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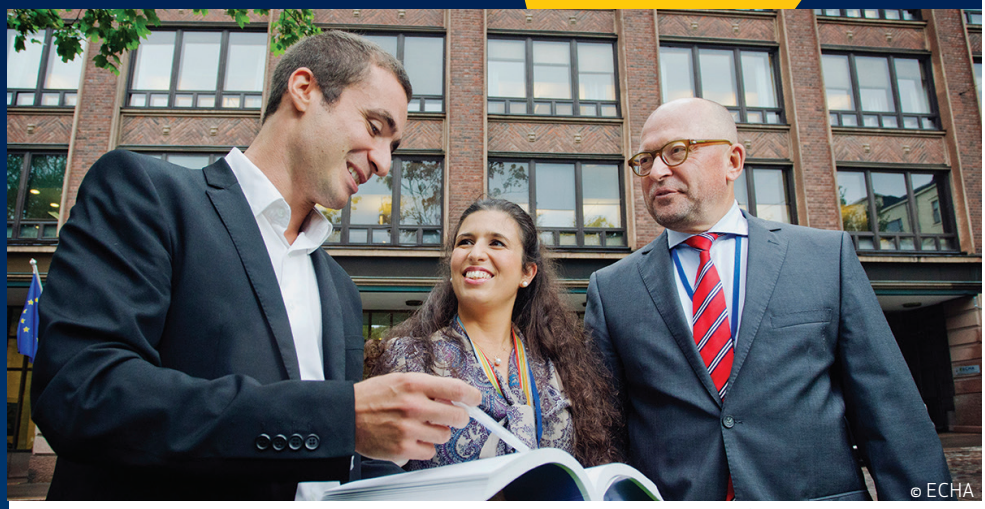
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Delivering during times of change

In a diverse career spanning 42 years, the end of my term as one of ECHA's senior management is a clear milestone in my life. As I head towards retirement from active service, I am leaving ECHA at a time of change. In January, Bjorn Hansen took over as Executive Director. In May, the 2018 deadline for registering phase-in substances marked the end of the beginning in making REACH work. ECHA has defined new strategic objectives to support the regulatory priorities for the next decade and our Management Board will endorse these in December.

Delivering on the third **REACH registration deadline** was a landmark achievement. An article in this issue takes a closer look at the outcomes. This historic step has seen registrants make the properties of all chemicals on the EU market publicly known, and has enabled ECHA to populate the world's largest database on chemicals. This is key for mapping the chemical universe and our work in managing their risks. As soon as we finalise our work on the tail of the 2018 registrations, we will also see whether any substances essential to vital supply chains are missing.

In this effort, the **Directors' Contact Group (DCG)**, where I have served as an ECHA Sherpa, is crucial. Through the DCG, ECHA, industry associations and Commission services have together facilitated REACH registrations. How intense our work was back in 2010, ahead of the first deadline! Registration was new; concerns created anxieties; and we drew up pragmatic solutions to help registrants. In 2018, the DCG elaborated further recommendations. I think the joint effort has proven itself useful.

The REACH, CLP and Biocidal Products regulations require all EU Member States and EEA countries to establish national helpdesks to provide guidance and support to companies. Together with industry associations, they are valuable partners for ECHA

in implementing the EU chemicals legislation. With the phase-in registrations now done, their focus will shift to other topics, such as communication in the supply chain. I feel honoured to have chaired their HelpNet network for the past 10 years and would like to give my thanks to all national helpdesk correspondents for their involvement!

Many registrants and downstream users are SMEs. As ECHA's **SME Ambassador**, I have raised awareness of their needs. From medium-sized companies with specialised chemicals to micro businesses and downstream users with only marginal experience of the EU chemicals regime, SMEs are faced with significant administrative and data generation burdens, often with limited resources. There is no one-size-fits-all approach to supporting them. As the Commission's REACH Review also recently stated, SMEs will need to remain a focus of attention, and I therefore welcome that my Director colleague *Christel Musset* will continue this work as ECHA's SME Ambassador.

During the last two years, I have also been coordinating ECHA's preparations for the **UK's withdrawal from the EU**. In this task, my professional experience as a lawyer and a diplomat has been useful. Having worked in the European Commission on the accession of Lithuania and the Czech Republic to the EU in 2004, working on the inverse process has been a peculiar exercise. I have been struck by the strong attachment the UK chemicals industry has expressed towards REACH as the most advanced regulatory regime for chemicals worldwide. As the UK's departure quickly approaches, we should not underestimate the impact of this event on our regulatory system. Our November Newsletter will draw attention to our updated advice to companies on how to adjust to the UK no longer being part of the EU as of 30 March 2019.

For everyone at ECHA, these last years have been intense. This will not change, as Europe and society continue to rapidly evolve. I leave ECHA with the impression that, apart from protecting human health and our environment, regulatory efforts are providing our industry with a global competitive advantage. I wish ECHA and all companies well in ensuring the safe use of chemicals and retire pleased to have played a role in caring for our citizens.

Andreas Herdina
Director of Cooperation

"Regulatory efforts are providing our industry with a global competitive advantage."

In this issue:

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REACH 2018: Keep your registration up to date

TEXT BY HANNA-KAISA TORKKELI

The seventh and last step to successfully register your chemicals is to maintain your registration data. REACH registration is not a one-off exercise, but rather the start for managing your substance portfolio responsibly under the EU chemicals legislation.

REACH registration is not a one-off exercise, but rather the start for managing your substance portfolio responsibly under the EU chemicals legislation.

The registration dossier is meant to reflect the current knowledge on how your substance can be used safely at production sites and through the supply chain all the way down to the end user.

This means that although you have successfully submitted a registration and gotten your registration number, **you still have work to do**.

It is up to you to review your registration on a regular basis and update it when new information becomes available – even if ECHA does not request you for an update.

Being proactive is not only good practice, but also a legal requirement.

WHAT TO UPDATE?

You need to update your registration dossier, when you learn something new about the composition of your substance, its properties, how it is used by your clients, or the specific risk management measures needed to ensure safe use.

Significant changes in the production or import volumes and the company information must also be reported.

In addition, new information may become available when new companies that want to register the same substance join the joint submission – this must also be reflected in the joint registration.

WHY UPDATE?

ECHA and Member State authorities use the registration dossiers as a basis for further regulatory work. The information needs to be up to date, so that authorities – and also you – do not waste time on clarifying potential concerns that are, in fact, no longer relevant.

ECHA's task is to examine the registrations to verify if the information in them is compliant with the legal requirements. We check at least 5 % of the registrations per tonnage band during compliance checks, for which dossiers are selected either randomly or by targeting certain endpoints of concern.

We study the most common shortcomings from the compliance checks and publish our recommendations online.

Check these recommendations to avoid having the same problems in your own registration. In addition, it is your responsibility to check whether a harmonised classifica-

REGISTRATION NUMBERS GRANTED TO 32 515 REACH 2018 REGISTRATIONS

Following ECHA's completeness checks on REACH 2018 dossiers (registrations for the tonnage band of 1 to 100 tonnes per year), registration numbers have been granted to **32 515** dossiers out of the **33 363** dossiers that were submitted by 31 May. These registrations cover **10 708** chemicals.

For the other dossiers, ECHA is still waiting to receive further information from companies. These include **477** cases where companies faced exceptional circumstances as defined by the Directors' Contact Group (DCG). They submitted their dossier with a DCG solution and were granted an extension for submitting the missing information. The Agency expects to conclude on all pending cases by May 2019.

tion and labelling applies for your substance.

Member States, on the other hand, scrutinise substances, which might be a concern for human health or the environment.

To clarify whether or not a concern exists, they may ask you to generate information beyond the registration requirements laid down under REACH.

It's good to keep in mind that although the lead registrant updates the joint part of the registration dossier, all affected registrants are responsible – and must share costs – to fix the situation if an incompliance is found or further information needs to be generated.

*ECHA will publish advice on how to organise the maintenance of your registration within your company and with your co-registrants on **6 November 2018**. We will also share our tips on where to pay attention in order to have good-quality data.*

Further information:

Registration numbers granted to 32 515 REACH 2018 registrations – ECHA news release
https://echa.europa.eu/-/registration-numbers-granted-to-32-515-reach-2018-registrations

Phase 7: Keep your registration up-to-date
https://echa.europa.eu/reach-2018/keep-your-registration-up-to-date

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

Registered substances
https://echa.europa.eu/information-on-chemicals/registered-substances

REACH 2018 statistics - completed registrations as of 31 August 2018
https://echa.europa.eu/documents/10162/5039569/reach_2018_deadline_statistics_en.pdf/ecfe225f-caf0-5bad-7c7f-ce57d2c8938f

REACH registration statistics since 2008
https://echa.europa.eu/registration-statistics-infograph#

Substance identification needs strong analytical data, ECHA Newsletter 4/2015
https://newsletter.echa.europa.eu/home/-/newsletter/entry/4_15_substance-identification-needs-strong-analytical-data

Help with terminology – in your language
https://echa-term.echa.europa.eu

(Un)loading lead – saving wildlife and nature in wetlands

TEXT BY NEDYU YASENOV

Lead shot has been widely used for decades in hunting and sports shooting. Yet, we know that lead has toxic effects on ecosystems and wildlife. This is why the EU is looking into restricting its use in wetlands in the near future. ECHA Newsletter explains the background.

