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Newsletter

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The chemicals in our bodies come almost exclusively from food. They are largely harmless and are even essential to us. But to protect consumers, the levels of chemicals in food need to be monitored and assessed for safety. This is where the European Food Safety Authority steps in.

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Things are changing in the US with talk of 30 % cuts to the Environmental Protection Agency (US EPA). Jim Jones, the former Assistant Administrator for Chemical Safety at the US EPA, tells what does that mean for chemicals and the US-Europe cooperation.

Four important developments on biocides still this year

Autumn kicks off with the big biocides event of the year. The **Biocides Stakeholders' Day** takes place on 26 September in Helsinki. You will get the latest news from us and have a chance to hear from companies and national authorities. If you aren't coming to Helsinki, the event will be web streamed so you can follow it online. On 27 September, an IT tool training on how to use R4BP 3, IUCLID and the SPC Editor will take place.

The **enforcement of the biocides** regulation will be on the agenda, too. Since March, the biocides enforcement authorities have had their own network under ECHA's Enforcement Forum – the Biocidal Products Regulation subgroup (BPRS). The group is setting up common approaches to practical enforcement cases to help national inspectors. One of its first decisions was to join the Forum's REF-6 project to check the classification and labelling of biocidal products. Later this year, the group will also decide on their first EU-wide enforcement project devoted solely to biocides.

The recent example of the non-authorised use of the insecticide fipronil highlights how important enforcement is for protecting human health and the environment. Fipronil was used to get rid of insects in chicken breeding facilities, but its use led to eggs and chicken meat being contaminated in several European countries. The group will discuss this case in its November meeting.

Also coming up later this year will be the **criteria to identify substances with endocrine-disrupting properties**. These criteria will apply to plant protection products and biocides. If both the Parliament and the Council accept the criteria proposed by

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the European Commission this summer, the regulations will be published in the Official Journal, possibly in December. This would mean that the criteria would be applicable by summer 2018.

ECHA has been working with the European Food Safety Authority (EFSA) and the Joint Research Centre (JRC) on a guidance document to implement the criteria. Once the criteria are adopted by the European Parliament and the Council, the draft guidance will be opened for public consultation. Make sure to send your comments and help us make the guidance as useful as possible.

In December, we are also expecting the Biocidal Products Committee (BPC) to give its **first two opinions on applications for Union authorisation**. Since the entry into force of the Biocidal Products Regulation (BPR), companies have been able to apply to get biocidal products authorised across the whole EU without having to apply separately in each Member State.

Currently, there are 54 Union authorisation applications and 26 same biocidal product applications for Union authorisation in ECHA's pipeline. The first applications for Union authorisation, which are for biocidal product families, have now been evaluated by the responsible competent authority – in this case, the Netherlands – and are undergoing peer review by the other Member States.

After the BPC's opinion, the European Commission will decide on whether to grant the authorisations. This means that for the first time, authorisation may be granted through a new route that didn't exist before the BPR.

So, plenty going on this autumn. Keep following our news to stay up to date.

Jack de Bruijn
Director of Risk Management

"Coming up later this year will be the criteria to identify substances with endocrine-disrupting properties."

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Editor-in-chief: Lindsay Jackson
Editor: Päivi Jokiniemi

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

newsletter.echa.europa.eu
echanewsletter@echa.europa.eu
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What happens with potential chemicals of concern?

TEXT BY NEDYU YASENOV

Thanks to REACH and CLP, the amount of information available on chemicals is increasing. As a result, chemicals of potential concern can be better identified. But what do we do when our scientists suspect that a chemical may be of concern, but there is insufficient data to make a judgement? How do we manage the risks?

FOCUSING ON SUBSTANCES THAT MATTER THE MOST

Among all substances, ECHA, the Member States and the European Commission have agreed to prioritise those of potential concern where the impact on human health and the environment is the greatest. Together, we also identify the most effective way of confirming and addressing concerns. Priority is given to substances that have the highest exposure potential combined with their potentially hazardous properties, for example, substances that are carcinogenic, mutagenic and toxic to reproduction (CMR); persistent, bioaccumulative and toxic/very persistent, very bioaccumulative (PBT/vPvB) or endocrine disruptors.

