ECHA
EUROPEAN CHEMICALS AGENCY
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Newsletter

Onboarding new tasks

It's been almost a year since I became the head of ECHA. And it has been as exciting, as challenging and as fun as I had hoped for. I am grateful to the staff of the secretariat, the management board, the board of appeal, our committees, the Forum and my predecessor, Geert Dancet, and many others for their patient help in getting me firmly into the job!

Three highlights are already clear to me: ECHA has started on a number of new tasks requested by the Commission; we have worked on a new strategic plan and we are reorganising the Agency.

This Newsletter provides more details on two of the new tasks that we are already in full swing on. In 2017, the Commission proposed to ask ECHA to implement the scientific and technical parts of the **Persistent Organic Pollutants Regulation**, the EU regulation implementing the Stockholm Convention. The legislator is still negotiating the final text, but the Council and the Parliament are supporting. ECHA has already gained experience in similar tasks by working on its sister regulation, the Prior Informed Consent Regulation implementing the Rotterdam Convention.

On adoption of the new **Waste Framework Directive**, we were asked to build a database helping to track substances of very high concern in the supply chain. The aim is ultimately to improve the information flow for recyclers.

The Commission also asked us to develop a one-stop portal to find all EU legislation which applies to a specific substance. You'll hear more about this in a later edition of the Newsletter.

To me, getting these tasks shows that the Commission sees ECHA as **the** chemicals agency – giving consistent scientific and technical advice across many regulations and directives and doing so more efficiently as all is under one roof.

Our **new strategic plan**, up for adoption by the Management Board in December, is inspired by the learnings from onboarding and integrating new tasks. Each piece of legislation we implement contributes to all three strategic priorities:

1. identifying and managing the risks of chemicals of concern;
2. safe and sustainable use of chemicals by industry; and
3. sustainable management of chemicals through EU legislation.

Under the first priority, we implement our tasks, integrating them into our work and doing so consistently. Under the second, we use our tasks to foster safer and more sustainable use of chemicals by industry. And finally, under the third, we ensure the consistency of our tasks with that of other EU chemicals legislation and support international activities.

We are also **aligning our organisation** with the new strategic plan. Our aim is that this would contribute to improved efficiency, and help us to better take on new tasks and promote staff development. The final organisational chart will be ready by December, but I am sure you will already have noticed that we are looking for management talent to join ECHA.

These are just a few highlights of my first 11 months in office. I look forward to our continued collaboration. I would also like to take this opportunity to wish all of you a peaceful and warm holiday season and all the best for 2019!

Bjorn Hansen
Executive Director

"To me, getting these tasks shows that the Commission sees ECHA as *the* chemicals agency."

In this issue:

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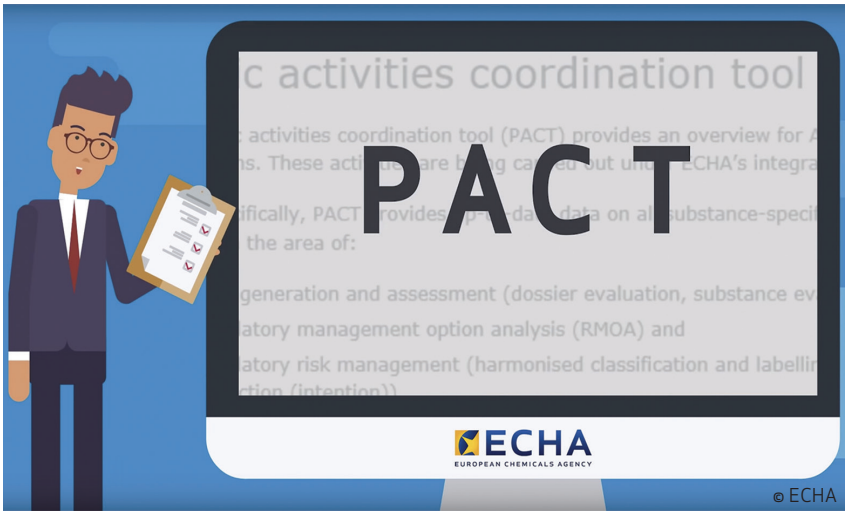
What's happening with your substance? Check PACT!

TEXT BY TIIU BRÄUTIGAM

If you want to check which substances are on the authorities' radar for potential regulatory action, ECHA's PACT is the tool for you. It gives you an overview of the substance-specific activities under REACH and CLP in a user-friendly format. Learn more about what you can do with this public activities coordination tool (PACT) and what features were added in the recent update.



PACT brings together eight different REACH and CLP processes into one dynamic table. This helps you to easily find information on which substances are on the rader of authorities.

The updated tool now covers information about substance and dossier evaluation and allows you to follow the substance through the whole evaluation process.

It also contains information on substances that are in the registry of intentions for further risk management: harmonised classification and labelling, substance of very high concern (SVHC) identification or restriction.

USE THE EARLY WARNING SYSTEM

As a registrant, you can use PACT to see, for example, if ECHA plans to check the compliance of your dossier or if national authorities are going to evaluate your substance soon.

With the help of this information, you can better plan, take the opportunity to update your registration data and consider the best business strategy to address any substances of potential concern.

However, PACT is not only for registrants but also for other industry, scientists and non-governmetal organisations that can benefit from the overview.

They, for example, may have important data on a specific substance or information on safer alternatives.

Checking the status of the substance in the tool helps you to better prepare for public consultations. These are organised as part of the restriction, application for authorisation and harmonised classification and labelling processes to gather all relevant scientific information to manage the risks of substances.

WHAT INFORMATION CAN YOU FIND?

PACT brings together eight different REACH and CLP processes into a dynamic table. The eight processes are:

1. **Dossier evaluation**.
2. **Substance evaluation**.
3. Assessment of substances that are **persistent, bioaccumulative and toxic (PBT)**.
4. **Endocrine disruptor** assessment.
5. **Regulatory management option analysis (RMOA)**.
6. **Harmonised classification and labelling**.
7. Identification of **substances of very high concern (SVHCs)**.
8. **Restriction**.