WHAT IS THE ISSUE?

European wetlands are a habitat for numerous species of waterbirds, including wildfowl like ducks and geese. Hunting them on wetlands with lead gunshot is directly associated with lead poisoning in wildlife.

This poisoning arises after waterbirds ingest spent lead gunshot that they find on the ground or in water after mistaking it either for food or for small stones (called grit) that they swallow to help them digest their food.

Scavenging birds that feed on unretrieved waterbirds killed using lead gunshot can also consequently suffer from lead poisoning.

After the lead gunshot is ingested, it is ground down into small pieces in the bird's gizzard (a muscular digestive organ unique to birds). These pieces are then absorbed from the gut and into the bird's tissues. As lead is highly toxic, this frequently results in birds dying through lead poisoning.

Depending on the quantity of lead ingested, death can occur soon after the shot has been consumed or after a period of two to three weeks. Ingestion of a single lead shot can cause the death of a small duck. Where lead poisoning is not fatal, it can also cause harmful, sub-lethal effects on reproduction and the immune system.

The amount of lead released into EU wetlands due to hunting has been estimated to be around 4 000 tonnes per year. Sports shooting in wetlands contributes an additional amount, although this is difficult to precisely assess.

These uses of lead shot are believed to result in the **deaths of up to one million waterbirds** each year throughout the EU. There could also be additional impacts on scavenging and predatory birds.

HOW LEAD CAN AFFECT HEALTH

Although there is no quantitative data available on the risks to humans from consuming wildfowl

The amount of lead released into EU wetlands due to hunting has been estimated to be around 4 000 tonnes per year. The use of lead shot is believed to result in the deaths of up to one million waterbirds each year.

hunted with lead gunshot, lead remains a concern for human health.

Exposure to it is associated with a wide range of negative health effects, including **neurodevelopmental impairment**, **reduced fertility**, **hypertension** and **damage to the kidneys**. It is considered as a non-threshold toxic substance, meaning that **there is no safe level of consumption**.

Any reduction of dietary lead exposure will therefore contribute to reducing the human health risks posed by lead, particularly for children and adults who regularly consume game meat.

Avoiding the contamination of groundwater from shooting ranges could also reduce human exposure to lead through drinking water.

REGULATING LEAD SHOT ACROSS THE EU

In the EU, all but three Member States – Poland, Romania and Slovenia – have signed up to the **African Eurasian Waterbird Agreement (AEWA)**, which has been in place since 2000 and proposes to phase out the use of lead gunshot in wetlands.

Several Member States have implemented legislation that completely prohibits the use of lead gunshot, including the Netherlands, Belgium and Denmark. In others, partial bans are in place.

However, four Member States – Ireland and the three AEWA non-signatories have not implemented any restriction on the use of lead gunshot in wetlands.

Regulating the risk at EU level will therefore ensure an appropriate and harmonised level of protection for European wetlands and wildlife. A restriction will harmonise the level of protection across Member States, which as a consequence of the different levels of protection still see millions of birds die each year. Those Member States without current legislation account for 13-15 % of these deaths.

WHAT IS BEING PROPOSED?

In December 2015, the European Commission asked ECHA to prepare a restriction proposal for the use of lead in shot in wetlands. ECHA analysed the evidence and submitted its dossier in April 2017.

ECHA's proposal suggests restricting the use of gunshot that contains more than 1 % of lead, for shooting with a shotgun over or within wetlands, including at shooting ranges or on shooting grounds in wetlands.

At the same time, the Commission also asked ECHA to start collecting information on the potential risks of using lead in ammunition for hunting in terrestrial environments outside of wetlands. This work is being done separately to the restriction of lead in shot used in wetlands.

ARE THERE ANY VIABLE ALTERNATIVES?

Experience from those countries where a ban is already in place shows that hunters and sports shooters have adapted to using alternatives without any significant problems in relation to ricochet and other safety issues.

WHAT IS A WETLAND?

Wetlands are defined differently in different Member States. In the restriction dossier, the internationally recognised definition in the **Ramsar Convention** has been used.

This defines wetlands as “areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water, the depth of which at low tide does not exceed six metres”.

https://www.ramsar.org

Indeed, several scientific studies have shown that the use of steel gunshot cartridges results in similar hunting success to that achieved with lead gunshot cartridges, and without causing concerns related to crippling or wounding waterbirds.

The need to replace older shotguns with newer ones so that alternatives to lead gunshot can be used has also been a topic of fierce debate.

However, evidence gathered while preparing the restriction indicates that modern shotguns (those manufactured after 1970) are capable of using standard steel shot, and this has been confirmed by major gun manufacturers.

Lead-free gunshot cartridges are suitable for all types of shooting in wetlands and are widely available in the EU. They are also similarly priced to lead gunshot cartridges. If 'high-performance' steel cartridges are needed, for example, when hunting larger waterfowl, older shotguns may need to be modified or replaced.

Bismuth- or tungsten-based gunshot cartridges can also be used as alternatives to lead cartridges and can be used in any shotgun, including vintage shotguns.

However, bismuth- and tungsten-based shot cartridges are about four to five times more expensive than equivalent lead gunshot cartridges.

Hunters will need to decide how best to comply with the restriction depending on their individual circumstances and preferences, although it is assumed that most will switch to steel.

WHAT HAPPENS NEXT?

ECHA's **scientific Committees for Risk Assessment (RAC)** and **Socio-economic Analysis (SEAC)** finalised their opinions in June 2018.

Their opinions supported ECHA's proposal to restrict lead and its compounds in gunshot as well as the conclusions on the number of birds currently being killed by lead gunshot and the costs of the restriction to hunters.

In its final opinion, SEAC concluded that further action on a Europe-wide level is required to address the risks associated with lead gunshot in wetlands.

Furthermore, SEAC concluded that the effective implementation of the AEWA requires a consistent minimum level of protection of waterbirds across the EU, which would be achieved by the proposed restriction.

The compiled RAC and SEAC opinion was submitted to the European Commission on **17 August 2018** for decision making. The Commission now has three months to produce its draft decision.

If adopted, a transitional period of 36 months after entry into force is proposed, to allow a smooth transition to the use of alternatives.

Further information:

Registry of restriction intentions – lead and its compounds
https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180c0ac38

Adopted opinions on restriction – lead compounds in shot
https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/17005/term

Proposal for a restriction
https://echa.europa.eu/documents/10162/6ef877d5-94b7-a8f8-1c49-8c07c894fff7

Help with terminology – in your language
https://echa-term.echa.europa.eu

DID YOU KNOW?

In 2004, the **European Federation for Hunting and Conservation (FACE)** and **BirdLife International** both asked to phase out of the use of lead shot for hunting in wetlands throughout the EU as soon as possible (and in any case by 2009 at the latest).

http://ec.europa.eu/environment/nature/conservation/wildbirds/hunting/docs/agreement_en.pdf

The proposed EU-wide restriction on lead in shot used in wetlands would ensure the effective implementation of the **Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA)**, to which the EU has been a contracting party since 2005. One of the obligations of AEWA parties is to phase out the use of lead shot for hunting in wetlands as soon as possible.

The AEWA was developed under the auspices of the United Nations Environment Programme and is an intergovernmental treaty dedicated to conserving migratory waterbirds and their habitats across Africa, Europe, the Middle East, Central Asia, Greenland and the Canadian Archipelago.

http://www.unep-aewa.org

The future for hazardous mixtures in the EU

TEXT BY JAKOB AAHAUGE

An upcoming poison centres notification portal will offer an easy-to-use and secure way for industry to prepare and submit information, in a recently released harmonised format, to appointed bodies in different Member States. Here's what you need to know to start preparing.

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If citizens are accidentally poisoned with hazardous mixtures, such as household chemicals, detergents or paints, they can call a national poison centre for emergency health advice.

Most citizens don't think much about what the household bottles they keep under their kitchen sinks contain. They usually have shiny labels with phrases like *Deep clean!*, *Ultra power!* or *Advanced cleaning!* But if you are an importer or downstream user of mixtures, you know that behind these colourful descriptions, there are some rather potent chemicals hiding. They are efficient at cleaning or for other purposes, but they may also be misused and cause a poisoning incident.

If citizens are accidentally poisoned with hazardous mixtures, such as household chemicals, detergents or paints, they can call a national poison centre for emergency health advice.