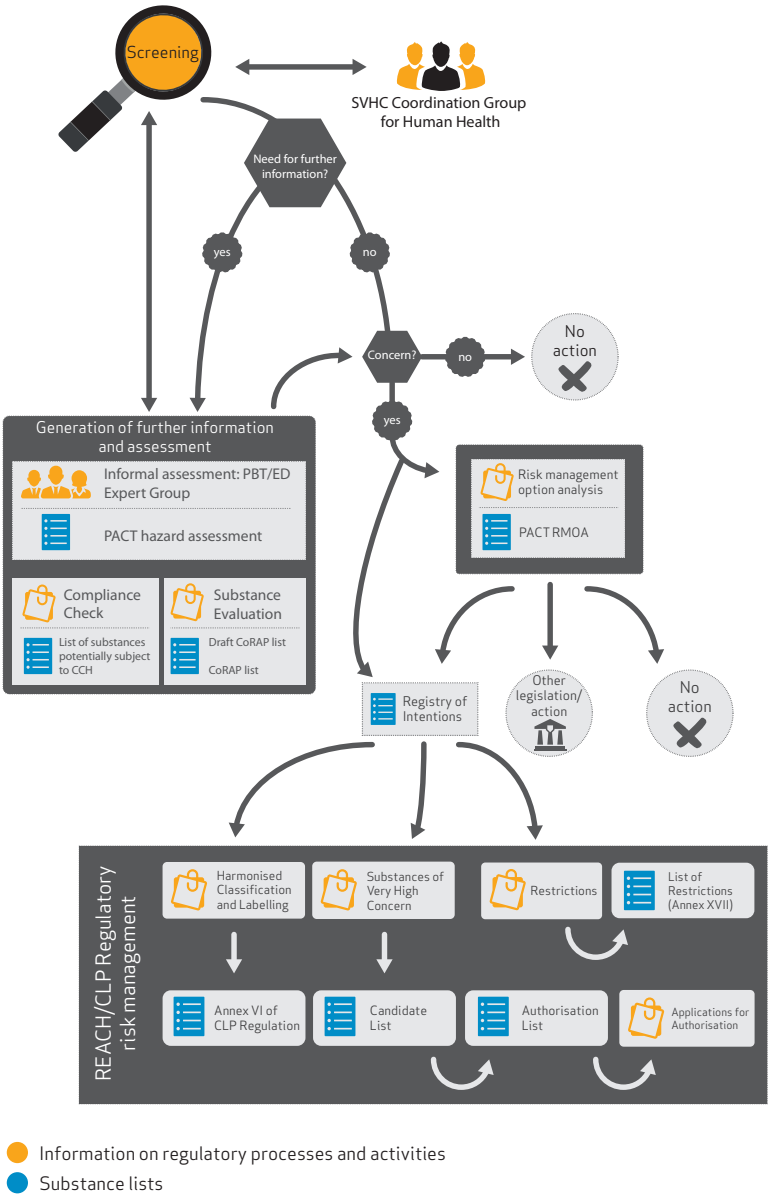
This approach (we call it our **integrated regulatory strategy**) brings together all REACH and CLP processes in a coherent way and contributes to meeting the 2020 goals of the World Summit on Sustainable Development.

SCREENING TO FIND POTENTIALLY HAZARDOUS SUBSTANCES

One central element of the strategy is the common screening. It integrates how substances are prioritised and selected for different risk management measures under REACH and CLP.

ECHA maintains the largest database on chemicals in the world with information on more than 120 000 chemicals. It is the main source of data for screening that aims to identify substances that matter the most.

Therefore, it is vital that registrants keep their dossiers up-to-date so that information on hazards and also uses, tonnages and conditions of use in the database is correct. If the information in registration dossiers is not up-to-date, authorities may target regulatory measures at the wrong substances.



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A representation of how activities and processes are linked. Substances might also enter these processes or activities at any point in time, without strictly following this flow.

The screening now looks at groups of substances with similar hazardous properties. This allows well informed decisions to be made on a higher number of substances in a shorter period than if they were examined one-by-one.

Registrants are informed if their substance has been identified as being of potential concern during the screening. If more data is needed to conclude whether the substance is of concern or not and the registrants are not complementing the data on their own initiative, then we can opt for a compliance check of the dossier, or suggest that the substance is evaluated as a whole, taking into account all the data from dossiers for that substance.

GENERATING FURTHER INFORMATION

During a **compliance check**, ECHA ensures that the registration dossier complies with the standard information requirements of REACH. If it does not, the registrant must submit the missing information, which could mean carrying out new tests, by a specified deadline.

Compliance checks mainly focus on eight hazard properties – genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation. We focus on these properties because they are the most crucial for protecting human health and the environment.

To help companies and stakeholders see which substances are being worked on, we publish a list of substances that may be subject to compliance check. This list is updated several times a year and announced in our weekly news bulletin.

There are other ways of generating data too – for example by **evaluating the substance** as a whole. Substances are selected according to risk-based criteria. Again, the aim is to detect those substances that are of greatest concern. Companies and stakeholders can see which substances Member States are going to look at in the Community rolling action plan (CoRAP). The CoRAP also indicates which Member State will conduct the evaluation.

During substance evaluation, Member States look at all the data, including the information in registration dossiers, to see if using the substance poses a risk to human health or the environment. In this case, registrants may have to send additional information or perform tests also beyond the standard registration requirements for REACH.

REGULATORY PROCESS	WHERE TO FIND INFORMATION?
Compliance check	▸▸ List of substances potentially subject to CCH https://echa.europa.eu/documents/10162/13628/substances_compliance_checks_en.pdf/
Substance evaluation	▸▸ CoRAP list https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances
PBT/vPvB assessment **ED assessment** **RMOA**	▸▸ Public Activities Coordination Tool (PACT) https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact
CLH/SVHC identification/ Restriction intentions and proposals	▸▸ Registry of Intentions https://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions
Substances with harmonised classification and labelling	▸▸ Table of harmonised entries in Annex VI to CLP https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp
Substances of very high concern	▸▸ Candidate List https://echa.europa.eu/candidate-list-table ▸▸ Authorisation List https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
Restricted substances	▸▸ Restriction List https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach

Where to find information on your substance within different regulatory processes.

Based on the additional information provided, Member States may conclude that risk management measures are needed.

CHOOSING THE BEST OPTION TO MANAGE THE RISKS

Once a concern has been identified and confirmed, ECHA and the Member States analyse the different risk management options for a particular substance or group of substances.

