direkt/produktregistret

DID YOU KNOW?

ECHA has launched a **European Union Observatory for Nanomaterials (EUON)**.

It aims to make use of a variety of information sources, including that collected in different national inventories, to deliver accurate information to the public on nanomaterials in the EU.

The EUON:

- was **established in July 2017**;
- **brings together information about nanomaterials** on the EU market from a wide range of different sources; and
- **aims to compile data from national inventories** into a searchable list.

https://euon.echa.europa.eu

EUON
EUROPEAN UNION OBSERVATORY FOR NANOMATERIALS

© ECHA

The European Union Observatory for Nanomaterials (EUON) was established in July 2017 and aims to deliver accurate infromation to the public on nanomaterials in the EU.

Bridging the gap between academia and regulatory science

INTERVIEW BY PAUL TROUTH

Assessing the hazards and risks of chemicals is complex. Chemical assessments may be hampered by data gaps, which can sometimes result in lengthy discussions and controversies about how hazardous a substance really is. We spoke with *Dr Marlene Ågerstrand*, from the Department of Environmental Science and Analytical Chemistry (ACES) at Stockholm University to ask how academic research could be used to ensure that chemicals policy is based on all reliable and relevant information.

WHICH FACTORS DETERMINE WHETHER RESEARCH IS USED FOR REGULATORY PURPOSES?

In the EU, producers and importers of chemicals are responsible for providing data on human health and environmental hazards. According to legislation, new (eco)toxicity studies should be performed according to **good laboratory practice (GLP)** and **validated test guidelines**, such as those adopted by the Organisation for Economic Cooperation and Development (OECD).

Industry can also – or under some legislation is obliged to – include peer-reviewed studies in the information package submitted for assessing a chemical's hazards.

The EU chemicals legislation specifies that all available data of sufficient **reliability** and **relevance** – including peer-reviewed studies – should be used. But before they are, their design, performance and analysis have to be evaluated to make sure that they are trustworthy.

"Reliability deals with the inherent quality of the study and addresses issues such as whether appropriate controls are performed and if tested concentrations have been verified. Relevance looks at how appropriate a study is for a particular assessment and whether tested endpoints and life stages are suitable to assess the hazards or risks of a substance," Dr Ågerstrand explains.

Some researchers perform studies only with a view of the scientific community, while others also think about regulatory decision making when doing research. "In any case, it is up to the risk assessor to decide whether a study can be used in a regulatory setting. Whether it is performed by academia or by industry is not a criterion that should affect the evaluation," she adds.

PROMOTING PEER-REVIEWED STUDIES FOR REGULATORY USE

Peer-reviewed studies are sometimes excluded from regulatory processes because they lack crucial information on the test organism, test substance or test design. As such, it is important for risk assessors to differentiate between poorly-reported studies and those that have low reliability.

"A poorly-reported study could still be useful for regulatory purposes as long as the missing information can be made available on request. It is also important for researchers to publish open access studies, to make raw data available and to answer information requests from regulators," Dr Ågerstrand tells.

TEST GUIDELINES AND GOOD LABORATORY PRACTICE

Regulatory agencies try to ensure that the (eco)toxicity studies they use are credible and useful, and that they follow test guidelines and GLP.

Marlene Ågerstrand.

However, Dr Ågerstrand maintains that studies that follow these principles are not always the best choice.

"It is a problem to assume that studies performed according to test guidelines and GLP are always better. These standard studies are limited in number, and they do not always address the most relevant or most sensitive endpoints, test species or life stages. For instance, there is a lack of test guidelines that sufficiently deal with endocrine disruption or nanomaterials," Dr Ågerstrand tells.

"Another important aspect to consider is that studies performed according to test guidelines and GLP are often produced by parties that also have an economic interest in showing low toxicity. Therefore, to ensure the credibility of the system, it is important to combine the use of both industry studies and peer-reviewed research studies in the regulatory process, if they are judged to be of sufficient reliability and relevance," she adds.

INCREASING RESEARCHERS' OWN REGULATORY AWARENESS

To contribute to decision making, it is important for researchers to learn how regulatory systems work. Researchers could interact more with authorities by commenting and submitting their studies to public consultations, creating a dialogue with relevant stakeholders, and writing scientific reports for policy makers.

"This requires an in-depth knowledge of relevant legislation, guidance documents and decision-making procedures, as well as being able to understand and evaluate the content and conclusions of regulatory assessments," Dr Ågerstrand suggests.

"There should also be an onus on researchers to train the next generations so that future academics are in a better place to be able to understand regulatory processes," she encourages.

INCREASING THE USEFULNESS OF DATA

While researchers can improve their own knowledge on regulatory matters, one key action that could boost the use of their studies for regulatory assessment is thorough reporting of their findings.