The poison centres in the EU receive more than 600 000 calls a year. About half of those incidents involve children and in more than 40 % of cases identifying the product is difficult.

MAKING IT EASIER TO IDENTIFY THE PRODUCT

The main reason for the challenges in identifying the product involved in a poisoning incident is that the trade name is not always clear. This means that even if you are standing with the bottle in your hand while on the phone, identifying it for those on the other end of the line may not be straightforward.

A new label element called the **unique formula identifier (UFI)** links the product with the information provided by industry, for example, the product trade name and its composition.

The UFI is a unique code for each mixture composition which helps to identify the mixture and allows accurate and rapid medical advice to be given when there is a poisoning incident. The UFIs are generated with a tool available on ECHA's Poison Centres website and added to the labels.

WHAT DO I NEED TO NOTIFY?

If you are an importer or downstream user placing a mixture on the market that is classified as hazardous for human health or as a physical hazard, you need to submit information on this to appointed bodies in the Member State where the mixture is marketed. The required information includes:

- the full chemical composition of the hazardous mixture; and
- the product category according to a new harmonised **European product categorisation system (EuPCS)**.

There are some exemptions for mixtures classified for environmental hazards, medical devices, cosmetics, gases under pressure and explosives.

All the information has to be compiled using a harmonised **poison centre notification (PCN) format**.

PCN FORMAT

Currently, the poison centres' emergency health advice is based on information that industry submits nationally in different formats. The CLP Regulation was amended in 2017 to include the harmonisation of the information submitted across the EU. ECHA has since then released a harmonised submission format that will be used for notifications across the EU and which will replace national formats.

Currently, when a European company submits information on hazardous mixtures that are placed on the market in different Member States, it is done through national submission systems, which makes the information less consistent.

The PCN format is compatible with IUCLID software and takes advantage of this platform and its features. IUCLID is being further

developed so that it provides a PCN-specific, user-friendly interface.

NEW PORTAL WITH USER-FRIENDLY INTERFACE

ECHA is working on a **poison centres notification (PCN) portal** that will allow industry to prepare and securely submit notification data to appointed bodies through a single entry point.

The portal is expected to be released in 2019. Different ways to prepare and submit notifications will be provided, including an online guide that will show step-by-step advice to prepare notifications, as well as options to notify large numbers of mixtures for bigger companies like a system-to-system integration. Building a user-friendly interface has been one of the main aims of this portal.

One of the most beneficial features for industry is the support for **automatically translating standard data fields to other languages** and the submission of this information to the Member States where you place your hazardous mixtures on the market.

The new functionalities will enable Member States to access the information from the notifications through the EU portal. All use of this central system is free of charge.

The launch of the portal in the beginning of 2019 is only the first step. A series of extended versions of the portal are being planned and could include more features such as:

- functionalities for national authorities to search, retrieve and view the notifications online;
- supporting the automatic verification of completeness of the incoming submissions;
- additional quality checks performed by appointed bodies;
- the possibility to annotate or flag potential issues found during the completeness and quality checks as well as recording the status of the review;
- aiding communication between national appointed bodies and submitting companies; and
- reporting capabilities on the notifications received.

ECHA has published an In brief publication with more details on the notification portal.

START PREPARING FOR THE SUBMISSION

The deadlines for submitting the information in the new harmonised format are:

- **1 January 2020** for mixtures for consumer use;
- **1 January 2021** for mixtures for professional use; and
- **1 January 2024** for mixtures for industrial use.

These deadlines might seem far away but preparing now is in no way too early.

Start by identifying the mixtures that require submission, i.e. those that are affected by Annex VIII and the use of those mixtures. Are they for consumer, professional or industrial use? This will determine your deadline. If they are for

IMPACT OF THE PORTAL

We asked **BASF**, one of the large chemical producers, what impact the new portal would have for industry.

"Having a central notification portal with these features is definitely a strength in our view. It is valuable that we will now have a one-stop solution for the notification to all Member States in all the EU languages with automated features. It will definitely make life easier for industry," says *Ingolf Kuehn* from BASF.

Also **CEPE**, the European Association of paints formulators, sees advantages for industry.

"We fully support the establishment of a central notification portal for Europe, which will facilitate compliance with the requirements for almost all companies. We urge all Member States to accept submissions through this portal, whether as the sole route or as an option in parallel to a national portal," says *Janice Robinson*, Director for Product Regulations.

"Refusal to accept central submissions would increase the administrative burden for a significant number of duty holders and have a negative impact on the implementation of Annex VIII," she adds referring to the Annex of the REACH Regulation on harmonised information relating to emergency health response.

PORTAL HIGHLIGHTS

- User-friendly interface
- Multilingual – submit in your own language!
- Automatically supports multimarket submissions
- Guidance and easy-to-follow step-by-step instructions
- Your data is handled securely, in line with other ECHA systems
- All use of the ECHA portal is free of charge, although some Member States may choose to levy charges at national level

industrial use only, you can submit less information provided there is a contact number for rapid access to more information in the event of an emergency.

You could also get to know the new EuPCS, which defines mixtures according to their intended uses; a product category will have to be allocated to each of your mixtures when submitting information.

If you have an IT provider that supports you, you should also contact them and consider the necessary next steps.

ECHA has updated the Poison Centres website with new pages on how to prepare for industry. If you have any questions, you can contact ECHA using the contact form.

Further information:

Poison Centres website
https://poisoncentres.echa.europa.eu

Poison Centres Notification (PCN) Portal In brief
https://poisoncentres.echa.europa.eu/documents/22284544/22295820/prepare_and_submit_information_to_pc_en.pdf/a69d2287-8a90-0265-26dd-8a481f7fc2f4

Unique Formula Identifier (UFI) animation
https://www.youtube.com/watch?v=BkhjqpTyc_w&feature=youtu.be

Harmonised Poison Centres Notification (PCN) format
https://poisoncentres.echa.europa.eu/poison-centres-notification-format

Steps for industry
https://poisoncentres.echa.europa.eu/steps-for-industry

National helpdesks web page
https://echa.europa.eu/support/helpdesks

ECHA's contact form
https://echa.europa.eu/contact

New guidelines to improve your export notifications

INTERVIEW BY HANNA-KAISA TORKKELI

ECHA is publishing guidelines for EU-based companies that export hazardous chemicals to countries outside the EU under the Prior Informed Consent (PIC) Regulation, to help them improve the quality of their export notifications.

These guidelines specifically focus on prohibited and allowed uses of exported substances in the EU, which companies have to include in **Section 6.2 of their export notification** in the IT tool ePIC.

Authorities in non-EU countries rely a lot on the information provided in this section of the export notifications when deciding whether or not to allow a certain import. Complete and accurate information about these uses gives non-EU authorities in the receiving countries a clearer and more comprehensive picture of how these substances are used in the EU. This information is valuable as the EU is considered to be a reliable source of information.

"Our experience has shown that many companies fail to report the prohibited and allowed uses correctly. They seem to be unaware of the regulatory measures concerning their substances and, for example, put the use for which they are exporting the product as allowed – although it might not be in the EU. Currently, we are requesting approximately 17 % of the export notifications to be resubmitted due to errors in this field, which means that on a yearly basis we handle around **8 000 export notifications**, of which **1 350 need to be resubmitted**. This is not sustainable for the companies, ECHA or the designated national authorities," says *Chiara Macchi*, ECHA's PIC team leader.

The Agency now aims to help companies with their notifications by providing clarity on what the section is about, on how it should be used and, where possible, practical examples on how to fill in the relevant section correctly.

Better notifications will save exporting companies time, as requests to resubmit will be less likely, and will also reduce ECHA's administrative burden.

"Another result is that countries to which the substances are imported will get reliable information to enable them to make sound decisions on imports. After all, the aim of PIC is to share information on hazardous chemicals between countries and promote shared responsibility and cooperation in international trade," says Ms Macchi.

FIVE TOP TIPS

The guidelines will be published in early October on ECHA's website. However, we already want to share five top tips for completing Section 6.2 of the export notification:

1. Section 6 refers to the regulatory situation (including the allowed and prohibited uses) in the EU and not in the country of destination of the export.

2. The information provided should be clear, to the point and not misleading.

3 When exporting a mixture, the information provided must refer to the PIC substance it contains and not to the mixture as a whole (or to other non-PIC components in the mixture).

4 If a reference to a legal text is provided, it must be correct and complete to allow the recipient to identify the source document. For example, if a substance is subject to PIC because it has been restricted under REACH, a complete reference to the REACH restriction (including the entry number) should be provided.

5 If specific uses are provided, they should be relevant in the context of the PIC Regulation – for example, stating that a certain PIC chemical is banned for military use is not considered relevant in the context of the PIC Regulation, which specifically deals with industrial chemicals, plant protection products and biocides.