There are several regulatory risk management options available under REACH and CLP, i.e. harmonising the classification and labelling of the substance, requiring its use

to be authorised, or restricting its placing on the market or use.

A risk management option analysis (RMOA) can also conclude that no risk management measures are needed at that time. This could be the case, for example, where the identified concern is found to be already addressed under another piece of EU legislation.

The substances for which ECHA and the Member States are considering the best risk management option can be found in the Public Activities Coordination Tool (PACT) on ECHA's website. This list is useful for many stakeholders. Those companies using a listed substance can start thinking if it is possible to replace it with a safer alternative. Those companies having an alternative to a listed substance can further plan how to market it. It also gives companies and concerned citizens more time to prepare their input for the public consultation on the substance, which runs during the formal risk management processes.

REGULATORY RISK MANAGEMENT

Substances that fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity (CMR) or respiratory sensitisation, should normally be subject to **harmonised classification and labelling** (CLH). The classification is legally binding for all suppliers who place the substance on the EU market – on its own or in mixtures.

Sometimes companies have a strong reason to continue using substances of very high concern (SVHCs). However, these substances are prime candidates for being made subject to **authorisation**, particularly if they are widely used. If these substances are placed on the Authorisation List, their use requires a specific permission from the European Commission.

Substances with harmonised classifications are considered SVHCs. These include those categorised as CMR 1A (known carcinogens based on human evidence) or 1B (presumed carcinogens based on animal studies); persistent, bioaccumulative or toxic (PBT); very persistent, very bioaccumulative (vPvB); or substances of equivalent level of concern to these, for example, due to endocrine-disrupting properties.

If a chemical poses an unacceptable risk that needs to be addressed at EU level, a **restriction** on the manufacture, placing on the market and/or uses of the substance of concern may be proposed by a Member State or ECHA, at the request of the Commission.

The **Registry of Intentions** includes all notifications of intention to submit a harmonised classification and labelling, SVHC identification or restriction dossier. The notification is done by a Member State or ECHA, at the request of the European Commission. It is updated regularly and gives stakeholders time to prepare their comments for upcoming public consultations for which an intention is registered.

ECHA'S AIM IN MANAGING POTENTIAL CHEMICALS OF CONCERN

- To efficiently select substances that raise potential concerns. This often requires generating further information to assess their safety so that any remaining concerns can subsequently be addressed through the most suitable risk management measure.
- To make the outcomes of the evaluation and risk management processes more transparent for stakeholders and registrants.
- To ensure that the different actors (industry, NGOs and authorities - Member States, the European Commission, ECHA) can intervene in an appropriate and timely way so that chemicals of concern are addressed as soon as possible.

Further information:

ECHA's integrated regulatory strategy
https://echa.europa.eu/documents/10162/22837330/mb_44_2016_regulatory_strategy_en.pdf/

Addressing chemicals of concern
https://echa.europa.eu/addressing-chemicals-of-concern

Potential routes to regulatory risk management (infographic)
https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

Annual reports: SVHC Roadmap to 2020 implementation
https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

Screening
https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

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

Substance evaluation
https://echa.europa.eu/regulations/reach/evaluation/substance-evaluation

Harmonised classification and labelling
https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

Substances of very high concern identification
https://echa.europa.eu/support/authorisation/substances-of-very-high-concern-identification

Restriction
https://echa.europa.eu/regulations/reach/restriction

Guest column | Barbara Gallani, EFSA

Chemicals in the food chain – what do you need to know?

Chemicals are the building blocks for all life. All living organisms – including people, animals and plants – are made of them.

The chemicals that make up our bodies come almost exclusively from food. The chemicals in our food are largely harmless and are even essential and desirable – for example, nutrients such as carbohydrates, proteins, fats and fibre are composed of chemical compounds. These chemicals contribute both to a rounded diet and to our eating experience by affecting how our food tastes, smells and feels.

HOW DO MAN-MADE CHEMICALS GET INTO OUR FOOD?

In addition to the natural chemicals in food, additives play an important role in food production and preservation. They are added to food for specific purposes. For example, some can prolong the shelf life of foods, making them safer to eat for longer, while food colours can make food more appealing.

However, chemical substances can also end up in food unintentionally. For example, the bottles your drinks come in and the plates your food is served on contain chemical substances, which can migrate into the food.

The packaging used to keep food fresh and easy to handle needs to be resistant to fat and water and have non-stick properties – this has often been achieved by using fluorinated chemicals such as bisphenol A. So, it is important that we study the ongoing research on the effects of chemicals like these on human health.

Residues of chemicals used to fight diseases in farm animals or crops – like pesticides and weedkillers – can also end up in our food.

They can also enter food as a result of decontamination treatments such as chlorine-washed chicken (which is currently not allowed in the EU), or because of heating during food production. A well-known example of the latter is acrylamide, a substance produced naturally when starchy food is cooked at high temperatures. This process helps to enhance the flavour of these foods but the acrylamide can potentially increase the risk of developing cancer for consumers.

The food chain can be contaminated by both naturally occurring and man-made chemical compounds that are present at various levels in the environment, for example, in soil, water and the atmosphere.

These could be industrial pollutants such as dioxins, and toxins produced by plants or fungi or marine crustaceans. A variety of metals can be found naturally in the environment or as a result of human activity.

Barbara Gallani.