To look for information on a particular substance, you can either scroll down the table or use the search option. In the search, you can look for information based on different substance identifiers such as the EC or CAS numbers or search specifically for each of the eight different processes.

Once you have found the substance, you will be able to see whether there are any planned, ongoing or completed activities under these processes.

If there are, there will be a number displayed in the relevant column in the PACT table. The number indicates how many activities there are for each process.

So if, for example, you find a substance and it has a number in the RMOA column, clicking on the number will enable you to retrieve more details, such as which authority has worked on the RMOA, which concerns were addressed, and the status and outcome of the process.

PACT SUPPORTS INTEGRATED REGULATORY STRATEGY

ECHA's **integrated regulatory strategy** brings together all the substance-specific activities under REACH and CLP and aims to efficiently:

- **select substances** with potential concern;
- **address chemicals of concern** through the regulatory risk management measures and;
- **improve communication on safe use** in the supply chain.

Companies are reminded to keep their registration dossiers up to date, and provide better use and exposure information for their substances.

In 2019, ECHA will publish the first report on the integrated regulatory strategy, combining the previous report on the SVHC Roadmap and the annual evaluation progress report.

The integrated regulatory strategy report will describe how ECHA, together with Member States and the European Commission, has progressed in addressing the registered substances and clarified which substances need further regulatory action.

Further information:

Public Activities Cordination Tool (PACT)
https://echa.europa.eu/pact

Understanding PACT
https://echa.europa.eu/understanding-pact

PACT: Overview of substances authorities are working on (Video)
https://www.youtube.com/watch?v=kjXSDsq-xM8

Integrated regulatory strategy
https://echa.europa.eu/echa-irs

Here's what you need to know before Brexit

TEXT BY JAKOB AAHAUGE

The United Kingdom is withdrawing from the European Union at the end of March 2019. This decision has consequences not only for everyone in the UK, including those working in the chemical industry, but also for companies in the remaining EU Member States and EEA countries doing business with the UK. We walk you through the most important issues so you can be prepared.

If an agreement is reached and subsequently ratified, it may contain a transition arrangement, which would give companies a longer period to adapt to the consequences of Brexit.

The EU and the UK have announced a draft Withdrawal Agreement.

If the agreement is ratified, it may contain a transition arrangement, which would give companies a longer period to adapt to the consequences of Brexit.

However, based on the information currently available, we are providing advice to help companies prepare for the UK's withdrawal taking full effect on 30 March 2019.

How the withdrawal affects you depends on the role your business plays in the supply chain. If your UK-based business is connected to one of the remaining 27 EU Member States (the EU-27) or one of the three EEA countries, you will face some changes.

But it's not only UK companies that need to pay attention – companies in the EU-27 and EEA doing business with UK companies will also see things change.

The following examples highlight some of the changes, and you can find more explanations and support from our updated web section on the UK's withdrawal.

REGISTRATIONS WILL CEASE TO EXIST

If your company is based in the UK and you have registered a substance under REACH, your registration with ECHA will no longer exist after the withdrawal.

If you are a manufacturer, and you plan to continue doing business in the EU, you can appoint an only representative to manage your registrations. You should make sure that the only representative is knowledgeable and experienced enough to handle the information related to your substances, and that they are located within the EU-27.

If you are a UK-based importer, the non-EU manufacturer or formulator can appoint an only representative, located in the EU-27. Another option is to move the part of your business related to the registered substance to a legal entity within the EU-27. Remember though, that responsible staff will need to be physically present at the EU-based address – setting up a company in the EU-27 on paper only will not do.

WHAT ABOUT REACH AUTHORISATIONS?

REACH authorisations granted to UK-based companies will also no longer exist after the withdrawal. This means that if you are an EU-based company relying on such authorisations, you will have to find a new supplier that has a valid authorisation in the EU-27 or EEA. Alternatively, you can apply for an authorisation yourself, but remember to reserve enough time to do so.

If you are a UK-based holder of an authorisation, you can transfer the authorisation to an only representative in the EU-27. The transfer can be made after the withdrawal but you can already now prepare and make a formal agreement with your intended only representative.

BASED IN THE EU-27 OR EEA?

Companies based in the EU-27 or EEA that do business with UK-based companies will also face changes. For example, if your company is a member of a joint submission that has a UK-based company as the lead registrant, the lead registrant will need to transfer the lead role to an EU-based company.

CLASSIFYING AND LABELLING YOUR PRODUCTS

If you are a UK-based company, you will no longer have to comply with the CLP Regulation after the withdrawal unless you export to the EU-27. In this case, you will still need to classify and label your product in accordance with CLP.

When placing a substance, that has not been registered, on the EU market, it needs to be notified to the Classification and Labelling (C&L) Inventory. This needs to be done within one month. Notifying to the C&L Inventory will no longer be your task, but needs to be done by your EU-based importer.

MANUFACTURING OR SUPPLYING BIOCIDES

To be included in the Article 95 list of substances and suppliers, suppliers of biocidal substances or products need to either be based in the EU-27 or have an appointed representative there. If you are a UK-based supplier, you therefore have to appoint an EU-27 based representative before the UK's withdrawal to avoid being removed from the Article 95 list.

If you want to apply for an active substance approval or product authorisation, the application needs to be submitted in R4BP 3 to an EU-27 Member State or an EEA country.

Remember also that UK-based companies can continue to request active substance approvals and renewals, but after the UK withdrawal, biocidal product authorisations can only be granted to EU-based companies.

FOLLOW THE NEGOTIATIONS

The status of the UK's future chemicals legislation is uncertain. At the outset, the UK intends to transpose the EU legislation into domestic legislation. If there is a transition period, UK-based companies will still have obligations under EU legislation for an additional time. To stay up-to-date, follow the publications issued by ECHA, the European Commission and the UK authorities as well as the further developments of the withdrawal negotiations in the coming weeks and months.

Further information:

ECHA's web pages on the UK's withdrawal from the EU
https://echa.europa.eu/uk-withdrawal-from-the-eu

Question and answers for companies
https://echa.europa.eu/advice-to-companies-q-as/general

ONLY REPRESENTATIVES AFTER WITHDRAWAL

- If you plan to continue marketing your substance in the EU-27 or EEA after the withdrawal, **consider appointing an only representative**.
- **Remember to notify ECHA** of only representative changes through REACH-IT as soon as the Agency announces this possibility is available.
- Make sure that the only representative has **experience and knowledge on handling substances and the information** related to them.