ECHA TO IMPROVE THE REGULATORY SUMMARIES IN THE EXPORT NOTIFICATIONS

In addition to working on the guidelines, ECHA is currently improving **Section 6.1 on the summary of the final regulatory action** and ensuring that all translations are in place. This section summarises how the exported substance is regulated in the EU.

These summaries are automatically inserted in export notifications in English, Spanish or French, depending which language is the most relevant in the country to which the substance is being exported.

For example, if you are notifying an export of ferbam to Paraguay, the text highlights the EU legislation that regulates the use of ferbam in Spanish. The improved summaries are already in place for approximately 50 entries (starting with the most exported substances) and the rest will be finalised by ECHA in the coming months.


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The guidelines focus on the prohibited and allowed uses of exported substances in the EU. Authorities in non-EU countries rely on this information when making their decisions on whether or not to allow a certain import.

DID YOU KNOW?

A **new amendment to the PIC Regulation** is expected before the end of the year. Substances will be added to **Annex I** and will be subject to the export notification and to the explicit consent procedure to be exported. The added substances are those that are included in the REACH Authorisation List and substances not approved under either the Plant Protection Products Regulation or the Biocidal Products Regulation.

In addition, the **list of chemicals and articles which are banned in the EU and should not be exported (Annex V)** will be updated with the next amendment. Developments under the Stockholm Convention on **persistent organic pollutants (POPs)** and to the **POPs Regulation** will be taken into account and the amendment will also reflect the recent changes introduced by the **EU regulation on mercury**. Once the amendment enters into force, ePIC will also be upgraded to enable exporters to comply with their obligations in relation to the export of certain mercury compounds.

The update will keep the existing total export ban on metallic mercury and make the export of more mercury compounds subject to specific conditions.

Further information:

Export notification procedure
https://echa.europa.eu/regulations/prior-informed-consent/export-notification-procedure

List of chemicals subject to PIC
https://echa.europa.eu/information-on-chemicals/pic/chemicals

ePIC
https://echa.europa.eu/support/dossier-submission-tools/epic

EU Regulation on mercury
http://ec.europa.eu/environment/chemicals/mercury/regulation_en.htm

Help with terminology – in your language
https://echa-term.echa.europa.eu

Making sports pitches and playgrounds safer

TEXT BY PAUL TROUTH

In July 2018, the Netherlands submitted a proposal to ECHA recommending to lower the legal concentration limits under REACH for eight polycyclic aromatic hydrocarbons (PAHs) found in granules and mulches. These granules and mulches are commonly used on sports pitches and in playgrounds, but there is a concern that they contain chemicals (such as PAHs) that may cause health risks. Let's take a deeper look at what is being proposed and the implications of restricting the PAHs.

A SHORT RECAP

ECHA first looked at this topic back in 2017 and, at that point, found that the health concerns of the granules used on pitches were very low due to the small concentrations of concerning chemicals measured, including metals, plasticisers and PAHs.

However, our report also mentioned some uncertainties. For instance, there was a general concern over whether the studies used were representative for the whole of Europe given that samples were not taken from all Member States.

Due to these reservations, we suggested a number of actions that could be taken, including whether a restriction should be considered under REACH so that the granules could only be supplied with very low concentrations of PAHs and other relevant hazardous substances.

These findings were sent to the European Commission on 28 February 2017.

WHAT IS BEING DONE TO ADDRESS THE UNCERTAINTIES?

At the same time, the **Dutch National Institute for Public Health and Environment (RIVM)** also published a study on the health risks of rubber granules in use in the Netherlands. RIVM's findings echoed those of ECHA's report, stating that playing sports on these pitches was safe.

However, the Dutch study also reiterated the uncertainties mentioned in ECHA's report and recommended to lower the concentration limits of PAHs in granules to protect the health of those who come into contact with them.

On 30 June 2017, RIVM followed this suggestion up by announcing its intention to prepare a proposal to **restrict eight PAHs** used in granules and mulches in synthetic turf pitches, at sports facilities and on playgrounds. The proposal was submitted to ECHA on 20 July 2018 and was made publicly available on **16 August 2018**.

WHAT DOES THE RESTRICTION PROPOSE?

The Netherlands' proposal looks at the health risks for **footballers (including goalkeepers)**, **children** playing on the pitches or at playgrounds, and **workers** installing and maintaining such surfaces.

The eight PAHs restricted in granules and mulches are known or presumed to cause cancer in humans. They have a harmonised classification as carcinogenic (category 1B) under the CLP Regulation.

The proposal outlines that the currently permitted concentration levels – **100 mg/kg** for two PAHs (BaP and DBAhA) and **1 000 mg/kg** for the other six – in entry 28 of Annex XVII of REACH makes it difficult to ensure that health risks are controlled.

GRANULES AND MULCHES

Artificial playing surfaces often use granules as infill to make the pitches more durable, weatherproof and to add shock absorption and traction.

Playground surfaces also often use loose granules and mulches underneath swings, slides and other playground equipment to cushion the ground if a child falls.

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Granules and mulches are often used on sports pitches and playground surfaces, but there is a concern that they contain chemicals (such as PAHs) that may cause health risks.

These limits are seen as not protective enough, as the excess cancer risk following lifelong exposure to the granules would be too high.

Therefore, RIVM is proposing to restrict the placing on the market and use of granules or mulches that contain a combined concentration for the eight carcinogenic PAHs of more than **17 mg/kg**.

WHY IS THE RESTRICTION BEING PROPOSED?

In the Netherland's view, reducing the concentration limit for the eight PAHs will be an affordable and proportionate measure for society as it will ensure that:

- **too high PAH concentrations and their risks will be avoided** for those who come into contact with the granules during sport or play;
- **societal concern related to human health effects may reduce** over a 10-year period as high PAH concentrations are avoided;
- **no major administrative burdens on public authorities** in terms of cost for implementation, monitoring, inspection and enforcement are expected; and
- **costs to society will be affordable** and relatively limited.

WHAT ARE THE NEXT STEPS?

ECHA's committees are checking the conformity of RIVM's proposal and a public consultation is expected to begin later in September 2018.

If you are an interested party, you will have six months from that date to comment on the proposed restriction and its anticipated impacts. **Have your say!**

ECHA committees will evaluate the dossier and formulate their opinions. ECHA's Committee for Risk Assessment (RAC) will adopt its opinion in July 2019.

DID YOU KNOW?

Granules (often made from rubber) used as infill material for sports pitches are mainly made from scrap end-of-life tyres. These are broken up and ground down to form the granules. The granules are used on synthetic sports pitches to make them more durable, weather-proof and last longer. They also add shock absorption and traction.

Rubber **mulches** are also predominantly produced from end-of-life tyre buffings and nuggets and have a wide range of uses in the EU. It is believed that about 60 % of rubber mulch ends up being used in playgrounds, but it is also used in landscaping, gardens, golf courses, horse arena footings and athletic arenas.

The Committee for Socio-economic Analysis (SEAC) will give its expert opinion on the proposal by September 2019, taking into account the submitted information.

The opinions of both committees will be submitted to the European Commission. The final decision is to be taken in a comitology procedure with scrutiny involving the Member States and the European Parliament.

ECHA will continue to look at the health impacts of other substances contained in the granules and mulches derived from end-of-life tyres (ELTs).

There may also be further investigations into environmental effects, too.

This is expected to lead to the publication of an intention to restrict other substances in ELTs in early 2019.

Further information:

Are artificial football pitches safe?
https://chemicalsinourlife.echa.europa.eu/are-artificial-football-pitches-safe

Hot topics: granules and mulches on sports pitches and playgrounds
https://echa.europa.eu/hot-topics/granules-mulches-on-pitches-playgrounds

SUBSTANCE	CAS NUMBER
Benzo[a]pyrene (BaP)	50-32-8
Benzo[e]pyrene (BeP)	192-97-2
Benzo[a]anthracene (BaA)	56-55-3
Chrysen (CHR)	218-01-9
Benzo[b]fluoranthene (BbFA)	205-99-2
Benzo[j]fluoranthene (BjFA)	205-82-3
Benzo[k]fluoranthene (BkFA)	207-08-9
Dibenzo[a,h]anthracene (DBAhA)	53-70-3

The proposal suggests to limit the combined concentration limit for the eight PAHs to 17 mg/kg. The current limits are 100 mg/kg for BaP and DBAhA, and 1 000 mg/kg for the other six.

Why Union authorisation?

INTERVIEWS BY VEERA SAARI

Union authorisation was introduced by the EU's Biocidal Products Regulation in 2013. It allows companies to place their biocidal products on the entire EU market, without needing to get specific national authorisations. The first biocidal products are now expected to be granted access to the EU market. We talked with *Isabelle Demoment* from Kersia Group and *Gosia Oledzka* from Ecolab, which were among the first companies to opt for Union authorisation.