These can then enter the food chain and be potentially harmful for human or animal health. For example, mercury is often found in the fat of fish and therefore some population groups, such as children, pregnant women and women of child bearing age, are recommended to limit their intake of these fish.

HOW ARE YOU PROTECTED?

There are lots of things you can do to ensure that you have a healthy diet, in particular by varying what you eat regularly. But when it comes to avoiding harmful chemicals in our food, we rely on scientists to analyse research and politicians to take decisions to protect us. The good news is that the system of food safety in the EU is one of the strongest in the world.

To protect consumers, the levels of chemicals in food need to be monitored, measured and assessed for safety. This is where the work we do at the **European Food Safety Authority, EFSA**, plays a key role. One of our tasks is to analyse and then produce reports, such as the annual report on pesticide residues.

For each individual chemical, scientists then review the data on its toxicity to set a safe level for human health, animals and/or the environment. We compare this with the levels of the chemical that we are likely to be exposed to – for example through food – to predict potential risks.

The European Commission and the Member States of the EU then use this scientific advice on chemicals in food to regulate them. For example, they decide if a substance should be authorised for use in food, how much of it can be safely added in different food types and what kind of labelling is required. These measures

contribute to protecting the health of consumers from possible harmful effects.

Sometimes food products are withdrawn from the market or their use is limited. This can happen, for instance, if certain plant or marine toxins are found to be present in unacceptably high amounts.

MORE COMPLEX MIXTURES REQUIRE MORE CHALLENGING ASSESSMENTS

But in today's world, we are not simply exposed to individual chemicals. Humans, animals and the environment are constantly exposed to multiple chemicals from a variety of sources – and that makes evaluating their toxicity more complex. Some chemicals become more toxic when combined with others, but others become less so. Therefore, not only do we have to look at increases or decreases in the toxicity of the chemicals, but we also have to assess the body's ability to detoxify and eliminate them.

To meet these challenges, EFSA's scientists are developing new frameworks and tools – what we call Mix-Tox – for assessing the risks posed by chemical mixtures and their cocktail effects on humans and the environment. It is not an easy task to understand how combined chemicals behave since the number of combinations is almost infinite.

Initiatives such as Mix-Tox will help to ensure that EFSA's advice to decision-makers keeps pace with scientific knowledge and will continue to allow European consumers, animals and the environment to enjoy one of the highest levels of food safety in the world.

Barbara Gallani is the Head of Communications & External Relations at the European Food Safety Authority (EFSA).

EFSA is a European Union agency based in Parma, Italy. It was set up in 2002 to be a source of scientific advice and communication on risks associated with the food chain.

https://efsa.europa.eu

Murano: removing arsenic brings benefits to health and the environment

INTERVIEW BY PAUL TROUTH

Arsenic trioxide used to be one of the most important chemicals used in Murano, Italy to create their world-famous artistic glass. However, the substance was included in the Authorisation List in February 2012 with a sunset date on 21 May 2015. The glassmakers had to make a difficult decision – to apply for authorisation or to substitute. They opted for the latter. We spoke to *Giorgio Cipolla*, Coordinator of surveillance activities at the REACH Regional System, to ask about the impact that the substance's removal has had on the region.

Historically, Murano Island in Italy has used a large amount of arsenic trioxide (As_2O_3) to produce its renowned artistic glass. Indeed, in the year before the substance's sunset date – the date by which the use of the substance is prohibited unless an authorisation is granted – 8 000 kilograms of the substance were used.

Back in 2014, we published a case study about attempts to remove arsenic trioxide from artistic glass made in Murano. Many of the glassmakers in the region are small enterprises and artisans. When the substance was placed on the Authorisation List, they had a difficult decision to make. Choosing to substitute or apply for authorisation both required resources that were already limited.

"Traditionally, each furnace had a secret recipe for their own artistic glass products. For some of these, arsenic trioxide was an essential ingredient used to refine and decolour the glass, but also to give it a finer clarity," Mr Cipolla says.

INTERMEDIATE OR NOT?

It was not immediately clear that the glassmakers would need to replace arsenic trioxide as they felt that the substance was being fully consumed during the chemical processing.

"Its use was considered as an intermediate by the glass trade association as the arsenic compounds are completely consumed during the glassmaking process and are no longer present in the final product," Mr Cipolla explains.

However, the Italian Ministry of Health and ECHA disagreed and concluded that using arsenic trioxide as a refining agent could not be considered as an intermediate use.

There were a number of reasons for the glassmakers not to apply for authorisation. Firstly, most of their furnaces are small scale and not big enough to justify the costs of requesting an authorisation for such a specific use. Secondly, it was felt that it would be too difficult to apply the technical requirements for achieving an authorisation to the traditional processes in place for producing artistic glass, particularly those related to using substances of very high concern in closed cycles.

In the end, glassmakers opted to substitute the substance.

So, as no application for authorisation was submitted, Italian enforcement inspectors warned the glassmakers not to use the substance after the sunset date of 21 May 2015.

POSSIBLE SUBSTITUTES

Once the decision not to apply for authorisation was made, the glassmakers had to find alternatives. Some substitutes for the substance had already been identified.

Two substitutes had previously been proposed: cerium oxide and ground granulated blast furnace slag (GGBS). However, they were seen to be too expensive and not always meeting the production requirements.

"While the use of alternative substances reduces the occupational health risks and improves the environment, the glass does not have the same fine clarity that is formed when using arsenic trioxide," Mr Cipolla says.