Don't *waste* the chance – make recycled products safer

TEXT BY TIIU BRÄUTIGAM

Under the revised Waste Framework Directive, ECHA has been given a task to build a database on articles containing substances of very high concern (SVHCs) from the Candidate List. The main aim is to support circular economy, prevent waste being generated and reduce hazardous substances in materials and products.

The database is part of the EU's new package, aiming to reuse recycled waste as a reliable source of raw materials in the future.

By having a better knowledge of which articles contain hazardous substances, waste treatment operators can improve their waste separation and recycling processes. It will also increase authorities' information on Candidate List substances in articles.

WHAT THE DATABASE WILL BE ABOUT

The ECHA database will contain information on articles containing Candidate List substances in quantities of more than 0.1 % of their weight.

Companies who supply such articles – either produced in the EU or imported – will need to submit company data, Candidate List substance data, the article description and safe use instructions of the article to ECHA.

This information requirement is not new. Under REACH, companies already have to communicate information on articles containing Candidate List substances down the supply chain.

ECHA has been given a task under the Waste Framework Directive to build a database on articles containing Candidate List substances of very high concern. The database aims to support circular economy, prevent waste being generated and reduce hazardous substances in materials and products.

However, there is very little information for waste operators about the hazardous substances in the waste they are processing.

This can lead to hazardous substances ending up in recycled materials. The database aims to resolve this gap in the information flow.

WHO WILL BE USING IT?

The primary users of the database will be waste treatment operators and consumers. The database should increase knowledge on which substances are used in which articles.

It will ultimately help waste operators to improve their waste separation and recycling processes. All of this will steadily contribute to a more circular economy.

Consumers can use this information to find out more about the SVHCs in the products they buy and make informed choices. This will also increase pressure to substitute substances of concern.

Also, Member State authorities can use the database to improve their understanding of substances of concern in certain products and adapt their waste reduction and treatment policies at national level.

WHAT IS THE SCOPE?

The scope is potentially very large – both in terms of articles to be notified and companies who need to submit information to ECHA.

All articles supplied in the EU that contain Candidate List substances above 0.1% of their weight are covered as well as all actors in the supply chain:

- producers;
- importers;
- assemblers;
- distributors; and
- retailers.

ECHA has published a draft scenario for the database and collected feedback through a public call for input, meetings with stakeholders and a dedicated workshop.

Discussions have included, for example, information flow in the supply chain and data requirements (who should submit what?), dissemination of information to waste operators and consumers, and technical solutions for submitting data.

NEXT STEPS

ECHA will continue to work on the scenario for the database and develop detailed IT requirements, taking into account the feedback received.

This work will be done together with the Member State authorities and the European Commission.

There will also be specific stakeholder focus groups working on technical aspects of the project.

The timeline now depends on the available resources for the long-term project. According to the revised Waste Framework Directive, ECHA has to establish a database by **5 January 2020**, while duty holders will have to submit information to it as from **5 January 2021**.

Further information:

ECHA's draft database scenario
https://echa.europa.eu/documents/10162/24198999/scenario_en.pdf

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The amount of articles on the EU market is very large. For example, a bike consists of many different articles that should be notified to the database if they contain Candidate List substances above 0.1 % of their weight.

Workshop on Waste Framework Directive database
https://echa.europa.eu/-/workshop-on-waste-framework-directive-database-22-23-10-2018

Presentation from Workshop on Waste Framework Directive database
https://echa.europa.eu/documents/10162/24205171/wfd_database_presentation_en.pdf

Candidate List substances in articles
https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles

Waste management and recycling: Council adopts new rules
https://www.consilium.europa.eu/en/press/press-releases/2018/05/22/waste-management-and-recycling-council-adopts-new-rules

Implementation of the circular economy package: options to address the interface between chemical, product and waste legislation
https://ec.europa.eu/docsroom/documents/27321/attachments/1/translations/en/renditions/native

WASTE FRAMEWORK DIRECTIVE

The **Waste Framework Directive** is part of the EU's waste package. It addresses environmental issues, covering the impact of inappropriate waste management on greenhouse gas emissions, air pollution and littering.

The package ensures that valuable material in waste is effectively re-used, recycled and re-injected into the European economy. It will thereby help Europe to move towards a circular economy and reduce the EU's dependence on the import of raw materials by promoting prudent, efficient and rational use of natural resources.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008L0098

Coming soon: find a biocide with its trade name

INTERVIEW BY VEERA SAARI

At the end of November, ECHA will make more information available on biocides. You will be able to pick up a biocidal product in a shop and type its name into our database. You will know where in Europe its use is authorised, what its main ingredients are and how to use it safely. The aim is to make information on biocides more transparent.

MORE TRANSPARENCY

With the help of our public database, it will be easier for companies and consumers to make more informed choices on biocides.

For every biocidal product that has been authorised in the EU area, you will see a map of the countries where the product is authorised to be used. You will also know what its main ingredients are and how to use it safely. As well as this, you will have access to the assessment done by national authorities on each product and information about their risks to humans, animals and the environment.

Karina Kubinakova from ECHA's dissemination team explains the need for the project. "The aim is to improve transparency on biocides. The main development is the fact that the summary of product characteristics, which companies are required to create for each product, will now be publicly available in our database".

The summary of product characteristics includes information on the safe use of the products, such as:

- substances in the product and their concentrations;
- product composition;
- the manufacturer of the product;
- the manufacturer of the active substance;
- hazard and precautionary statements;
- the organism the product is targeted at;

Karina Kubinakova.

- application methods;
- type of packaging; and
- instructions for use.

FIND A PRODUCT WITH ITS TRADE NAME

In the database, biocidal products will be listed with their trade names. "This means you can pick up a hand sanitiser, a toilet cleaner or a mosquito repellent in a shop and type its name into our database to find the exact product," Ms Kubinakova says. This will work whether the product's name is in Spanish, Hungarian, Swedish – or any other EU language.