HARMONISED ASSESSMENT IN ALL EU COUNTRIES

While national authorisations are managed by Member States independently, **Union authorisation** is managed by ECHA and the final decision comes from the EU countries and the European Commission.

According to Ms Oledzka, **harmonisation** and **predictability** are the two main reasons why Ecolab applied for Union authorisation.

"We have always been in favour of the harmonisation that Union authorisation brings – since the beginning, when the regulation was being drafted. Not only does it streamline the evaluation of the application, but it also ensures that each Member State can comment on the application and influence the outcome," says Ms Oledzka.

Ms Demoment agrees: "When you make just one unique application that covers all EU countries, the process is easier to manage," she says. "My team came to the conclusion that Union authorisation would decrease our workload. It also gave us an opportunity to explain our product to all of the authorities in one go rather than going through the same things with several Member States."

Having one central contact point can also simplify the coordination. "We believe that bringing ECHA into the process helps keep deadlines on track, which is critical for any biocidal product formulator," Ms Oledzka tells.

She also believes that Union authorisation helps to bring consistency to customers. "We can now offer veterinary hygiene products evaluated by all EU biocidal experts. The end result is one product label with one clear message for the end user. In our case, a French farmer would see the same product label as a farmer in Spain," she explains.

MORE ECONOMICAL FOR MULTINATIONAL MARKETS

If your product is available in one Member State only, it is clear that a national authorisation is the best way forward. But when you want access to several markets in the EU, it is worth investing some time to decide whether to go for Union authorisation or to expand a national authorisation to other countries (this is called **mutual recognition**). For this, doing a thorough analysis of the fee costs is crucial.

"As we wanted to market our product in at least 15 EU countries, we thoroughly analysed the costs and concluded that Union authorisation would be less costly for us than the mutual recognition process. Generally speaking, if you are placing your product on the market in 10 or more countries, Union authorisation is likely to be more economical for you," Ms Demoment says.

"How a company chooses their authorisation path is always an individual decision based on their business strategy. By definition, Union authorisation opens access to the whole EU market. Before pursuing it, consider the number of Member States you wish to market your product in – and also think about whether this may expand in the future," Ms Oledzka adds.

CLOSE DIALOGUE WITH AUTHORITIES

The key to a successful application is close cooperation with authorities.

1 The first step is **deciding which Member State authority you want to ask to evaluate your application**. "We chose the Netherlands because of their vast experience in evaluating biocides dossiers," Ms Demoment explains.

WHEN TO APPLY

For biocidal products containing **new** active substances, you can submit your application for Union authorisation at any time.

For biocidal products containing **existing** active substances, the timelines are the same for all biocidal product authorisations: you can apply once the active substance in your product has been approved. You are usually given two years to do this.

You can check the upcoming deadlines for 2018 and 2019 on ECHA's website.

"Working very closely with the selected evaluating authority is crucial and therefore it is good to work with one that is active and has a high level of competence in this field," she expands.

2 The second step is **establishing a dialogue with the evaluating authority** to build the foundation of the dossier. "Once you have the base, you start gathering scientific data and arguments to support your case. It's a long process involving many different disciplines. Besides consultants, we were a team of five or six, representing different fields, from regulatory and research and development to microbiology and marketing," Ms Oledzka explains.

Ms Demoment stresses the importance of understanding the latest scientific discussions. "Make sure you follow the developments and always have the latest guidance in hand, as guidance is never final but keeps evolving. For example, the EU's scientific criteria to identify endocrine disruptors under biocides was only adopted in 2017 – just when we were at the end of our authorisation process. We are now preparing for how this might affect us."

3 The third step is the first discussion at the working groups of the **Biocidal Products Committee (BPC)**.


© ISABELLE DEMOMENT


© GOSIA OLEDZKA

From left: Isabelle Demoment and Gosia Oledzka.

"You only know if what you have submitted is sufficient once the working groups have positively concluded on your application," Ms Oledzka highlights. "The fact that experts from each Member State take part in the discussion makes the evaluation more harmonised. In some cases, though, you may be faced with new or emerging guidance or requirements which were not in place when you started your preparations. It is a continuous learning exercise."

4 The fourth step is the **final BPC conclusion on the application** and whether it is supported by the committee. The final decision is taken by the European Commission and Member States.


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Union authorisation allows companies to place their biocidal products on the entire EU market, without needing to get specific national authorisations.

Support from ECHA is available throughout each step. "You can contact ECHA and they will remind you about upcoming deadlines. Most of the communication is done through the biocides IT tool R4BP 3," Ms Oledzka says.

In Kersia Group's case, the company was assigned a coach from ECHA who supported them throughout the task. "This was extremely helpful to us, as we were all new to the process," Ms Demoment confirms.

NEW INNOVATIONS WITH A PRODUCT FAMILY

With a product family, products can be grouped into the same Union authorisation application if the difference in their composition is limited.

For example, both Kersia Group and Ecolab applied for Union authorisation for a veterinary hygiene product family where all the products contain the same active substance.

Ms Demoment says that the product family approach can help a company to innovate and launch new products easily. "In one application, you can manage a family of similar products. The products can then be adapted to suit the needs of different markets, for example, you can create different formulations for different markets, or launch a new

formulation on one market. In this way, Union authorisation combined with a product family supports new innovations."

BIGGEST CHALLENGES: TIMELINES AND FEES

Reaching audiences in different markets also requires reaching them in different languages. Both companies highlight the translation of their product information as a challenging step mainly due to the **timelines involved**.

"We found the translation of the **summary of product characteristics (SPC)** to be a big hurdle," Ms Oledzka says. "After ECHA's Biocidal Products Committee gave its opinion, we only had five days to provide all the translations in 23 EU languages. This is challenging because, even if all the translations have already been done beforehand, the committee may change some wording. Creating the documents in XML format and correcting them in 23 languages is a time-consuming exercise and extending this deadline would be helpful," she suggests.

Fees are another issue that both companies highlight as a challenge. "This is a big investment for a company and requires lots of resources," Ms Demoment stresses.

"I believe that if the fees were lower, Union authorisation would be taken up more by companies," she concludes.

Kersia Group combines Hypred, Antigerm, Medentech, LCB, G3 and KILCO, which develop products, solutions and services for water purification and biosecurity in farming and food processing.
https://www.kersia-group.com

Ecolab provides water, hygiene and energy technologies and services to customers in over 170 countries.
https://www.ecolab.com

TIPS FOR UNION AUTHORISATION

1. **Calculate the costs**
If you market your product in several EU countries, see whether Union authorisation is cheaper than applying for authorisation in several countries. Consider the whole production lifecycle – not only the initial application.

2. **Plan your application**
The whole process may take up to six years. Preparing your application takes two to three years.

3. **Work closely with your evaluating authority**
Organise a discussion with your evaluating authority, ECHA and the European Commission at the start to make sure you are eligible and to clarify any specific questions.

4. **Ensure the right expertise**
Applying requires expertise on the process as well as in specific areas, such as risk evaluation and efficacy.

5. **Follow newest guidance**
Guidance is updated regularly to reflect the latest knowledge in the field. Always make sure you have the latest advice at hand – even if it is just a draft update.

6. **Follow regulatory discussion**
Follow ECHA's news to make sure you are in the know about any new developments in regulatory practice.
http://analytics-eu.clickdimensions.com/cn/ag2hn/subscribe

7. **Consider a product family approach**
Products can be grouped in the same Union authorisation if the difference in their composition remains limited. With a Union authorisation, the products can be adapted to suit different EU countries.

8. **Launch your product in new markets**
Once you have a Union authorisation, you can launch your product in any EU country with a simple notification to ECHA or the European Commission.

Further information:

Union authorisation
https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation

Union authorisation deadlines
https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation/deadlines-union-authorisation-applications/2018

Product family
https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation/product-family

Practical guide on Union authorisation
https://echa.europa.eu/documents/10162/21742587/pg_on_bpr_9_union_authorisation_en.pdf/93fedd6e-cb7d-4af3-a3aa-fca60c804a8c

Are the new REACH information requirements for nanos relevant for you?

INTERVIEW BY ADAM ELWAN

Despite increasing amounts of nanomaterials in products on the EU market, not enough is known about their hazards to adequately assess and control their risks. To bridge this knowledge gap, the REACH annexes that specify what information is required from companies placing chemicals on the market have been revised, legally obliging industry to also provide data for substances in nanoform. If adopted, the new changes will enter into force in January 2020. *Jenny Holmqvist*, ECHA's coordinator for nanomaterials, shares her views on how companies can prepare.

WHAT DO THE REVISED ANNEXES CHANGE?