Other alternative substitutes include a mix of antimony trioxides and nitrate or carbonates of alkaline metals. As has been their tradition, the glassmakers' recipes remain confidential. Some companies are using the alternative chemicals, others have found a way to adjust


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Giorgio Cipolla.

their process so they do not need to use arsenic trioxide – the quality of the glass is a bit different, but considered acceptable. Others have stopped producing the type of glass for which arsenic trioxide was used.

CONTROLLING ARSENIC LEVELS

Arsenic trioxide is typically in the form of white, glassy lumps or as a crystalline powder resembling sugar. It has no odour or taste, but when it burns, it releases fumes and arsine gas, which is highly toxic.

After the substance's inclusion in the Authorisation List, local health authorities informed the glassmakers about the suspected health concerns related to its use. Moreover, all glassmakers were invited to fill in a detailed questionnaire on the processes applied, including information about arsenic trioxide and other arsenic compounds (i.e. their specific uses, quantities in use and storage).

"The authorities campaigned to inform about the ban of arsenic trioxide and held specific meetings about the steps being taken to control it," Mr Cipolla says. The aim was to control and be able to inspect the levels of the substance still being used and found in the environment.

Information was gathered on 300 companies producing glass in Venice. 104 companies were producing artistic glass and 18 of these (17.3 %) were using arsenic trioxide in 2014.

ENVIRONMENTAL BENEFITS

The shift from arsenic trioxide has resulted in tangible benefits for the environment. In 2013, air monitoring sampling stations had been installed throughout the Veneto region. The Veneto Environmental Protection Agency monitored the levels of arsenic in the air in Murano from June to November 2014 (before the sunset date), September to November 2015 and July to December 2016 (both after the sunset date).

The data from the environmental monitoring stations (one located in the neighbourhood of the primary school of Murano) showed a dramatic decrease in arsenic levels.

The concentrations at these stations dropped from an average of 200 to 4 nanograms/m^3 bringing the levels below the target annual limit of 6 ng/m^3 of arsenic in the EU.

"Concerning the environmental impact, there is a direct improvement in the air quality. After the sunset date, there has been a dramatic decrease with the recorded values lower than the threshold limit allowed for arsenic in Europe. In contrast, some previous data had even shown peak concentrations above 800 ng/m^3. At the same time, epidemiological studies are being done to check the wider impacts on human health," Mr Cipolla explains.

INSPECTIONS CONTINUING THROUGHOUT 2017

Since December 2015, 15 inspections have been carried out to check that the substance is no longer being used.

"Inspections include checking documents and screening raw materials to detect elements of the banned substance. If arsenic is detected in quantities of more than 1 000 parts per million (ppm), a sample is taken and analysed in an accredited laboratory. If arsenic's presence is confirmed to be higher than 0.1 %, it is a criminal offence and the regional and national authorities are notified," Mr Cipolla explains.

"44 samples were screened and seven have been further scrutinised in the laboratory. Two glassmakers were found to still be using arsenic trioxide to produce their glass products," he adds. The companies that have been found in breach of REACH requirements on authorisation have been imposed an administrative sanction and the arsenic trioxide has been confiscated. Since breaching authorisation requirements is considered a criminal offence, the cases have also been deferred to court.

The programme of inspections will continue during 2017 and extend to the whole Veneto region, not only Murano Island.

REACH AS AN INCENTIVE

The inclusion of arsenic trioxide into the Authorisation List forced glassmakers to find alternatives to replace the ingredient, while trying to maintain the quality of their glassware. At the same time, human health and the environment have been protected.

"We absolutely consider REACH as the best way to ensure high levels of human health and environmental protection because it gives us information on the real properties of chemicals and how to use them safely along the whole supply chain," says Mr Cipolla.

While big companies have the resources and tools to invest in improving their processes, SMEs are in danger of being left behind as their capacity to do so is extremely limited.


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Historically, Murano Island in Italy has used a large amount of arsenic trioxide to produce it's renowned artistic glass.

"Replacing substances used for centuries is not easy. SMEs naturally consider it as a burden rather than a positive thing. REACH should avoid any kind of discrimination between small and big companies by offering more support to SMEs. In this case, the smaller companies (often artisans) were faced with an emergency situation to eliminate the substance and replace it quickly while the larger companies had the capacity to analyse the situation and plan their replacements properly," Mr Cipolla tells.

Giving better support for SMEs so they can improve the substitution process for themselves, for instance, by helping them interact with university or research centres or work more closely with expert stakeholders, could help to change this mindset.

"It could be interesting to think about a programme of incentives at European level, to help SMEs develop new ways of production and support them to preserve production like the famous fine art glass in Murano," Mr Cipolla concludes.

Further information:

Murano glass: substituting to stay in business
ECHA Newsletter, April 2014
https://newsletter.echa.europa.eu/home/-/newsletter/entry/2_14_murano-glass_substituting-to-stay-in-business

Contributions to this article were provided by Giorgio Cipolla, Maria Gregio and Massimo Peruzzo from the Prevention Department of the Local Health Authorities of Veneto Region; and Gianni Formenton, Giovina Gallo, and Roberto Lava from the Regional Environmental Protection and Prevention Agency.

ARSENIC TRIOXIDE

Arsenic trioxide (As_2O_3) (CAS No. 1327-53-3, EC No. 215-481-4) was used in artistic glass production as a refining agent that helped to remove bubbles.