"Studies need to be transparently reported so that regulators can easily assess how appropriate they are for regulatory assessment. This means that all the parameters that are normally reported in test guideline studies need to be available, including details on validity criteria, controls, which compounds and organisms have been tested, what the exposure conditions are, dose-response relationships and how the study is statistically designed," Dr Ågerstrand highlights.

Researchers could help regulators by comparing new study results with the current regulatory assessment, explaining why it does or does not support the conclusions and clarifying the significance of new research results. "Researchers can also ensure that their peer-reviewed studies are easy to find by giving them informative titles and abstracts, and by making them publicly accessible," she adds.

WHERE REGULATORY AGENCIES CAN PLAY A BIGGER ROLE

Regulatory agencies and bodies are the gatekeepers of research studies and key disseminators of information, which is why Dr Ågerstrand calls on regulators to make more effort to reach out to academia and to encourage industry to start using all available studies. "I would like to see more forums where regulators and academics can meet to discuss different scientific questions that are relevant for chemicals legislation. This would help to deepen the understanding between the regulatory authorities and academia and to create an environment that is naturally more collaborative," Dr Ågerstrand says.

ENCOURAGING PARTICIPATION IN PUBLIC CONSULTATIONS

To increase the amount of comments provided during public consultations, Dr Ågerstrand feels that agency procedures and guidance documents should explicitly encourage academia to take a more active part. To increase academic participation, two things are needed – awareness-raising campaigns and incentives for researchers.

"While it would require significant resources, direct contact with relevant researchers is always better than waiting for them to respond during public consultations. For the majority of academic researchers, time is limited and as long as external relations are not rewarded within the academic system, participation in agencies' public consultations will continue to be low," Dr Ågerstrand explains.

Technical solutions could also be utilised better. "It is possible for regulatory authorities to link their own databases to those that publish research results so that finding suitable research would become easier," she adds.

TRANSPARENCY IS THE KEY TO SUCCESS

To maintain a high level of credibility, it is important for authorities to be transparent in how they conduct themselves throughout regulatory processes and to promote a full understanding of the steps undertaken when assessing the hazards and risks of a chemical.

DEPARTMENT OF ENVIRONMENTAL SCIENCE AND ANALYTICAL CHEMISTRY (ACES)

Stockholm University's **Department of Environmental Science and Analytical Chemistry** (ACES) is a multidisciplinary department that gathers scientists from diverse fields in the natural sciences to study environmental phenomena and contribute to a sustainable society. In addition to its core responsibilities in teaching, research and outreach, the department is strongly engaged in supporting government agencies, such as the **Swedish Environmental Protection Agency**, the **Swedish Chemicals Agency** and the **Swedish Agency for Marine and Water Management** among others.

The department's research spans across five major areas: chemical contaminants, atmospheric aerosols, biogeochemical cycles of carbon and nutrients, ecotoxicology, and analytical chemistry.

"Risk assessments performed by industry, Member States and expert committees should always be reported transparently – not only in terms of which data and methodologies are used, but also in terms of how data is valued and how any uncertainties are handled," Dr Ågerstrand insists.

"The public should have full access to industry studies so that they can be evaluated externally and so that the results can be trusted based on the scientific merits rather than the affiliations of those performing the studies," she concludes.

Dr Ågerstrand is a researcher at the Department of Environmental Science and Analytical Chemistry (ACES), Stockholm University. Her research concerns regulatory (eco)toxicology, with a focus on assessing and managing chemicals – including reliability and relevance of (eco)toxicity data, weight of evidence, systematic review, bias and uncertainty in risk assessment. The aim of her work is to improve the scientific basis and increase the transparency and predictability of hazard and risk assessments of chemicals. She has developed reporting recommendations to help researchers perform studies that will enable risk assessors to fully evaluate their studies.

Further information:

Recommendations for toxicity and ecotoxicity studies
http://www.scirap.org

Science in Risk Assesment and Policy – Risk and hazard assessment of chemicals
http://www.scirap.org/Page/Index/47c0a960-0321-491b-92d3-42a44d43c3ef/assessment-of-chemicals

Stockholm University's Department of Environmental Science and Analytical Chemistry (ACES)
http://www.aces.su.se

Zebra A/S – working with non-EU suppliers

INTERVIEW BY PAUL TROUTH

Earlier this year, we had the opportunity to interview *Ms Jane Pors*, the Head of Quality, Product Compliance and Packaging at Zebra A/S, owners of the fast-evolving retail chain Flying Tiger Copenhagen. We asked how her company goes beyond the minimum to ensure compliance while working with non-EU suppliers.

Up until a few years ago, Zebra A/S used external consultants to make sure that they were compliant with legislation for the different types of products that they buy.

By centralising their compliance department in-house, the company has been able to benefit from receiving direct information about the composition of the products they purchase and to assess whether they can approve the materials and substances used to form the end-products.