"You will be able to find the product sold in your country and see its sister products authorised in different EU countries." This will come in handy if you are, for example, on holiday abroad and need to find a particular product.

SEARCH TO FIND WHAT YOU NEED

It will be easier to search for information in the database. You can search for products using, for example, the product-type, the product authorisation holder's name, or the market area.

WHAT BIOCIDES DO

Biocides are products designed to kill unwanted pests or bacteria. To be able to have this effect, they often contain hazardous substances and that is why their use is heavily regulated. Biocides are divided into four groups:

1. **Disinfectants** protect your skin or surfaces in your home from bacteria.
2. **Preservatives** protect your products from bacteria.
3. **Pest control products** protect you from insects or rats.
4. **Other products** such as antifouling products that protect your boat from fungi.

We rely on biocides for many things in our daily lives. For example, we use mosquito repellents to avoid bites, or we disinfect our hands at hospitals to avoid spreading bacteria. While we rely on some biocides, some we can do without or use less of. National and EU authorities weigh the benefits and risks of using these products before deciding whether to allow them on our market.

Anita Rynkänen from ECHA's dissemination team gives examples. "If you are interested in buying a mosquito repellent, you can search our database with "mosquito" to find all the products currently approved on the EU market. If you just want to know which products are authorised in your country, you can then search by Member State."

COMPARE PRODUCTS

A feature that is probably the most helpful to consumers buying biocides is the option to compare products to find less hazardous options.

"If you are interested in finding a disinfectant, you can run a search in our database and then choose several products to compare them. Do any of the products contain an active substance that is considered less hazardous? Or do the products contain substances of concern or those that are considered candidates to be substituted? In this way, you can easily identify products with a more favourable profile for health and the environment," Ms Rynkänen explains.

CHECK THE CURRENT STATUS FOR ACTIVE SUBSTANCES

The information on biocidal active substances will also improve. "In one glance, you will easily be able to trace where a substance is in the EU approval system: is it approved or is it still under evaluation by a Member State or waiting for an opinion by the Biocidal Products Committee, or for the final decision by the European Commission?" Ms Rynkänen remarks.

Anita Rynkänen.

The database currently includes over 300 active substances used in different biocidal product-types.

"With the help of our icons and tooltips, you will also be able to easily identify if a substance is considered less hazardous: it will be marked with a green symbol," Ms Rynkänen continues.

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With the help of our public database, it will be easier for companies and consumers to make more informed choices on biocides.

LIMITATIONS AND FUTURE DEVELOPMENTS

The public database has information only on those biocidal products that have already been authorised for use in the EU. "This means that you should not worry if a product you search for cannot yet be found," Ms Kubinakova clarifies.

"The most probable reason for this is that either the product or the active substance in it is still under evaluation by the authorities."

All biocidal products containing approved active substances are evaluated for safety and efficacy before they are allowed to be sold in the EU, whereas products that were on the market before 2000 can continue to be sold while the authorities are evaluating the active substances they contain.

The interface will continue to see improvements. "We will continue working on making the data more user-friendly. For example, the summaries of product characteristics are currently in PDF format, but we plan to make online versions available in the future," Ms Rynkänen concludes.

Further information:

Information on biocidal active substances
https://echa.europa.eu/information-on-chemicals

Understanding the Biocidal Products Regulation
https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Biocidal product-types
https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

Presentation of the new features
https://www.youtube.com/watch?v=seRiUemxock&t=12768s

Terrestrial environments also being polluted with lead ammunition

TEXT BY NEDYU YASENOV

In a recent report prepared by ECHA, the Agency recommends that measures are needed to regulate the use of lead ammunition in terrestrial environments. The report builds on the earlier proposal to restrict the use of lead shot in wetlands. We take a deeper look at the main findings of the report.

In a recent report prepared by ECHA, the Agency recommends that measures are needed to regulate the use of lead ammunition in terrestrial environments. The report builds on the earlier proposal to restrict the use of lead shot in wetlands.

EXPANDING TO NON-WETLAND USES

In August 2018, the European Commission received the opinion of ECHA's scientific committees on restricting the use of gunshot with more than 1% of lead content that is used over or within wetlands, including at shooting ranges or on shooting grounds in wetlands.

Now ECHA has published a report on the impact of lead ammunition on **terrestrial environments**.

This is a response to the Commission's request to collect information on assessing the risk and socio-economic impact of restriction for other uses of lead ammunition, including hunting in other terrains than wetlands, for target shooting, and for the use of lead weights for fishing.

Military uses of ammunition are not within the scope of the investigation.

WHY THE FOCUS IS ON LEAD

Lead-based ammunition is considered to be the most significant unregulated source of lead deliberately emitted into the environment in the EU.

Lead is a toxic heavy metal with no biological function. It is a non-specific poison affecting most body systems, and has negative effects on general health, reproduction and behaviour.

Absorbed lead affects all animals, from migratory birds to humans. Lead presents risks to wildlife, especially wild birds.

Lead differs from many contaminants in that there is no evidence for a threshold for a number of critical endpoints in humans including developmental neurotoxicity and nephrotoxicity, this means that there is no level below which observable effects cannot be seen.

USE OF LEAD SHOT AND BULLETS IN TERRESTRIAL AREAS

An estimated **14 000 tonnes** of lead shot is dispersed into terrestrial areas in the EU each year.

The use of shot and also lead bullets in terrestrial areas can contribute to the lead poisoning of various species.

As a preliminary assessment extrapolated from the mortality rates of birds in wetlands, this could see between one and two million terrestrial birds dying each year because of lead poisoning.

These numbers include predators and scavengers affected through secondary poisoning, due to commonly used hunting practices. Hunters often leave the intestines of the shot animal in the field where it is available for wild animals to scavenge on.

Mammals, birds of prey and scavengers that consume these intestines are then exposed to the lead. Some species of waterbirds, such as geese and swans, also forage for food and grit in terrestrial areas and can ingest lead while doing so.

USE OF LEAD AMMUNITION AT SHOOTING RANGES

There are also growing concerns in the scientific community on the exposure of target shooters to lead dust used in lead ammunition,

primers and propellants. It is estimated that sports shooters in the EU use around 10 000 to 20 000 tonnes of lead in shot cartridges per year on shooting grounds.