The substance was included in the Authorisation List with the latest application date on 21 November 2013 and a sunset date of 21 May 2015.

In situ generated active substances notified in 2016 – deadlines approaching

TEXT BY PÄIVI JOKINIEMI

A biocidal active substance that is generated where it is used is called an "*in situ* generated" active substance. If yours is not being evaluated under the Review Programme, but you notified it in 2016, then the next step is to submit an active substance application to ECHA. This must be done within two years of the acceptance of your notification. Read what to keep in mind when preparing your application.

DEADLINES APPROACHING AND WORK TO BE DONE

If you market an *in situ* generated active substance which is not under evaluation in the Review Programme, then you should have notified it to ECHA already in 2016, where possible.

If you did that in time, you were given two years to submit a full application for an active substance approval.

That application will allow you to continue using the *in situ* generated active substance until the evaluation of the substance in the Review Programme has been completed.

If you have not already started to prepare your application, it is time to start now.

The deadline for submitting the active substance application was specified in the letter that confirmed the compliance of your notification. You can also find the deadline in the list of compliant notifications.

WHAT IF MY SUBSTANCE IS NOT ON THE LIST?

If you failed to notify ECHA about your substance, you may still apply for its approval. However, you cannot market or use such a precursor/*in situ* active substance combination until the approval has been granted and the biocidal product has been authorised.

If your precursor/*in situ* active substance combination is listed but you do not submit the application for active substance approval by the given deadline, the European Commission will give a non-approval decision.

This means that you will not be allowed to market or use your precursor/*in situ* active substance combination from the date indicated in the legislation.

WHERE CAN I FIND ADVICE?

You need to assess the risks of your substance (and the manufacturing process) on human health and the environment. Details on what information you need to provide can be found in BPR Annex II.

You may also find it useful to look at the Recommendation of the BPC Working Groups related to *in situ* generated active substances.

More help is available on ECHA's web pages for *in situ* generated active substances as well as in answers to frequently asked questions.

If you need one-to-one advice, you can contact the competent authority that has agreed to evaluate your active substance application.

The deadline for submitting the active substance application was specified in the letter that confirmed the compliance of your notification.

TIPS

1. Collect and evaluate the existing data on your substances. If any data is missing, can you generate it through, for example, reading across from a similar substance or group of substances? If not, you need to send an inquiry to ECHA before carrying out any new tests.

2. Describe the process by which the active substance is generated *in situ*. This needs to include the conditions and their variations, and how these affect the composition of the technical active substance generated *in situ*.

3. When preparing the risk assessment, you need to assess both the pure active substance generated *in situ* as well as all the substances from which you make the active substance (the precursors) and any reaction by-products. You do not need to do risk assessments for precursors that are substances or mixtures that

In situ generation means that one or more substances, which are called precursors, react together to generate a new technical active substance in the same place where it will be used.

cannot themselves be authorised as biocidal products, for example, air or seawater.

4 You need to assess the risk to humans. Workers may be exposed to the precursors (before and during *in situ* generation) and the substances generated *in situ* (during and after *in situ* generation). You need to assess the risks to human health at all these stages. You also need to assess if the unreacted precursors or any of the reaction by-products affect the toxicity of the active substance generated *in situ*. Consider too whether any members of the public could be exposed to the *in situ* generated substance during the production process – perhaps there is a release to the air?

5 You also need to assess the risk to the environment. The environment is exposed to the precursors mainly after the generation of the *in situ* active substance, if they remain unreacted. Nonetheless, it is important to assess if any of the components of the technical active substance generated *in situ* are toxic to the environment. However, under certain conditions, you may not need to do the risk assessment for some of the components. The recommendation of the BPC Working Groups explains these exceptions.

6 Once you have your information, put it in a IUCLID dossier, export it and submit it to ECHA through R4BP 3. Remember that you need to create a separate substance dataset for the *in situ* generated active substance, each of the precursors and any of the reaction by-products.

7 Communication related to your application happens through R4BP 3, so remember to log in also after you have finalised your submission.

Further information:

Recommendation of the BPC Working Groups
https://echa.europa.eu/documents/10162/13564/situ_as_precursors_wg_recommendation_+2017_en.pdf

In situ generated active substances
https://echa.europa.eu/regulations/biocidal-products-regulation/in-situ-generated-active-substances

BPR Legislation
https://echa.europa.eu/regulations/biocidal-products-regulation/legislation

List of compliant notifications
https://echa.europa.eu/documents/10162/17287015/list_compliant_notifications_en.pdf/

Biocidal Products Regulation – Q&A
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/Biocidal+Products+Regulation/In-situ+generated+a.s

National and ECHA helpdesks
https://echa.europa.eu/support/helpdesks/

R4BP 3
https://echa.europa.eu/support/dossier-submission-tools/r4bp

TERMINOLOGY

***In situ* generation** – where one or more substances (precursors) react together to generate a new technical active substance in the same place where it will be used.

***In situ* generated active substance** – the pure active substance generated.

Technical active substance generated *in situ* – the pure active substance, as well as reaction by-products, unreacted precursors and other impurities (e.g. contaminants from precursors).

Precursor – a substance or a mixture from which the active substance is generated *in situ*. Unreacted precursors may be present as impurities in the composition of the technical active substance generated *in situ*.

Review Programme – the programme of review of biocidal active substances that were on the market in biocidal products on 14 May 2000.