STRAIGHT TO THE SOURCE

The majority of Zebra A/S's suppliers are non-EU and based in Asia – mainly in China. To find out the product information the company needs, it goes directly to its suppliers. "We know the information we get is accurate because we go straight to the source. Our suppliers get the information directly from their factories and it flows easily because they are very well aware of what they're doing. So even if they do not know something specific, like a particular CAS number, they can retrieve the information," Ms Pors says.

Having only established the compliance department in the last few years, forming an efficient working process with suppliers is important.

"The key to this has been clear communication. Our suppliers know what we want and understand that we mean it when we tell them our products need to be safe and compliant with legislation," she adds.

Each year, Zebra A/S holds a training for their biggest suppliers and, besides that, also travels to see them to build a stronger relationship, to go through documents with them and to reinforce the message of what the company expects from them.

Jane Pors.

"If we just stay in the EU and dictate from here what we require from our suppliers, communication will break down very quickly. We do all we can to ensure that the business relationship works, that communication is clear and understood, and sometimes that requires meeting our suppliers face to face," Ms Pors tells.

DIFFICULTIES IN GETTING INFORMATION

The company has changed some of their non-EU suppliers to suppliers based in the EU, especially for cosmetics where the legislation makes it easier to source such products from Europe. However, Ms Pors explains that sometimes there are actually more difficulties in getting information from suppliers in the EU.

"There is a big difference if you can actually talk directly to the manufacturer. For instance, if you go directly to a cosmetics manufacturer, they may well know everything about a product, but if the manufacturer does not produce it themselves, it can be difficult to get the information," Ms Pors says.

For Zebra A/S's other products, Ms Pors tells that it can actually be quite difficult to buy them directly from within the EU. "In Denmark, for instance, there are very few toys produced directly in the country," she adds.

There are also issues when EU suppliers do not have a knowledge of chemistry, as this can make it challenging for a company to really establish an understanding about what they need. "Imagine that the EU supplier purchases the product or material from outside the EU, they then need to communicate these needs to the non-EU suppliers, which adds yet another layer of difficulty," Ms Pors explains.

GETTING A FULL PICTURE OF PRODUCTS

When talking about EU suppliers and compliance with REACH, Ms Pors tells of Zebra A/S's passion to want to know about everything inside their products. "We want to have safe products and there is no other way than to know exactly what is inside them. We are adamant that we won't have any products in our stores where we are unsure over what substances they contain. When we think about textiles, for instance, we want to know what they are made of and what pigments are used. For our metal rings and hair accessories, we need to know more detail on what alloys are being used," she exemplifies.

Zebra A/S is a Danish retailer operating a chain of 900 design stores in 30 countries, including Flying Tiger Copenhagen.

To gain a better understanding, Zebra A/S has to collect all kinds of information. The first step in this is to check the product's **bill of materials (BOM)**, which outlines the raw materials, sub-components, assemblies, parts and quantities needed to develop the end-product.

"The check of the BOM is a crucial step for our business. We start with all this information gathered in a spreadsheet and then use a tool to filter the data based on what type of product we are looking at. The supplier fills in the information and it then comes to our department to see if any changes are needed and if anything is missing," Ms Pors explains.

When this check is complete, the final product assessment is done to see how the buyer intended the product to be used. "Think about the level of detail needed to decide if a product is to be used as a toy or not. It takes quite a lot of experience and expertise. You need to follow guidance from the EU on how to grade the product by age and therefore also need extensive knowledge on safety assessment in this area," Ms Pors says.

"This knowledge is also highly subjective and not all countries in the EU would categorise the same product in the same way," she concludes.

Jane Pors is the Head of Quality, Product Compliance and Packaging at Zebra A/S in Denmark. She holds an MSc in Biology and worked at a laboratory company for around 20 years, starting with ecotoxicology testing and moving on to product testing. Within the laboratory company, she started a consultancy service on legislation and the testing of materials and consumer products. After two years with her own consultancy company, Ms Pors joined Zebra A/S, where she has built the compliance department.

Zebra A/S is a Danish retailer operating a chain of 900 design stores in 30 countries, including Flying Tiger Copenhagen. It offers home decoration, toys, hobby, electronics, food contact products, cosmetics, fashion accessories, and other items. The company was founded in 1991 and is based in Copenhagen, Denmark.

Further information:

Flying Tiger Copenhagen
https://corporate.flyingtiger.com

How to work with non-EU suppliers
https://echa.europa.eu/documents/10162/23546172/pors_non-eu_supplier_en.pdf/9d464773-6227-b42a-f0e8-4f558dbba600

CMRs in textiles – Member States back Commission's restriction plan

TEXT BY HANNA-KAISA TORKKELI

The European Commission has proposed to limit the exposure to 33 chemicals that are carcinogenic, mutagenic or toxic for reproduction (CMR) by restricting their placing on the market in clothing, textiles and footwear. Member States supported the proposal, prepared under a simplified restriction procedure, in April. Now, the legislative proposal will undergo a scrutiny by the European Parliament and the Council.