In addition, shooting ranges using lead shot and bullets also represent a risk of soil contamination in terrestrial areas, and risk contaminating nearby (ground)water sources in the EU.

Expensive remediation may be needed based on the specific site's situation.

LEAD IN TERRESTRIAL ENVIRONMENTS

- It is estimated that in the EU as much as **2 000-6 000 tonnes of lead** is dispersed into the environment by fishing with lead sinkers per year.
- A position paper from 2015 by the **European Fishing Tackle Trade Association (EFTTA)** calls on the European fishing tackle trade to phase out lead fishing weights (sinkers) heavier than 0.06 grams.
- Several EU Member States (Denmark, Sweden and the UK) have **existing legislation or voluntary agreements** prohibiting the use of lead in fishing tackle. In some cases, only certain sizes of weights or sinkers have been prohibited as these are thought to pose the greatest risk to birds. Restrictions are also in place in North America.

HOW LEAD AFFECTS HUMAN HEALTH

Humans can also be exposed to lead when they consume game meat killed with lead ammunition. Both shotgun pellets and rifle bullets can fragment (in different ways) upon impact resulting in lead dispersing in the tissues of the target.

This dispersed lead has been believed to be removable by cutting away and discarding tissue from around the wound channel of game meat.

However, recent research suggests that lead fragments disperse widely as microscopic particles (potentially even nanoparticles) in tissues and that cutting away tissue from around the wound channel would not be sufficient to remove all of the lead that would be available for human consumption.

Furthermore, game meat is often consumed by hunters and their families outside of any food control mechanisms. Therefore, the consumption of game shot with lead-based ammunition can result in exposure that results in significant risks to frequent consumers of game.

Several European food agencies have advised citizens to be moderate when consuming game shot with lead.

The most recent development comes from the **French Agency for Food, Environmental and Occupational Health and Safety (Anses)** who advised not to consume game shot with lead more than three times per year and that children and pregnant woman should not consume game shot with lead at all.

INSTEAD OF LEAD

Alternatives to lead shot are already available (mainly steel, bismuth and tungsten). They are the same as the alternatives used for wetland hunting and sports shooting.

The ECHA dossier on lead in shot over wetlands found that the effectiveness of the alternatives is comparable to lead-containing shot.

Since alternative steel shot is already available, can be used in most shotguns (manufactured after 1970) and, on average, is not currently more expensive than lead shot, the costs of replacing lead shot for an individual hunter are considered to be limited.

With 14 000 tonnes of lead shot estimated to be dispersed into terrestrial areas in the EU each year, this could see between one and two million terrestrial birds die annually from lead poisoning including some waterbirds, such as geese and swans, when they forage for food.

Alternatives to lead-based bullets are also available and are increasing in popularity, for example, due to on-going regional restrictions in Germany.

The proposed California ban on lead-based bullets, which is expected to take full effect in 2019, has also helped stimulate the global development of lead alternatives (usually based on copper), which has increased the supply of these alternatives.

USE OF LEAD IN FISHING TACKLE

In addition to ammunition, the Commission asked ECHA to investigate fishing weights, sinkers and jigs as potential sources of lead contamination in the environment.

The main issue with lead-based fishing tackle is that it is frequently lost during use. In fact, some contemporary fishing practices encourage the deliberate release of lead weights to the aquatic environment in some circumstances (known as 'dropping the lead'; to ensure fish welfare in the event that rigs are lost or snagged).

There have also been risks identified for waterbirds linked to the use of lead fishing weights and their ingestion.

In addition, many recreational anglers create their own lead-based fishing tackle at home. The risks of consumer exposure to lead-containing dusts or vapours during these activities appears to be likely. Appropriate and effective risk management measures are not always consistently used to minimise the associated risks.

The risks from this practice could also be addressed by further regulatory action.

In addition to ammunition, the Commission also asked ECHA to investigate fishing weights, sinkers and jigs as potential sources of lead contamination in the environment. The main issue with lead-based fishing tackle is that it is frequently lost during use.

IN SUMMARY

ECHA's new report on non-wetland uses of lead in ammunition (shot and bullets) and in fishing weights has found sufficient evidence of risk to justify additional measures.

The report concludes that measures are needed because they would:

- limit additional pollution with lead and improve the quality of the environment, also reducing the potential need for expensive soil and (ground)water remediation;
- reduce health risks to a significant population of hunters and their families who frequently eat game meat that has been killed with lead shot or bullets;
- reduce the deaths of an estimated one to two million birds, such as pheasants and partridges, that may inadvertently swallow the lead shot and reduce the death and poisoning of scavengers and predators feeding on lead-poisoned birds in the terrestrial environment; and
- minimise associated risks of consumer exposure to lead-containing dusts or vapours during fishing activities.

The report was sent to the Commission in September 2018 where it will be further discussed within their respective services.

Further information:

ECHA identifies risks to terrestrial environment from lead ammunition, Press release, 12 September 2018
https://echa.europa.eu/-/echa-identifies-risks-to-terrestrial-environment-from-lead-ammunition

European Commission's request to ECHA
https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf

Investigation report "A review of the available information on lead in shot used in terrestrial environments, in ammunition and in fishing tackle"
https://echa.europa.eu/documents/10162/13641/lead_ammunition_investigation_report_en.pdf

(Un)loading lead - saving wildlife and nature in wetlands, ECHA Newsletter 3/2018
https://newsletter.echa.europa.eu/home/-/newsletter/entry/-un-loading-lead-saving-wildlife-and-nature-in-wetlands

Persistent organic pollutants – a new family of substances for ECHA

TEXT BY IRENE POZA LATORRE

Have you ever heard of *Silent spring*? This environmental science book written by Rachel Carson in the 1960s called on people to question which chemicals their governments allow into the environment. For the last two decades, persistent organic pollutants (POPs) have been in the spotlight due to increased global efforts to minimise the risks they pose to the environment and health. So how are POPs regulated and what will ECHA's future role with them be?