Reaction by-products – formed during generation of the active substance, considered as impurities.

Too many companies are not updating their REACH and CLP data

TEXT BY HANNA-KAISA TORKKELI

A study looking at companies' intentions to update their REACH registrations and CLP notifications tells a worrying story: updating data on chemicals is not a priority – unless prompted by ECHA.

Around 64 % of the dossiers submitted to ECHA since 2008 have never been updated. And those that have been, were mostly updated only after a letter from ECHA. Given that reliable data on chemicals is the foundation of safe use and the management of risk from dangerous substances, this is putting the protection of human health and the environment in jeopardy. Without data that reflects the reality, risk management becomes impossible.

Consequently, improving the data is one of ECHA's priorities. With many actions already underway (e.g. screening dossiers, completeness checks), the results of the study will help ECHA and the European Commission to analyse more closely what is needed to nudge companies into being more proactive in updating their REACH and CLP information.

FOUR MAIN SHORTCOMINGS

The study suggests that there are four issues that affect companies' willingness and readiness to update their data:

1. **Seeing registration as the end of the process**

Many companies have the perception that receiving their registration number is the end of the REACH registration process and that no further work is needed. This perception is worsened, for example, by the fact that the fees payable (for registering and getting access to data) are one-off payments. It is also difficult for the lead registrant to get contributions from the SIEF members when they are trying to update the dossier.

2. **Lack of clarity on what needs to be done, when and by whom**

The study respondents were unclear about what needs to be updated according to Article 22 of REACH. It places an obligation on the individual to decide when an update is needed – mentioning that it needs to be done based on 'new information' without 'undue delay'. As REACH is based on the 'one substance, one registration' principle, the responsibility for updates is ambiguous. Is it the lead registrant's task alone or should the other SIEF members support? Or are updates the responsibility of each individual registrant?

3. **Limited resources**

The costs of updating can be high and the benefits non-existent. In particular, small and medium sized enterprises (SMEs) felt that REACH is just a regulatory burden. The respondents also signalled a 'REACH fatigue' with a great deal of effort and cost already spent on the original registration.

4. **Limited use of the whole set of data**

The fourth issue has to do with the practical value of the data in the dossier. The respondents felt that the dossier as a whole contains highly technical information better suited for academics and regulators than for downstream users, who benefit more from up-to-date CLP classifications and exposure scenarios. They mentioned that the downstream users want good quality safety data sheets and that the focus should be on those.

RECOMMENDATIONS

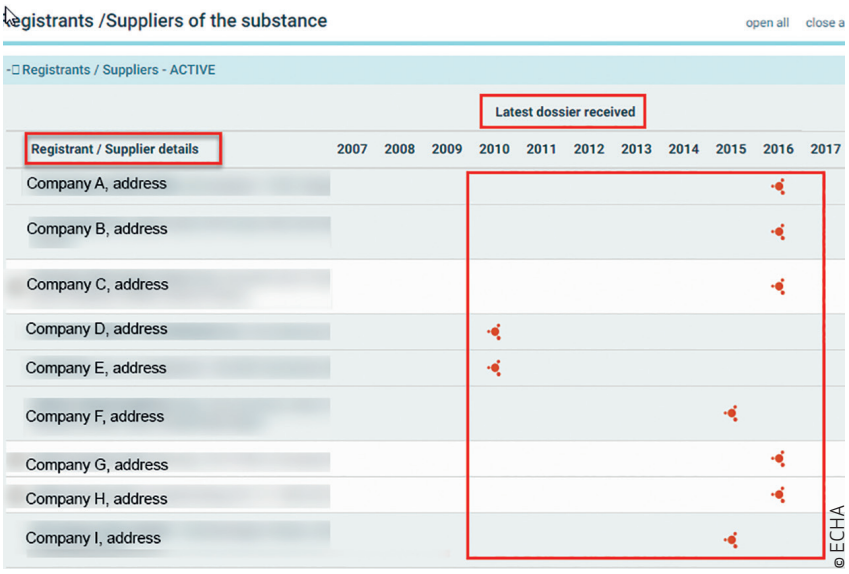
The study suggests actions for ECHA, trade associations and policy makers.

1. **Clarity on what needs to be updated**

ECHA should clarify Article 22 requirements and provide additional

LEGAL OBLIGATION TO UPDATE

Article 22 of REACH says registrants must update their dossiers 'without undue delay' whenever there is a material change or new information comes to light. This includes, for example, new chemical safety reports (CSR), changes in uses and tonnage as well as new toxicity data.



ECHA's chemicals database now shows when the registrant last updated their dossier. The updates are marked with the IUCLID symbol in the database.

guidance for SMEs (e.g. a clear overview of what the lead registrant can ask from the members).

2. **A clear definition of who is responsible for the updates**

For example, improving ECHA material and guidance on the roles of lead and co-registrants.

3. **Improved understanding of why updates are important**

Trade associations and ECHA are encouraged to increase awareness of the benefits of updating dossiers and risks of not doing so.

4. **An implementing act to make the update requirement clearer and enforceable**

The European Commission should consider a new implementing act, which would provide detail on clear circumstances and fixed intervals when dossiers need to be updated.

WHY ARE UPDATES IMPORTANT?