The substances targeted by the restriction proposal are found in products that consumers can be exposed to through direct and prolonged skin contact, inhalation, or unintentional ingestion of textile fibre dust.

These include clothing and related accessories, footwear, and textiles other than clothing that touch the skin, such as bed linen, upholstery and reusable nappies.

Each of the substances has different properties and is they are used in different processes in the textile and footwear industries, so maximum concentration limits have been specified for individual substances or groups of substances.

This allows us to consider the technical feasibility of achieving the limits and the availability of appropriate analytical methods to be considered.

The restriction covers 33 CMR category 1A and 1B substances from the following substance groups:

- cadmium, chromium, arsenic and lead compounds;
- benzene and polyaromatic hydrocarbons (PAHs);
- chlorinated aromatic hydrocarbons;
- formaldehyde;
- phthalates;
- polar aprotic solvents;
- azo-dyes and arylamines; and
- quinoline.

A full list of the proposed substances and restricted concentration limits by weight is available in the draft regulation.

Clothing, related accessories and footwear (or their parts) made of natural leather, fur and hide, as well as non-textile fasteners and decorative attachments have been excluded from the proposal as different processes are used in their production.

Textiles used in medical devices are exempt, as they need to fulfil specific safety and functionality requirements.

In addition, second-hand articles that are in consumer use before the restriction applies are excluded as it would be nearly impossible to enforce in products already placed on the market. However, articles made from recycled fibres are to be covered by the restriction.

FIRST OF ITS KIND

The proposal is the first simplified restriction prepared for articles using the structured approach agreed with Member States and stakeholders in 2014-2015.

The process started in late 2015 with a discussion between the Commission and Member States authorities on the criteria for implementation on articles, where textiles, clothing and footwear were listed as priorities.

Hazardous substances in these products had already previously raised concerns. The Commission had indications of the possible presence of CMR substances from the work done by some EU Member States and NGOs. So, it was a logical choice to target them through the simplified restriction route.

The simplified procedure makes it possible to address a larger number of CMR substances at once, rather than doing individual restrictions for each of the substances.

The restriction proposal targets 33 substances mainly found in products such as clothing accessories, footwear and interior textiles that consumers can be exposed to through skin contact, inhalation or unintentional ingestion of textile fibre dust.

The procedure omits some steps of a standard restriction, such as a public consultation of the proposal and the opinions of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Assessment (SEAC).

Even if not required by the REACH procedure, the Commission consulted stakeholders on the scope and the list of possibly relevant substances to obtain more information on their use and presence in the concerned products.

The Commission also organised a technical workshop with stakeholders and asked for feedback on the proposal.

FINAL ADOPTION IN AUTUMN?

The Member States first discussed the proposal at the REACH Committee in February. The vote took place on 26 April.

It will be published in the Official Journal of the EU after scrutiny by the Parliament and Council.

The regulation will enter into force 20 days after publication in the Official Journal. However, companies have 24 months to apply the law, so around autumn 2020 the restricted substances should no longer be present in the textiles mentioned in the scope.

★★★★★

EURATEX 'HAPPY WITH THE PROGRESS'

The **European Apparel and Textile Confederation (EURATEX)** has worked closely with the European Commission and other stakeholders for more than two years to ensure that the restriction can effectively protect European consumers, can be enforced and is also feasible for industry.

"An intense exchange of information between the Commission and stakeholders increased the understanding of our sector-specific technical requirements and the actual industrial manufacturing processes. We were particularly pleased with the very effective technical workshop organised by the Commission, which brought together experts from industry, Member States and civil society organisations. That showed clearly how alignment can be reached through open discussion," says *Ms Dunja Drmač*, Sustainability Officer at EURATEX.

What EURATEX is still advocating are: clarity in the scope to avoid different interpretations and applications across the EU single market and validated and harmonised test methods, the absence of which might lead to ambiguity over compliance. "These are essential for providing legal certainty," she says.

Dunja Drmač.