The implementation of REACH for nanomaterials has been challenging. This is because there is a general lack of information on the hazards of most nanomaterials as well as uncertainties on the applicability of test methods currently used to assess their properties. There have also been differing opinions relating to the legal aspects of how information requirements should be fulfilled by industry and what exactly should be considered when carrying out a hazard assessment. These have related to, for example, how nanomaterials or nanoforms should be characterised under REACH.

The revised REACH annexes clarify the existing information requirements and introduce some new ones for companies registering nanoforms of their substances. By making the requirements explicit, imlementing REACH will be easier and more efficient. Over time, these changes will also contribute to increasing knowledge on the hazards and risks of nanoforms of substances on the EU market.

A better understanding of the safety of nanomaterials will benefit consumers and workers, but will also help regulators identify whether further risk management measures are needed for specific uses or substances.

WHO DO THE CHANGES IMPACT?

The changes are relevant for companies manufacturing or importing nanoforms of substances that fall within the scope of REACH. Nanoforms of substances are those covered by the European Commission's recommendation for a definition of a nanomaterial.

It is important to point out that each nanomaterial can also exist in multiple forms depending on, for example, deliberate changes made to the surface of the particle.

Due to the various ways in which particles can be manipulated and thereby also characterised, I recommend that if you manufacture or import small particles, familiarise yourself, at the earliest opportunity, with the introduced changes to assess whether they are relevant for your substances.

WHEN WILL THE NEW ANNEXES COME INTO FORCE?

The draft Commission Regulation amending the annexes has not yet been formally adopted by the Commission. If adopted, industry will need to comply with the new requirements by **January 2020**. This might seem far away but this transitional period is needed for companies to not only assess if the changes apply to their substances, but also to conduct any necessary testing and further assessment.

Jenny Holmqvist.

WHAT IS ECHA DOING TO HELP COMPANIES PREPARE?

The positive vote among Member States in April 2018 to amend the annexes was also the starting point for us here at ECHA to prepare the necessary guidance to explain the changes to companies.

We are currently looking at which parts of the existing guidance need to be updated or whether new guidance is needed. A significant part of this work is based on updated guidance that was already published in spring 2017.

Preparing guidance requires a significant amount of consultation where Member States, NGOs and industry are able to contribute. This is, and has been, an important way of working for us to ensure the developed guidance is balanced and based on the collective knowledge of all relevant parties.

We also plan to increase our efforts in reaching out to industry organisations both in bilateral meetings and also through our guidance process.

DID YOU KNOW?

Guidance is already available on registering substances in nanoform to help you prepare for the revised information requirements:

- Practical guide: How to prepare registration dossiers that cover nanoforms
  https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/f8c046ec-f60b-4349-492b-e915fd9e3ca0
- Guidance on grouping and read-across between nanoforms
  https://echa.europa.eu/documents/10162/23036412/appendix_r6_nanomaterials_en.pdf
- Nano-specific appendices to the guidance on information requirements and chemicals safety assessment
  https://echa.europa.eu/-/reach-guidance-for-nanomaterials-published

This way, we hope to ensure that there is sufficient support available for companies that are preparing possible updates to their registration dossiers.

ARE THERE TEST METHODS ALREADY AVAILABLE TO COMPLY WITH THE AMENDED INFORMATION REQUIREMENTS?

Thanks to significant efforts in the research community, we know a lot more today about how to assess the risks of nanoforms of substances, than we did 10 years ago.

Based on several research projects, many of which have been funded by the EU, we have also increased our knowledge of how some of the commonly used OECD test methods should be amended to better address the specificities of nanoforms.

The actual revision of these methods is not yet finalised. However, thanks to close collaboration among EU Member States, I expect this important work to speed up.

I would also like to stress that even though this work is ongoing, there are recognised protocols available for the vast majority of the amended requirements to help registrants comply with their legal obligations.

An important sign of progress took place in 2017 with the publication of the updated version of the test method for assessing inhalation toxicity, which is particularly relevant for nanoforms of substances.

DO THE NEW INFORMATION REQUIREMENTS IMPLY THAT NANOMATERIALS THAT ARE CURRENTLY ON THE EU MARKET ARE UNSAFE?

Already in 2012, as part of their second regulatory review of nanomaterials, the European Commission wrote that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures.

However, without changing the legal information requirements, it would be very difficult for authorities to verify whether companies registering their chemicals have demonstrated the safe use of nanomaterials throughout the supply chain or whether further regulatory actions for managing their risks would be needed.

I want to emphasise the word **verify**. I think we all agree that the realisation of the great opportunities that nanotechnology and nanomaterials may offer society should go hand-in-hand with the transparent demonstration by industry of their safety and sustainability.

"The realisation of the great opportunities that nanotechnology and nanomaterials may offer society should go hand-in-hand with the transparent demonstration by industry of their safety and sustainability."

Against this background, I welcome the amendments of the annexes and the legal clarifications they bring.

Further information:

European Union Observatory for Nanomaterials (EUON)
https://euon.echa.europa.eu

ECHA's page on nanomaterials
https://echa.europa.eu/regulations/nanomaterials

ECHA's strategy on substances in nanoforms
https://echa.europa.eu/documents/10162/2792271/mb_57_2017_echa_strategy_nanoforms_en.pdf/f913484f-9a21-02bc-d386-8cb68d0027a4

European Commission: Amendments of the Annexes to REACH for registration of nanomaterials
https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011_en

European Commission: Definition of a nanomaterial
http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm

Nanomaterials in our daily lives
https://euon.echa.europa.eu/uses

The use of nanomaterials at the workplace
https://euon.echa.europa.eu/the-use-of-nanomaterials-at-the-workplace

Guest column | The Anhydrides Joint Industry Taskforce

An example of good supply chain communication

Implementing REACH requires a lot of communication within the supply chain, which is not always practical due to the legitimate business concerns of different parties.

LEGITIMATE BUSINESS CONCERNS

One such concern is the **spread of proprietary knowledge**. When downstream users need to give their suppliers a process description, it is not necessarily in their interest to provide in-depth details on how the substance is used. As the commercial interest of substance producers is to supply as much as possible, they could decide to release this process description to the downstream user's competitors. The interests of manufacturers and downstream users are then not always fully aligned.

Geoffroy Tillieux.

On the other hand, downstream users are getting more familiar with REACH and are realising how vital it is for registrants to have a detailed process description, to show how a substance can be used safely and avoid regulatory risk management measures. Another issue is that SMEs may generally have a **limited knowledge** on European chemicals legislation. Although frequently stated to be a poor excuse for non-compliance, this is actually an issue that deserves more attention. These matters can have significant consequences for companies, especially when critical substances enter certain REACH processes (e.g. authorisation).

Companies that do not communicate their use in enough detail may find that registrants are unable to produce a detailed enough risk assessment to convince authorities of the need for an exemption in a restriction procedure. Businesses, especially SMEs, could find themselves overwhelmed by an authorisation requirement that they could have seen coming years in advance if they had sufficient knowledge about REACH.

WORKING TOGETHER TOWARDS A SOLUTION

There is great potential for industry associations to contribute, both in communicating use descriptions and disseminating knowledge. The associations can bundle resources and better understand the detail needed by their members to help fulfil their obligations.

One such initiative by producers, formulators and end users is the **Anhydrides Joint Industry Taskforce (AJIT)**, founded in December 2015.

The purpose of AJIT is to:

- **gather information** on current exposure levels and risks associated with anhydrides and propose protective measures;
- **evaluate socio-economic impacts** of an authorisation; and
- **inform authorities of possible risk management options** for the use of anhydrides.

Hexahydrophthalic anhydride (HHPA) and **methylhexahydrophthalic anhydride (MHHPA)** are respiratory sensitisers and have been identified as substances of very high concern (SVHCs) that may be subject to authorisation in the future. It is therefore critical for their use to be well documented in the registration dossier and that end users are well informed about the procedure.

AJIT identified two epoxy uses where the anhydride functions as a monomer in a polymerisation reaction to produce articles (electrical insulation): high voltage rotative devices (i.e. motors and generators) and switch gears. The use of those substances is strategic to ensure continued power generation and distribution in Europe as well as enabling transport of people and goods. Their use is a result of improving costs, performance and durability over the last decades. There are currently no satisfactory substitutes, as products do not reach the required durability for outdoor use or an adequate electrical performance. One of AJIT's first actions was to reach out to all epoxy users of HHPA and MHHPA.

AJIT's immediate task was to respond to a public consultation. Within months, it had collected all available information from public sources and member companies on the use of the substances, as well as exposure information, any known cases of adverse health effects and socio-economic information. These were submitted in a public consultation report.

Since then, AJIT has developed an outreach programme whereby any interested company can join a two-hour webinar where the regulatory process is explained, the current status of the anhydrides is clarified and questions are answered by an expert. Furthermore, under the guidance of **Polymer Comply Europe**, the service company of the European Plastics Converters Trade Association, which provides the secretariat, coordination and supervision of the scientific and outreach activities to AJIT, working groups of experts in the epoxy use of anhydrides were set up.