POPs are chemical substances that remain in the environment, bioaccumulate through the food chain, and pose a risk to the environment and human health. Due to their intrinsic properties, these substances can also be transported across long distances, far from the locations where they have been produced or used.

They therefore have a high potential to contaminate, with samples found in our everyday environment but also even in the most remote places on the planet, like the Arctic. Once released, it is difficult to reduce their presence in the environment and humans. The impact on ecology and society is long-lasting and can even span across generations.

HOW ARE POPS CURRENTLY REGULATED?

The chemical substances that have been identified as POPs include:

- **pesticides** (such as DDT);
- **industrial chemicals** (such as polychlorinated biphenyls, which were widely used in electrical equipment); or
- **unintentional by-products** formed during industrial processes, degradation or combustion (such as dioxins and furans).

For the past two decades, POPs have been regulated at the global level. **The United Nations Economic Commission for Europe's (UNECE) Protocol on Persistent Organic Pollutants** (commonly known as the Aarhus Protocol) was adopted in 1998. This was closely followed in 2001, by the adoption of the **Stockholm Convention** which identified the initial 12 POPs (dirty dozen). Since then, this list has been expanded to include 33 POPs.

Some examples of newer POPs, which are gradually being phased out worldwide, include:

- **perfluorooctane sulfonic acid (PFOS)**, used in consumer products, such as some outdoor textiles and leather goods; metal plating; fire-fighting foams; and in stain repellents; and
- **hexabromocyclododecane (HBCDD)** widely used as a flame retardant additive in textiles, electrical and electronic appliances, and construction materials.

At the European Union level, the **POPs Regulation** is the Union's effort to implement the Stockholm Convention and the Convention on Long-Range Transboundary Air Pollution's Protocol on POPs. The regulation aims to eliminate the manufacturing, placing on the market and use of POPs, whether on their own, in mixtures or in articles.

It contains provisions to minimise the unintentional production and release of POPs, and ensure the safe management of stockpiles and waste. Furthermore, Member States have set up emission inventories for unintentionally produced POPs, national implementation plans, and mechanisms to monitor and exchange information.

For the last two decades, persistent organic pollutants (POPs) have been in the spotlight due to increased global efforts to minimise the health and environmental risks they pose both in everday environments and in the most remote places on the planet.

HOW POPS ARE LINKED TO ECHA'S CURRENT WORK

Already today, ECHA has an indirect role with POPs. The Agency's work to identify substances of very high concern (SVHCs) has been a springboard for identifying potential POPs. ECHA also manages the restriction process which further supports the EU's work for proposing new POPs to the Stockholm Convention.

Through evaluation activities under REACH and the Biocidal Products Regulation, the Agency generates data and assesses potential persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances. Furthermore, ECHA's PBT Expert Group has already provided advice on several POP assessments.

ECHA'S NEW POPS TASKS

In 2019, ECHA will receive new responsibilities under the recast of the POPs Regulation. Our role will be to support the European Commission and the Member States in fulfilling their international obligations on POPs.

The Agency will:

- Support the identification and proposals of new POP substances to the Stockholm Convention;
- Act as an interface for reporting duties on implementing the POPs Regulation. This would involve receiving and disseminating implementation reports from the Member State competent authorities, compiling a Union overview on the implementation and supporting the Commission to regularly generate Union implementation plans.

Other envisaged tasks include promoting an exchange of information on POPs between various EU actors and third countries, helping the Commission's work in the POPs Review Committee and supporting POPs enforcement activities through ECHA's Enforcement Forum.

Persistent organic pollutants (POPs) have been found in samples from remote areas such as the Arctic, far from locations where they have been produced or used. Once release it is difficult to reduce their presence in the environment and in humans.

Further information:

Persistent organic pollutants
http://ec.europa.eu/environment/chemicals/international_conventions/index_en.htm

Stockholm Convention
http://www.pops.int

Aarhus Convention
http://ec.europa.eu/environment/aarhus/index.htm

Dirty dozen
http://chm.pops.int/TheConvention/ThePOPs/The12InitialPOPs/tabid/296/Default.aspx

Recast of the POPs Regulation
https://ec.europa.eu/info/law/better-regulation/initiatives/com-2018-144_en

HUMAN MILK - A POPS TRACKING TOOL

According to the **World Health Organisation (WHO)**, exposure of humans to very small doses of POPs can lead to increased cancer risk, reproductive disorders, altered immune systems, neurobehavioural impairment, endocrine disruption, genotoxicity and increased birth defects, among other things.

Since 1976, the WHO's **Food Contamination Monitoring and Assessment Programme** has collected and evaluated information on levels of POPs in foods, including human milk. Human milk can provide information on the exposure of mothers and infants to the pollutants.

After the Stockholm Convention was ratified, the revised WHO guidelines for developing a national protocol describe the basic study design that can be used to monitor human exposure over time. This will help to see how effective the Stockholm Convention is in reducing the release of these chemicals into the environment.

From substitution to safe design

INTERVIEW BY PAUL TROUTH

With Europe aiming to transition towards a circular economy and a non-toxic environment, one contribution to this goal is coming from the Netherlands' Safe Chemicals Innovation Agenda. The agenda highlights research needs that, if met, will accelerate the safe design of chemicals, materials and products. We spoke with *Dr Jochem van der Waals*, a Senior Policy Advisor at the Dutch Ministry of Infrastructure and Water Management to find out more.

Jochem van der Waals.

The Safe Chemicals Innovation Agenda outlines areas of research that, if taken on board by scientists, technicians, businesses and policy makers, could play a greater role in accelerating the safe design of chemicals, materials and products.

The concept of **safe by design** aims to address safety issues during the research and development, and design phases of production. This is done to reduce the need for substitution at a later stage.

Designing for safety has become increasingly popular for addressing risks in emerging fields such as nanotechnology and synthetic biology, and it is hoped that the methods developed to assess and reduce risks during the design stage could also be adopted for chemicals.

"More innovation is needed to develop safe chemicals, materials and products and this needs toxicity to be understood and taken into account at the design stage," Dr van der Waals says.