SIMPLIFIED RESTRICTION PROCEDURE

- **Article 68(2) of REACH** provides a simplified procedure to restrict substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A and 1B, on their own, in mixtures or in articles that could be used by consumers.
- The **formal procedure is initiated by the European Commission**.
- **Does not include** some of the formal steps required to initiate a restriction under the standard procedure, such as the **preparation of a restriction dossier**, a **public consultation**, **opinions by RAC and SEAC** and a **consultation of the Enforcement Forum**.
- The Commission **used the simplified procedure for the first time on articles** when restricting polycyclic aromatic hydrocarbons (PAHs) in rubber and plastic. This restriction was adopted in December 2013.
- The current restriction proposed for CMRs in textiles is the **first of its kind using the structured approach** agreed with Member States and stakeholders in 2014-2015

Further information:

European Commission news on restricting the use of hazardous chemicals in textiles
http://ec.europa.eu/environment/chemicals/news_en.htm

Draft Commission regulation
http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&Dos_ID=15915&DS_ID=55248&Version=4

Statement of the European Consumer Organisation, BEUC (ECHA's accredited stakeholder)
http://www.beuc.eu/publications/eu-rightly-limits-toxic-chemicals-textiles-could-have-better-protected-consumers/html

Statement of seven NGOs ahead of REACH committee meeting
http://env-health.org/resources/letters/article/seven-ngos-ask-for-stricter-3660

REACH restrictions (European Commission)
https://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en

Basics of restriction
https://echa.europa.eu/regulations/reach/restriction

Chemicals of emerging Arctic concern

INTERVIEW BY IRENE POZA LATORRE

Far from industrialised areas, global human activities and climate change are threatening Arctic ecosystems. A recent study, 'Chemicals of Emerging Arctic Concern', by the Arctic Monitoring and Assessment Programme (AMAP) tells how many chemicals that were not expected to reach the region, have turned the Arctic into a sink for global pollutants. We spoke to *Dr Katrin Vorkamp*, Senior Researcher at the Arctic Research Centre and the Department of Environmental Science in Aarhus University, Denmark, and one of the editors of the report, to ask how Arctic pollutants are being monitored and what measures can be taken to preserve the region.

Katrin Vorkamp.

BEYOND COMMONLY DEFINED POLLUTANTS

According to AMAP's study, there are an estimated 150 000 substances registered for use in commerce and new substances continue to enter global markets each year. Fewer than 1 000 of these are routinely monitored and very little is known about the worldwide environmental release of these new chemicals or their effects on Arctic ecosystems.

AMAP works with a set of priority issues within Arctic contamination and climate change, and **persistent organic pollutants (POPs)** are one such issue, as they are toxic for humans and animals and can remain intact in the environment, including in the Arctic, for several years.

While AMAP uses the Stockholm Convention's definition of POPs in that it recognises their potential for **long-range transport**, **persistence**, **bioaccumulation** and **biomagnification**, the report highlights that there are other emerging chemicals that warrant attention even though they have traits that fall outside the POP criteria.

"We did not work with a stringent definition of an environmental pollutant, but extended our original focus on POPs to include other organic chemicals present in Arctic ecosystems. Some compounds can even be more problematic in the Arctic than elsewhere. Pharmaceuticals and personal care products, for example, have been shown to be more persistent in the region because of the low temperatures and darkness," says Dr Vorkamp.

With several substances listed under the Stockholm Convention being phased out, other chemicals with similar chemical characteristics have begun to be used in their place, such as replacement per- and polyfluoroalkyl substances (PFASs) and brominated and chlorinated flame retardants. "Initial data indicate that these compounds can also be transported to the Arctic and, to some extent, accumulate in food chains," she adds.

PLASTIC AND MICROPLASTICS OF CONCERN

Another increasing problem for the Arctic is the emergence of microplastics. These are small pieces of plastic material, typically less than 5 mm in size that can be formed unintentionally when larger pieces of plastic wear and tear, or can be produced intentionally for a specific purpose, such as for use in exfoliating beads in facial or body scrubs.

Marine plastics are an issue because they can cause physical damage to the region's ecosystems, especially to fauna. According to Dr Vorkamp, the **'European Strategy for Plastics in a Circular Economy'** is a timely response to the globally growing issue of plastic pollution. "We note that the strategy includes international collaboration towards

DID YOU KNOW?

Persistent organic pollutants (POPs) are carbon-based, organic chemical substances that possess a particular combination of physical and chemical properties such that, once released into the environment, they:

- **remain intact for exceptionally long periods of time** spanning many years;
- become **widely distributed throughout the environment** as a result of natural processes involving soil, water, and air;
- **accumulate in the fatty tissue of living organisms**, including humans, and are found at higher concentrations at higher levels in the food chain; and
- are **toxic to both humans and wildlife**.

a global solution. Our report describes that sources, transport and degradation pathways for marine plastics in the Arctic are poorly understood. While this is the case, a large-scale approach to tackling plastic pollution appears most likely to succeed in protecting Arctic ecosystems. The combination of ecological and economic goals outlined in the plastics strategy could act as a blueprint for other countries in a similar situation," she tells.

ISSUES NEAR AND FAR

Although chemicals may be used locally, they can spread globally causing environmental and health problems in regions where they have hardly been used. While you may think that the ocean currents are the main source of pollutants reaching the region, POPs accumulate in food chains, making the Arctic populations' consumption habits a prominent issue.