Using ECHA's use descriptor system, they produced detailed process descriptions of their uses. These have been provided to registrants, who have been incorporating them into their registration dossiers.

Additionally, all AJIT members have:

- voluntarily committed to **measure exposure** related to the different process steps and formulate exposure minimisation measures based on continuous improvement;
- **developed a medical diagnostic guideline** for early detection of any adverse health effects related to the use of the substances;
- created a **training programme for workers** on how to work with anhydrides; and
- reported on the progress of the **Voluntary Commitment implementation** in a transparent manner in an annual progress report.

Many companies using anhydrides operate in the electrical industry and perceive the work of AJIT as an eye opener, not just to their duties, but also to the strategic objectives that REACH aims to fulfil. As specialists from the electrical industry were mostly familiar with other pieces of EU legislation, they saw developments under REACH as a threat to fulfilling the strategic objectives of resource efficient power generation and distribution. More specifically, the eco-design directive that mentions that electrical equipment used to generate, distribute and use electricity should be as efficient as possible – which would be a challenge without HHPA and MHHPA as they are used to produce material with superior electrical insulation properties and essential for generators, switch gears and motors. These experts nevertheless realise that the targets under REACH are valid aspirations set by the EU and they are committed to both strategic EU objectives: ensuring the highest levels of energy efficiency while protecting health and the environment.

Geoffroy Tillieux is the Director of Regulatory Compliance at Polymer Comply Europe SCRL (PCE). He has been working for the European Plastics Converters Association since 2000 and at PCE since 2005. He coordinates plastics and raw materials issues including recycled materials, food contact issues and development of compliance tools, risk assessments and consortia related to implementing REACH.

The Anhydrides Joint Industry Taskforce (AJIT) represents producers, importers, formulators, and end users of the anhydrides HHPA and MHHPA. These anhydrides may fall under authorisation in the future.

http://anhydrides.eu

Stepping up to a challenge: increasing chemicals safety in developing countries

INTERVIEW BY MARJAANA LINDY

The Strategic Approach to International Chemicals Management (SAICM) aims to ensure the sound management of chemicals worldwide so that, by 2020, chemicals will be produced and used in ways that minimise adverse impacts on the environment and human health. We spoke to *Mr Jacob Duer*, Chief of the Chemicals and Health Branch of UN Environment, to ask how SAICM's ambitions can be achieved and what challenges developing countries face when setting up chemicals management systems.

Jacob Duer.

SETTING BROAD OBJECTIVES

SAICM comes to an end in 2020. The approach has set very ambitious goals for chemicals management and although these may not be fully met, many of them will be to an extent. These include:

- reducing risk;
- spreading knowledge and information on chemicals safety;
- creating good governance;
- building capacity and technical cooperation; and
- preventing illegal international traffic in toxic and dangerous goods.

"These broad goals have required sustained efforts from many of the strategic approach's stakeholders. I believe there are many lessons to be learnt from how SAICM has implemented its objectives and formulated indicators to monitor progress. Of course, developing safer chemicals management systems is an ongoing process and stakeholders will define a new policy approach from 2020 onwards that will carry on from the work already done under SAICM," Mr Duer tells.

HAVING THE FORESIGHT TO IDENTIFY EMERGING POLICY ISSUES

SAICM has proven successful in identifying future policy issues. So far, resolutions have been adopted for **eight emerging policy issues**, including nanomaterials, lead in paint, chemicals in products and pharmaceutical pollutants, to mention a few.

"By recognising the emerging issues, the strategic approach has been able to set specific targets. One such issue, where our chances of making legislative change are probably highest, is tackling lead in paint," Mr Duer says.

Lead is still used in paint sold in developing countries, even though safer alternatives have been available for decades. Lead exposure has been estimated to contribute to 600 000 new cases of children with intellectual disabilities every year.

"Consumers in developing countries might not even know that lead in paint is hazardous, so raising their awareness is crucial," Mr Duer highlights.

To address this, the United Nations Environment Programme (UNEP) and the World Health Organisation (WHO) have established the **Global Alliance to Eliminate Lead Paint**, which aims to safeguard the health of children and to minimise occupational exposures to lead-based paints.

ADDRESSING HAZARDOUS SUBSTANCES IS A POVERTY ISSUE

A key concern for SAICM has been how to set up legislation in developing countries that may not have governmental institutional infrastructures in place.

In addition, chemicals safety is secondary to economic growth in many countries and its link to environmental burden is not fully understood or recognised. Joint efforts on a global level have developed tools to help developing countries gain a better understanding of the costs of inaction and how to build necessary governmental structures to support the development and implementation of legal frameworks.

Addressing hazardous substances is a poverty issue. In predominantly agricultural communities, women may be the main users of chemical products both at home and work. In developing countries, it is often women who spray pesticides in fields and often they do so with little or no safety equipment.

However, where chemicals safety is not the main priority, it still remains a challenge. The situation is complex and often coupled with efforts to reduce poverty and satisfy the basic needs of citizens.

"It is a challenge to get chemicals safety on the political agenda, but more than that, in countries where the levels of education and literacy can be low, raising awareness on how to use chemicals safely can be an uphill struggle. In these settings, with many other matters to address, thinking of sound chemicals management can sound like a luxury, although the reality is that sound management of chemicals is critical to achieving the Sustainable Development Goals under the 2030 development agenda," Mr Duer tells.

But bringing discussions on the regulatory aspects of chemicals management out into the open remains important. "When you address hazardous substances in products, you also address poverty issues. Sound chemicals management promotes economic and social development. It brings benefits to society and aims to ensure that these benefits do not cause an extremely high cost," he adds.

GENDER ALSO HAS TO BE CONSIDERED

It is also critical to consider gender roles when formulating approaches toward safer chemicals management. For example, in predominantly agricultural communities, women may be the main users of chemical products, both at home and at work. They are also more susceptible to negative health effects caused by exposure to harmful chemicals, especially during pregnancy.

"In developing countries, it is often women who toil in the fields, spraying pesticides, sometimes even while carrying their babies on their backs," Mr Duer describes.

"At home, they might work in small-scale mining, using mercury to extract gold from its ore, and later use the same utensils to cook food for their families. This is why educating women is one way to improve safety across the whole of the society they live in," he adds.

DID YOU KNOW?

Have you ever thought about the difficulties facing many developing countries that are using synthetic pesticides? For example, in some countries in Africa, pesticides are one of the primary causes of damage to the health of people living in rural populations. Those communities living and working with pesticides in poor rural areas are at greatest risk from negative health effects from these chemicals. These risks are made worse by the circumstances of their relative poverty, lack of effective regulation systems, illiteracy and limited availability of appropriate information and training.

With funding from the **Quick Start Programme Trust Fund**, the Pesticide Action Network (PAN) Africa has implemented a number of activities with local communities and civil society organisations in Mali and Senegal, building awareness and capacity to reduce risks related to pesticide use in the agricultural sector, as well as managing data on pesticide use and chemical exposure incidents.

http://www.saicm.org/QuickStartProgramme/QSPStories/tabid/5858/language/en-US/Default.aspx

QUICK START PROGRAMME – A SUCCESS STORY

One efficient way of improving chemicals safety at the national level has been SAICM's **Quick Start Programme (QSP)** and the various projects funded through it.

"We established the programme in 2006, initially as a seed funding from SAICM. Despite the programme now being phased out, its results have been impressive, especially given the low levels of funding, which funded projects up to USD 250 000. The programme was open to governments, intergovernmental organisations and civil society actors, which helped it stay flexible and focused on the specific areas where funding has been needed," Mr Duer says.

Successful projects include initiatives for pesticide monitoring in communities in Mali and Senegal, worker protection in the Dominican Republic, and awareness raising about **substances of very high concern (SVHCs)** in products in Serbia. To date, 184 projects have been carried out in 108 countries.

In 2015, a Special Programme to support national institutional strengthening in the chemicals and waste cluster was established by the UN Environment Assembly. The programme, which is hosted by UN Environment, supports country-driven institutional strengthening at the national level so that developing countries can begin to manage their chemicals and waste programmes successfully.

"Due to its focus, the programme is only open to governments. This has caused some concerns for some, as obviously civil society would also like access to the funding to support countries," Mr Duer explains.

STRENGTHENING COOPERATIVE INTERNATIONAL ACTION

What more could institutions like ECHA do to strengthen their contributions on an international level?

Mr Duer has an answer: "ECHA is a repository of an incredible amount of information, and that is definitely something SAICM could benefit from," he explains. "At the moment, knowledge and information sharing is not happening to the extent SAICM would hope for."

SAICM has **Global Environment Facility (GEF) funding** to create a one-stop information platform bringing together data from various sources, including industry, NGOs and governments.