"It's not just about looking for like-for-like chemical replacements, which are not always necessarily much safer. For instance, instead of looking to replace bisphenol A with other bisphenols such as bisphenol S, the agenda promotes looking at the technical and scientific requirements for the chemical's use. We push research to ask whether we really need to print out our till receipts on thermal paper or whether there might be technological and more environmentally-friendly solutions," he explains.

PRIORITY AREAS FOR RESEARCH AND DEVELOPMENT

The agenda outlines seven priority areas where research and development could have an impact on EU and national policy and stimulate safe design. These areas are:

1. **Water, grease and dirt repellants** – developing effective fluorine-free alternatives.

2. **Fire safety** – developing alternatives (chemicals, materials) for flame retardants that have been linked with causing cancer, neurodevelopment impairment and endocrine disruption; alternatives to fire-fighting foams containing PFAS.

3. **Preservatives** – developing safer alternatives as some preservatives are associated with endocrine effects, oestrogenic properties, cancer, skin allergies and reproductive toxicity.

4. **Plasticisers** – developing alternatives without adverse effects on reproduction or endocrine activity. Such solutions could be alternative chemicals or materials.

The concept of safe by design aims to address safety issues during research and development, and design to reduce the need for substitution at a later stage.

5 **Solvents** – most solvents are volatile organic compounds, and developing alternatives could mean substantial reformulation and production process changes.

6 **Surfactants** – some surface-active agents are known or suspected endocrine disrupting chemicals. Here research is needed on their molecular behaviour and on production scale up.

7 **Curing agents** – research is needed to overcome technical barriers to effective substitution of hazardous curing agents used during polymerisation to strengthen resins, rubbers and foams.

Other avenues for research were also identified including fertilisers, pesticides, energy storage, surface protection, methodologies for assessing alternatives and legacy contamination.

"We hope that the agenda will inspire the European Commission and Member States to take up these areas for research as an input to Horizon Europe, the next research and innovation framework programme that will succeed Horizon 2020," Dr van der Waals explains.

"We are also engaged at national level with many research institutes and are encouraging them to concentrate their research on these areas".

Instead of looking for like-for-like chemical replacements, there may be more environmentally-friendly solutions. So, instead of replacing a substance like bisphenol A with other bisphenols, research should consider whether BPA-covered thermal paper should be used for till receipts or if there are technological alternatives.

BIO-BASED ALTERNATIVES

Within some of the research areas in the agenda, such as plasticisers, solvents and surfactants, **bio-based alternatives** may offer a viable solution.

A report from **Wageningen Food & Biobased Research** commissioned by the Dutch National Institute for Public Health and the Environment (RIVM) has revealed a number of promising bio-based alternatives to the polar aprotic solvents NMP, DMAc and DMF.

A broad scan of new and marketable bio-based chemicals was carried out focusing specifically on substitutes for the three solvents – since they are substances of very high concern (SVHCs). Their use may be limited under EU chemicals legislation in the future.

Within the EU project RESOLVE, Wageningen Food & Biobased Research is already developing safer alternatives to toluene and NMP. RESOLVE focuses on developing alternatives with a completely different chemical structure, entirely avoiding the chemical groups which make toluene and NMP toxic.

The alternatives are also deemed to be sustainable because they are made from carbohydrate-rich waste streams such as sugar beet pulp.

https://www.wur.nl/en/newsarticle/Promising-biobased-alternatives-to-polar-aprotic-solvents.htm

FROM SUBSTITUTION TO SAFE DESIGN

While progress has been made to reduce the use of harmful chemicals in Europe, thanks to regulations like REACH, Dr van der Waals feels that there are limits to what can be achieved with legislation.

"Regulatory requirements are not sufficient on their own, because we have seen that substitutes are often drop-in replacements and not necessarily safer," Dr van der Waals says.

"The shift towards safe design is also essential to achieve a circular economy. Avoidance of toxic chemicals enables safe recycling and reuse of materials, including in new life stages that are unknown at the design stage," Dr van der Waals tells.

In January 2018, ECHA launched its substitution strategy with a focus on the functionality of chemicals. "Moving to safer chemicals, materials and products should begin by considering what functions are needed, rather than just managing a chemical's risks," highlights Dr van der Waals.

"Considering the function of a substance rather than its chemical structure and risks would allow a wider range of substitution solutions to be available."

SUPPLY CHAIN APPROACH

The challenges in moving towards safer chemicals, materials and products are different depending on the products and specific supply chains involved.

"There is an economic barrier. Substitution can be costly, with uncertain results and high failure rates. Chemical companies have often invested heavily in their chemicals and associated production lines, and are reluctant to change until they get a return on their investment," Dr van der Waals says.

It is also not always clear what a safe product is or what will be sustainable. "When you replace a chemical, you need to be able to ensure that the replacement is safer and assessing this can be difficult."

A very important aspect is that for substitution to work, there needs to be effective communication and cooperation throughout the supply chain.

"You have to bring together the end users of products, chemical industry or suppliers of alternative materials, and all the actors in between," Dr van der Waals says.

"An important question is what exactly are the end-user requirements. The chemicals industry is not used to dealing with end users. With existing products, the supply chains generally know how to deal with them, but with new products, there is a greater need for the supply chain to adapt," he adds.

There are ways to overcome this, such as when there are downstream user companies with a strong market position that demand safer products. There are good examples of this in textiles and electronics.

The presence of a neutral facilitator can also help, and this is also the idea behind the substitution workshops that fit into ECHA's strategy.

PILOTING THE APPROACH

The Netherlands has piloted this approach in a recent international workshop about safe and sustainable antifouling products for recreational craft.

There is also a need for a stronger connection between chemicals policy and innovation policy both at Member State and EU level.

"Cooperation between ministries and institutions is not commonplace, and it should be encouraged," Dr van der Waals tells.

Dr van der Waals is a Senior Policy Advisor working in the asbestos, biocides and chemicals team at the Dutch Ministry of Infrastructure and Water Management.

The team operates within a larger directorate that deals with environmental safety and risks. The work of the team sees them involved in different aspects of chemicals policy including REACH, the Biocidal Products Regulation, the Persistent Organic Pollutants Regulation as well as substitution and innovation.

DID YOU KNOW?

The European Commission has published its proposal for **Horizon Europe**, an ambitious €100 billion research and innovation programme that will succeed Horizon 2020.