"There remains disconcertingly high concentrations of some pollutants in the Arctic's top predators, which is still a concern for people in the region who rely on traditional and local sources of food," Dr Vorkamp explains and continues, "In addition to long-range transport of POPs and other compounds, some less persistent chemicals can be emitted locally, for example, with wastewater. Despite a low population density with less cumulative emissions than urbanised areas, this is counteracted by less efficient or, in some cases, no wastewater treatment in the region".

The report notes that pharmaceuticals and personal care products are seemingly emitted locally, in particular with wastewater discharge, but also suggests that phthalates and siloxanes are being released in wastewater, in addition to reaching the region through long-range transport. Increased chemical production – and related emissions – in new source regions such as Asia, and climate change are factors that the report considers as new challenges for the region. "The melting of glaciers can release POPs and other chemicals, which have been retained in the ice after atmospheric deposition. Receding sea ice and warmer temperatures also increase the volatilisation of chemicals from the sea. Arctic ecosystems can change as predator-prey relations become affected by climate change phenomena and some Arctic animals are under stress in addition to being exposed to chemicals," Dr Vorkamp tells and adds that AMAP is going to address climate and contaminant interactions in a future assessment report.

IMPORTANCE OF SCIENCE-POLICY DIALOGUE

Although international conventions, such as the Stockholm Convention of POPs, have been successful in reducing POP concentrations in the environment, they do not cover the vast majority of substances that are currently present in the Arctic. "The Stockholm Convention seems to have had a significant effect on POP concentrations in the Arctic. However, unlike REACH, it is reactive rather than proactive, meaning that POP properties of a nominated compound need to be documented before the compound can be added to the annexes of the Stockholm Convention," Dr Vorkamp says.

AMAP's report argues that the situation is made even more difficult because several years can pass between the introduction of a new chemical to the market and an eventual agreement to ban or restrict its use if it is shown to be hazardous.

"Arctic data can provide evidence of long-range transport, persistence and, depending on the study design, bioaccumulation. As such, the data should be conveyed to the Stockholm Convention's POP Review Committee in a coordinated and efficient manner and nominating countries are informed about emerging compounds of concern early enough. The importance of science-policy dialogue cannot be stressed enough," Dr Vorkamp emphasises.

INNOVATION AND NEW TECHNOLOGIES ARE THE KEY

With the report estimating that less than 1 % of the 150 000 substances in commerce are being regularly monitored, it does, however, acknowledge that not all of these substances are in current use, and that not all of those that are currently used are likely to be Arctic contaminants.

There are some approaches that can be taken to identify which substances represent a potential concern for the Arctic region. "*In silico* approaches and non-target screenings can help to identify relevant compounds for monitoring or targeted analysis. These approaches can be used to narrow down the spectrum of chemicals to focus on, but *in silico* approaches do not provide empirical evidence on which compounds are being transported to the region, and non-target screenings do not necessarily quantify the amount of compounds in samples taken from the Arctic," Dr Vorkamp explains.

For non-targeted analysis, relatively new techniques based on high resolution mass spectrometry are used. For targeted analysis, methods are always optimised for the specific compound in question. "The purpose of the targeted analysis is to confirm the identity of a compound and to collect a sample which quantifies the concentration of a particular contaminant. These analyses are often highly specialised and require low detection limits," she informs.

The report also mentions the screening of databases including:

- the **list of pre-registered substances under REACH**;
- the **European Inventory of Existing Commercial Chemical Substances (EINECS)**;
- the **European List of Notified Chemical Substances (ELINCS)**;
- Canada's **Domestic Substances List (DSL)**;

- the US **Toxic Substances Control Act Inventory Update Rule (TSCA-IUR)**; and
- the **SMILECAS database** included in the **US Environmental Protection Agency's EPI Suite program**.

EVERYTHING'S NOT LOST

International efforts to reduce the release of POPs are already visible. Monitoring in the Arctic has shown a decline in the amount of the 'dirty dozen' POPs – the 12 initial POPs listed under the Stockholm Convention – since national regulations were established in Europe and North America in the 1970s and 1980s.

"The Stockholm Convention has prevented new production in other parts of the world and in this way has contributed to the ongoing decline," Dr Vorkamp tells. Later additions to the Stockholm Convention are also being monitored in the Arctic and are beginning to show decreases.

REACH and other regulatory activities have also had an impact on this according to the report. For example, the concentrations of some substances of very high concern (SVHCs) have also been dwindling in the Arctic in the last few years.

"One example of this that we document in the report is that several long-chain perfluorocarboxylic acids that are on the Candidate List have decreased in the Arctic in the last few years, even though they are not included in the Stockholm Convention," she ends.