This is where Mr Duer believes ECHA can play a key role in ensuring that policymakers are aware of the information that is already available. "ECHA's position sometimes makes it difficult for it to join the right tables, but inviting ECHA experts to technical briefings and getting them into SAICM working groups is already a step in the right direction," he tells.

"In general, ECHA could contribute more to the international efforts by promoting a better understanding of REACH, explaining its elements in a simpler and clearer way, and showing why it has been such a success so that other areas can follow suit," Mr Duer concludes.

Further information:

Strategic Approach to International Chemicals Management (SAICM) website
http://www.saicm.org/Home/tabid/5410/language/en-US/Default.aspx

Implementing SAICM towards the achievement of the 2020 goal
http://www.saicm.org/StrategicApproach/Towardsnbsp2020/tabid/5499/language/en-US/Default.aspx

Global Alliance to Eliminate Lead Paint
https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/global-alliance-eliminate-lead-paint

Emerging policy issues
http://www.saicm.org/Implementation/EmergingPolicyIssues/tabid/5524/language/en-US/Default.aspx

Quick Start Programme Trust Fund poster
http://www.saicm.org/Portals/12/Images/QSPPoster.jpg

Tracking microplastics: from sewage sludge to the oceans

INTERVIEW BY PAUL TROUTH

Microplastics contaminating freshwaters and the oceans is one of the world's most pressing environmental concerns. It is estimated that 2 to 5 % of all plastics end up in the oceans. To learn more about the impact that microplastics have on our environment, we talked with *Dr Rachel Hurley*, a post-doctoral researcher based at the Norwegian Institute for Water Research (NIVA).

Rachel Hurley.

At wastewater treatment plants, wastewater is converted to water that can be reused. However, tiny pieces of microplastic debris (about the same size as a sesame seed or smaller) can pass through some of the physical, chemical and biological filtration systems in use at these plants. Although up to 99 % of pollutants can be trapped, there are some concerns over the efficiency of the treatments used to capture microplastics.

"Evidence seems to suggest that most microplastics are captured during primary and secondary treatment processes, but we need more research so that treatment plant processes can be tailored to capture more of the microplastics, and so the concentrations of microplastics discharged from the plants can be reduced," Dr Hurley tells.

FROM SEWAGE SLUDGE TO LAND

A proportion of the microplastic particles that evade the treatment plant's processes are added to sewage sludge – a by-product of the wastewater treatment processes. NIVA's study of microplastic content in sludge from eight treatment plants in Norway shows that there is variation in the concentrations of total microplastics and the composition of the contamination.

"We observed different particle types including beads, fragments, fibres and glitter composed of a wide range of polymers; however, polyethylene, polyethylene terephthalate, and polypropylene were the most common. It is likely that particle size, shape and density play an important role in determining the behaviour and potential risks of microplastic particles," Dr Hurley informs.

NIVA's researchers also revisited two treatment plants to check whether the microplastic content in the sludge remained stable over time or whether there were any variations. "In one treatment plant, the concentrations were steady. However, in the other, we noticed a significant difference in the amount of microplastic particles traced during each visit. This variability shows how important it is to gain a better understanding of the source of the microplastics entering the plants," Dr Hurley says.

While there has been a lot of work done to optimise wastewater treatment processes, not much has been specifically focused on particles with similar sizes and densities to microplastics. It is also important to track how microplastic particles mobilise, to see whether sludge added to agricultural soils only contaminates the soil system or whether the microplastics transfer to the wider environment.

THROUGH RIVER SYSTEMS TOWARDS THE OCEANS

As part of Dr Hurley's doctoral research at the University of Manchester, patterns of microplastic contamination in channel sediments were also studied at 40 sites in river catchments near Manchester, in northwest England. Microplastics were found in all of the river channel beds.

WHAT ARE MICROPLASTICS?

Microplastics are small pieces of plastic debris that are typically less than 5 mm in size (about the same size as a sesame seed). They come in different types, shapes and sizes, including beads, fragments, fibres and glitter. They come from a variety of sources, for instance, when larger plastics degrade into smaller pieces either by wear and tear caused by sea wave action, ultraviolet radiation or when marine animals shred them. In addition, they can also be intentionally added to household and personal care products, such as some cleaning products and toothpastes.

ECHA is currently working on a restriction on intentionally added microplastics.

However, after a period of severe flooding in winter 2015-2016, they resampled the areas and found that the concentrations of microplastics had drastically reduced and that microbeads had been completely eradicated at some sites.

"High magnitude flood events like this are capable of flushing microplastic particles further downstream. In our study, the evidence shows the microplastic particles being exported from the catchment sites, moving downstream and eventually being discharged into the Irish Sea," Dr Hurley says.

Therefore, it is important to control the source of microplastics entering the rivers to avoid them being further carried towards the oceans. Future studies on the same catchments by the Geography department at the University of Manchester may provide a deeper understanding of the processes underpinning the microplastic contamination of riverbeds.

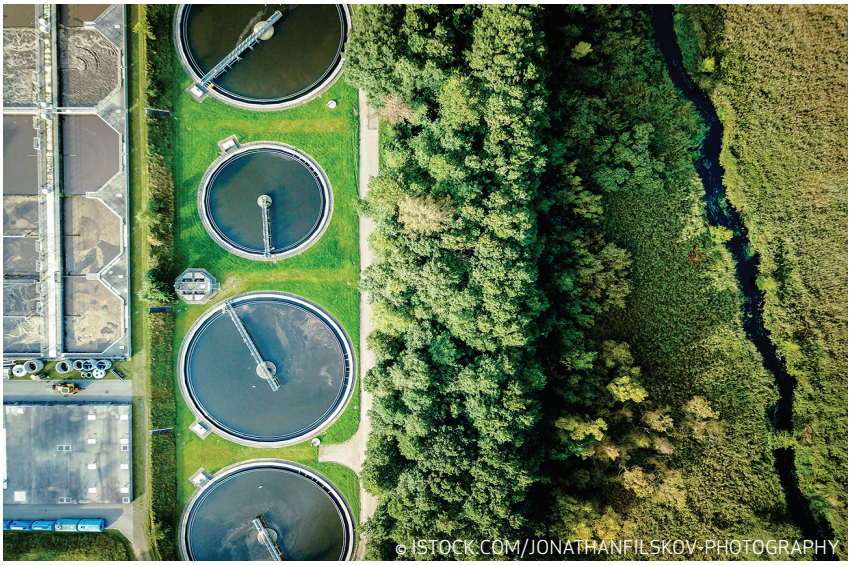
WHAT MORE CAN BE DONE?

So far, the majority of research on environmental microplastics has focused on monitoring.

"The next step would be to quantify processes related to microplastic contamination including identifying their sources and associated release, looking in more detail at the amount of time microplastics stay in different environmental compartments, and examining how they degrade in more detail," Dr Hurley informs.

More research is also needed to understand the effects that ingesting microplastics could have on organisms. "We do not yet know whether ingestion of particles or accumulation of microplastics up the food chain leads to adverse effects," she tells.

Several internationally-funded projects and working groups are currently tackling issues related to definitions and standardised methodologies for microplastics research. Much of this has been focused on further optimising methods and improving analytical capabilities related to analysing different sizes of microplastics and different environments.



A proportion of microplastic particles evades the filtering processes of treatment plants and ends up in sewage sludge. When sludge is added to agricultural soils it can contaminate the soil system with microplastic content, but may also contaminate the wider environment.

"This process takes time, as there is not yet a 'perfect' method for analysing plastic particles, and research is necessary to identify methodological constraints and propose solutions. Over the coming months, we expect to see further clarifications on how to define and look for microplastic particles," Dr Hurley tells.

It is also important to continue to improve methods to increase the quality and reduce the time and cost of microplastics research in the future.

"At NIVA, we are working to contribute to this ongoing process by developing certified standard reference materials for different microplastic particle shapes and sizes. We hope this will help to validate methods and to ease the comparison of results from different laboratories," she concludes.

Rachel Hurley is a post-doctoral researcher working on the Water JPI IMPASSE project (Impact of MicroPlastics on AgroSystems and Stream Environments). She is based at the Norwegian Institute for Water Research (NIVA) in Oslo, where she also works on other projects within the Microplastics research group.

The Norwegian Institute for Water Research (NIVA) is Norway's leading competence centre for environmental and resource issues relating to the fields of water, biodiversity, sustainable development, contamination, and development work. The institute has an active, strategic research programme with several initiatives concerned with modelling and monitoring microplastics in different environmental compartments, as well as investigating potential effects of microplastic particles on biota.

https://www.niva.no/en

Further information:

Stakeholder workshop on microplastic particles
https://echa.europa.eu/-/stakeholder-workshop-on-microplastic-particles

Hot topics on microplastics
https://echa.europa.eu/hot-topics/microplastics

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- eNanoMapper – Data and tools for the risk assessment of nanomaterials

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