Horizon Europe will incorporate policy missions to ensure the effectiveness of research and innovation funding by pursuing clearly defined targets. This approach to policy making will set defined goals, with specific targets and working to achieve them in a set time.

https://ec.europa.eu/info/designing-next-research-and-innovation-framework-programme/what-shapes-next-framework-programme_en

Further information:

Workshop on the Safe Chemicals Innovation Agenda
https://www.chemischestoffen-goedgeregeld.nl/nieuws/workshop-safe-chemicals-innovation-agenda

Substitution to safer chemicals
https://echa.europa.eu/substitution-to-safer-chemicals

Strategy to promote substitution to safer chemicals through innovation
https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf

How to substitute
https://echa.europa.eu/know-your-substances-and-needs-substitution

Guest column | Eurometaux

MISA – a new cooperation model for improving metals information

INTRODUCING MISA

Europe's metals and inorganics sector is committed to progressing the science and information available on the substances we produce and use. For that reason, we have worked hard this year with ECHA to set up the **Metals and Inorganics Sectorial Approach (MISA)**.

MISA is a landmark cooperation agreement involving 15 metals sectors and covering close to 300 inorganic substances.

We hope that our targeted work with ECHA will result in a better understanding of the hazards and risks posed by these substances, including their use in a circular economy.

We have made a commitment to continually improve our knowledge and data, and to communicate on this transparently.

REACHING OUR SECTOR'S LONG-TERM VISION FOR A RISK-CONTROLLED ENVIRONMENT

Violaine Verougstraete.

300 substances might not sound like a high number, but their collective tonnage is more significant than most other sectors. These substances are also essential to Europe's priority low-carbon technologies, including clean mobility, renewable technologies and batteries. It's critical for Europe's sustainable future that we get their management right.

Our sector's long-term vision is to achieve a risk-controlled environment, where our substances are only used when their exposure is controlled to levels that are safe for human health and the environment.

To reach that vision, we fully subscribe to the REACH and CLP objectives and, in that perspective, recognise the importance of providing accurate and understandable information on hazards, risks, and conditions of safe use for our substances throughout the supply chain. The registration dossiers are a key tool for doing so.

Metals and inorganic substances have several specificities that require a targeted regulatory approach. We will continue working with ECHA to define how to deal with complex concepts like bioavailability, the occurrence of hazardous constituents after recycling, and the use of naturally occurring materials.

MISA is a fantastic opportunity for industry and policymakers to engage with these complexities together, overcoming the need for simplified one-size-fits-all assessment.

FOCUSING ON CONCRETE ACTION

MISA will require our companies to go beyond their basic compliance obligations, which will need extensive resources and knowhow from our people. That is not a responsibility we take lightly. We want MISA to be defined by concrete actions.

Together with ECHA, we have defined a three-year programme including a series of key activities, plus their expected deliverables. The metals consortia have developed and applied a self-assessment tool that screens their registration dossiers to identify issues and possible data gaps related to information requirements for human health endpoints, including data adaptations and waiving.

EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

In October, ECHA and Eurometaux co-organised a MISA workshop on this theme discussing the conditions to use read-across and other possible data adaptations in detail.

As a follow-up, consortia will communicate by mid-November to ECHA their work plan to improve their dossiers where relevant, including data generation if needed.

A second workshop has already been planned for February 2019, where we will discuss the information requirements for environmental toxicity. We will be following that up with initiatives covering the other agreed priority issues (e.g. UVCBs, exposure assessment, materials flow analyses, impurities management).

We think it's equally important to ensure that the results of our collaboration are publicly available. Our 'Framework for Cooperation' with ECHA, plus our jointly agreed priorities, can already be reviewed.

We will also be publishing the list of substances covered by MISA on the Eurometaux REACH metals gateway and the ECHA website. Finally, regular updates will be provided to Member States and Commission through the competent authorities for REACH and CLP (CARACAL) expert group and open MISA workshops.

ACHIEVING TANGIBLE IMPROVEMENTS

In a nutshell, we're confident that our cooperation with ECHA through MISA will help ensure that a deeper knowledge on metals is built into the EU's regulatory science.
We want to make sure that all data on our substances is accurate and comprehensible. This will allow us to understand their hazards and any risks posed to human health and the environment.

With that foundation in place, we can take major steps towards our long-term ambition of a safe and sustainable use of metals and inorganic compounds.

Dr Violaine Verougstraete is the Environment, Health and Safety (EHS) Director at Eurometaux. She has a PhD in Public Health and has been coordinating Eurometaux's EHS and REACH activities since 2012.

Eurometaux is an umbrella organisation representing the interests of the combined non-ferrous metals industry towards EU policy makers. The organisation aims to promote the sustainable production, use and recycling of non-ferrous metals in Europe, as well as a supportive business environment for its members, which include producers, transformers and recyclers of non-ferrous metals, European and national metals associations.

https://eurometaux.eu

Event calendar

NOVEMBER 2018 - FEBRUARY 2019

Committee for Risk Assessment
20-23 November and
27-30 November

Committee for Socio-economic Analysis
27-29 November

Member State Committee
10-14 December
4-8 February (tentative)

Biocidal Products Committee
11-14 December

Management Board meeting
13-14 December

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Upcoming webinars
Poison centres: getting prepared to notify your hazardous mixtures
11 December
https://echa.europa.eu/-/poison-centres-getting-prepared-to-notify-your-hazardous-mixtures

International cooperation - Speaking engagements

Chemical Watch Regulatory Summit Asia
21-22 November
Singapore
https://events.chemicalwatch.com/60014/regulatory-summit-asia-2018/programme/?dayID=69847

ONE LOGIN, MANY FEATURES

INCLUDING NEW FEATURES

'Follow My Substance'

Receive a weekly email alert whenever your substance is updated or included in:

- the Community rolling action plan (CoRAP)
- the Candidate List
- the Authorisation List
- the List of Restrictions
- a registered substance factsheet

'Save my search'

Offers you the chance to save specific settings in the Advanced Search so that you can reuse the same query next time without needing to fill in the form again.

echa.europa.eu/c/portal/login