ARCTIC MONITORING AND ASSESSMENT PROGRAMME (AMAP)

The **Arctic Monitoring and Assessment Programme** (AMAP) was established in June 1991 by the eight Arctic countries – Canada, Denmark, Finland, Iceland, Norway, Russia, Sweden and the United States. Since its establishment, the programme has documented the extent and effects of pollution in the Arctic and tracked new developments to help to inform policy decisions.

AMAP aims to provide **reliable and sufficient information on the status of the Arctic environment** and any threats to it. The programme provides scientific advice to support Arctic governments in their efforts to take remedial and preventive actions to reduce adverse effects of contaminants and climate change. The AMAP Secretariat is located in Tromsø, Norway.

AMAP Assessment: Chemicals of Emerging Arctic Concern
https://www.amap.no/documents/doc/AMAP-Assessment-2016-Chemicals-of-Emerging-Arctic-Concern/1624

Guest column | Toy Industries of Europe (TIE)

Safety by design and smart market surveillance – the recipe for safe toys in the EU

Would you be surprised to learn that a toy fork used by a child to feed its teddy bear has to meet stricter rules than the real fork the child eats with? What about if you were told that if oranges were toys, they would require a safety warning because of their fragrance?

As the tools of play, toys are an important part of growing up and have a central role in children's development, learning and wellbeing. Toys are also one of the most well-regulated consumer goods in the EU. Because they are destined for children to play with, they must be of a higher standard than many of the other everyday products children come into contact with.

REPUTABLE COMPANIES UNDERSTAND AND RESPECT IMPORTANCE OF SAFETY BY DESIGN

The reputable companies who make up the vast majority of the sector understand the importance of designing safety into their toys from the start of the development process. They invest a lot of time and resources into testing to make sure they are safe for children to play with.

EU'S COMPREHENSIVE LEGAL FRAMEWORK HELPS KEEP TOYS SAFE

The **Toy Safety Directive (TSD)** is the reference point for industry. Manufacturers also ensure they are compliant with other relevant legislation, including **REACH**, the **Restriction of Hazardous Substances Directive (RoHS)**, the **Radio Equipment Directive (RED)** and, when toys are built for connected play, the appropriate security and privacy regulations.

In addition to this, manufacturers look to the myriad of standards that have been developed over time to handle specific aspects of toy safety. Reputable manufac-

turers know that by following these rules, the toys that they put on the market will be safe.

ADAPTABILITY OF TOY SAFETY DIRECTIVE MAKES SURE IT STAYS RELEVANT

Furthermore, the safety of toys in the EU is reinforced by the wide margins included when limits are decided and the 'living' nature of the TSD, which means it can be revised if new scientific evidence comes to light.

This flexibility helps to make sure that the rules and standards are kept relevant and up to date. Examples of this in action include the changes to migration limits we have seen in recent years for lead, bisphenol A and chromium VI.

Catherine Van Reeth, Director General of TIE.

SCIENCE MUST BE THE BASIS FOR DECISION MAKING

Given the emotive nature of issues regarding children's safety, it is essential that changes to legislation are made on the basis of science-based evidence and rational decision making. This is why the work of the **Commission's Expert Group on Toy Safety** and its scientific committees are so important.

ROGUE TRADERS ARE A CHALLENGE, BUT REPRESENT ONLY A SMALL MINORITY OF MARKET

However, there are a small group of rogue traders who don't play by the rules. These are the operators who are responsible for 97 % of notifications for toys on the **Rapid Alert System (RAPEX)** and are the source of the toys featured in ECHA's recent report on compliance.

By ignoring the rules, they gain a competitive advantage over reputable manufacturers and put children at risk.

Toy Industries of Europe

© TOY INDUSTRIES OF EUROPE (TIE)

Reputable companies that make up the vast majority of the toys sector understand the importance of designing safety into their toys from the start of development.

EFFECTIVE MARKET SURVEILLANCE KEY IN CATCHING OPERATORS WHO IGNORE RULES

The only real way to tackle the challenge posed by rogue traders who ignore the rules is through smart and effective market surveillance. This includes strong cooperation and reputable economic operators. The Commission's recent **Goods Package Proposal** provides a number of opportunities in this respect: the formation of a Union Product Compliance Network is a clear example of how to optimise coordination of enforcement activities within the EU.

PARENTS CAN BE CONFIDENT TOYS FROM REPUTABLE COMPANIES ARE SAFE FOR CHILDREN TO PLAY WITH

The EU framework for toy safety is fit for purpose: it covers all aspects of toy safety and is designed to be responsive to new evidence – parents can rest assured that the toys that they buy from reputable manufacturers are safe for their children to play with. Effective market surveillance and enforcement is vital in keeping toys that don't meet the EU's high standards out of children's hands.

Catherine Van Reeth is Director General of Toy Industries of Europe (TIE). She leads TIE in promoting a positive environment in which the toy sector can thrive and continue to bring safe and fun play experiences to children. Catherine has worked in EU public affairs for over 20 years and is an expert in consumer protection policy.

TIE is the voice of reputable toy manufacturers in the EU. TIE was founded in 1991 and today represents 12 international toy companies, nine national toy associations and six affiliate members. TIE provides its expertise and knowledge about toys and the sector to members, stakeholders, and policymakers and provides a neutral platform for discussion and exchange. TIE's main focus is ensuring that toys are safe for children. Other topics covered by TIE include responsible communications, ethical manufacturing, environmental sustainability, intellectual property rights and market access and promoting the value of play and the importance of toys in helping children develop and grow.

Will this tool change safety data sheets?

INTERVIEW BY JAKOB AAHAUGE

Have you ever read a safety data sheet (SDS) and wondered whether it has all the information, or maybe even found it hard to understand? A new online tool has been developed that checks whether SDSs contain the right information and sends feedback to suppliers. We interviewed *Mr Nathan Kuper*, Dangerous Substances Expert at the Dutch Labour Inspectorate (Inspectie SZW), and asked what benefits the tool will bring to downstream users of chemicals and mixtures.

The **VIB check tool** gives users a better idea of whether their **safety data sheets (SDSs)** are complete and meet the main requirements under REACH and CLP about health and safety at work.

The tool runs through a series of simple questions that help users check their SDSs. Do they, for example, say if safety equipment is needed? Do they contain correct information about the hazard classification of the chemicals? By answering these types of questions, users can easily see whether their SDSs contain what they need. And if they do not, users are asked to notify their suppliers by sending an email through the tool.

IMPROVING SAFETY DATA SHEETS

Looking at the tool, it quickly becomes clear that it is simple to use. It uses a simple language aimed at people who may use chemicals but who do not need to have a full understanding of the properties of chemicals to run their core business. One example could be painters, but the tool is also useful for other SMEs.

"In the Dutch Labour Inspectorate we checked with some downstream users to find out whether they have safety data sheets and whether they were reading them at all. It turned out that most safety data sheets are still not being read – people get them, but they don't read them," says Mr Kuper.

"We also checked the safety data sheets and concluded that not all the information was always present and that, in some cases, the information was not understandable. This is why we decided to create something easily accessible and intended for people who struggle to process the information," he continues.

ASKING THE USERS

Manufacturers can make the products, but only the users of the chemicals know what is going on when the chemicals are actually being used, Mr Kuper argues. "We have seen safety data sheets indicating that painters should use an emergency shower or eye wash unit when they use a certain paint, but painters obviously don't carry around emergency showers. This is just one example of information that just doesn't really make any sense for the target group."

Nathan Kuper.

The challenge is to get people to read the SDSs and to point out when there is something wrong with the information. "There is a need for more information to float upstream from the users. That's why the VIB check tool allows users to give feedback and point out what is missing. Users can fill in a checklist and give feedback to suppliers on the quality of the safety data sheets when they have finished the check on the VIB website," Mr Kuper explains.

THINKING ABOUT THE AUDIENCE

In Mr Kuper's view, the spotlight should be on the usability and comprehensibility of SDSs and not only on their quality and correctness. "In a safety data sheet, there is a lot of information that is not easy to understand for the user.

VIB CHECK TOOL

The **VIB check tool** is for companies that purchase hazardous substances and mixtures from suppliers. With the VIB check, you can see whether a **safety data sheet** (SDS) meets the most important requirements from the REACH and CLP regulations related to health and safety at work.

The tool checks whether an SDS that you receive from your supplier contains the correct information to ensure that you can work with hazardous substances and mixtures in a healthy and safe working environment.

We need to change that and have the audience in mind when creating them. The quality is good, but the usability is bad. When it comes to things like personal safety protection at the workplace, it is essential that people can understand what it says," Mr Kuper points out.

EMPOWERING DOWNSTREAM USERS

When asked about how to enforce the usability of the SDSs, Mr Kuper says that empowering downstream users would make REACH work better. "It is about maturing the whole system. Everyone in the REACH chain has a role to play."

The Dutch version of the tool, which guarantees privacy and that the information will not end up in any government institutions, has already been used thousands of times in the Netherlands. The tool was developed with the aid of Dutch branch organisations.

The tool is being translated and an English version will be available in the future, which is expected to make the number of users grow rapidly.

DID YOU KNOW?

Use maps set out the most common ways in which chemical products are used in different sectors. The maps have been standardised to improve the quality of information on uses and conditions of use up and down the supply chain.

The maps benefit registrants by giving them **direct information from downstream user sectors** to help them create their chemical safety assessments based on realistic conditions of use. They also help downstream users by making it **easier for companies to process the exposure scenarios** they receive from their suppliers.

Use maps
https://echa.europa.eu/csr-es-roadmap/use-maps/concept

Further information:

VIB check tool (in Dutch, English version under construction)
http://www.vib-check.nl