Poor data means poor quality protection of human health and the environment and poor risk management. Registration dossiers are your business asset. Good quality, up-to-date information helps appropriate communication in the supply chain and makes sure that adequate safe use advice is given further down the supply chain, eventually to end users like consumers and workers.

For ECHA and the national authorities, good data enables effective decision making on further risk management measures and leads to better information being published for the general public.

Further information:

Study report
https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf/

Study finds companies lack incentives for updating their REACH registrations,
News item 4 September 2017
https://echa.europa.eu/-/study-finds-companies-lack-incentives-for-updating-their-reach-registrations

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

THE STUDY

A study to gather insights on the drivers, barriers, costs and benefits of updating dossiers was conducted from April-June 2017. ECHA stakeholders responded to an online questionnaire with volunteers interviewed in depth. The online questionnaire had 322 respondents. Telephone interviews were done with 20 organisations of which 13 were large companies, four SMEs and three trade associations.

The study was commissioned by ECHA and carried out by Amec Foster Wheeler Environment and Infrastructure UK Limited in association with Peter Fisk Associates Limited.

DID YOU KNOW?

Updates visible in the chemicals database

Since May 2017, ECHA's chemicals database shows the year of the latest dossier received by a registrant. You can find that by searching for the chemical and going to the registered dossier data.

Under the section *General information – Registrants/Suppliers of the substance*, you can see a list of registrants and an indication of the registrants who have updated their dossier and when.

Chemical safety post-Trump?

INTERVIEW BY PÄIVI JOKINIEMI

Things are changing in the US with talk of 30 % cuts to the Environmental Protection Agency (US EPA). What does that mean for chemicals and the US-Europe cooperation? We met with *Jim Jones*, the former Assistant Administrator for Chemical Safety at the US EPA, to discuss the political changes in the US, the reform of the Toxic Substances Control Act (TSCA) and the future for chemical safety.


© JIM JONES

Jim Jones.

The TSCA reform in summer 2016 – its first for nearly 40 years – was supported by both the Republicans and Democrats. The new law says that the government is obliged to examine chemicals in priority order according to strict deadlines and clear safety standards. This makes the law stronger and more efficient than the previous version. "If the basic principles of the law are not met, the government can and will be challenged in court. If it hasn't taken care of its duties as the law states, it will lose, because the deadlines are really quite clear," Mr Jones explains.

But a lot has happened in US politics and leadership since the new law was passed. According to Mr Jones, the changes are likely to have an impact on its implementation. "If you listen to the rhetoric of the Trump administration, they are not interested in regulating. But under TSCA, you are required to regulate if you find a chemical that doesn't meet the safety standards. So, it will be interesting to see how they manage that reality when their aspirations run counter to what is required by law".

Nevertheless, he believes that the TSCA reform will be a success and will do what it was designed to do – to improve chemical safety. "One of the things I am pleased about is that the law was written well enough so that it will survive whether its purposeful wrong-doing on the part of the executive branch or just early struggles to get things started. It has clear enough deadlines with clear enough standards that it will ultimately survive this time and be effective," Mr Jones says.

WHAT ABOUT THE 30 % CUTS?

The potential cuts to the US EPA budget are something that Mr Jones is worried about. He reminds, however, that so far the proposed cuts are just that – proposals. In the end, Congress will decide if and how big the cuts will be.

Although the chemical safety programme is one of the few programmes that the new administration have said they would save from the cuts, any larger cut to the EPA as a whole would, without a doubt, harm all its activities. "If the reductions in the EPA are remotely close to the 30 % that the new administration has proposed, the chemicals programme will not be immune to the disruption it creates," he says.

Mr Jones is particularly concerned about the cuts planned to the research arm of the EPA because those would hurt the chemicals programme the most. The research work has enabled the chemicals programme to develop new methods that can be used to assess risks of chemicals. "If we are ever really going to get to grips with tens of thousands of chemicals, we are going to need more of the cutting edge tools that can help us to evaluate them without doing more animal testing. These tools may not be operational this year, next year or even in the next five years, but our successors will need them in the future. If funding for the research is cut now, it will affect the long-term viability of chemical safety programmes".

BRINGING BACK THE TRUST ON SCIENCE

Bringing back people's trust in government science is something that Mr Jones sees as a critical issue to address. "The majority of people have so far agreed that chemical safety should be based on science that informs risk management. That can only work when civil society broadly supports that. However, when people start saying that they don't trust what the scientists are doing, over time it will erode the government's ability to do their job," he explains.

Instead of pressure and doubt, Mr Jones hopes to see more collaboration between the different groups. "It is important that everyone gets their voices heard on the science because the government is not always right in their decisions. In

the best case, we learn something from engaging with companies, the citizens and the academic community, as long as everyone takes their own responsibility".

WHAT ABOUT REACH?

According to Mr Jones, American companies that have obligations under REACH are generally well aware of their responsibilities. "My sense is that the chemical manufacturers in the United States are in pretty good shape when it comes to understanding the REACH requirements. I think the challenge is mostly the downstream companies trying to understand what their roles and responsibilities under REACH are," Mr Jones says.

"In many other aspects, downstream companies are already telling their suppliers exactly what they expect from the components they buy, for example, when it comes to their functionality and meeting safety standards. Knowing what chemicals they contain needs to be added to that list, to become a new dimension, something that they will have to know in the future. But it will not happen overnight," he explains. To get there, Mr Jones suggests that the government supports downstream companies by educating them about the importance of chemical safety.

IT'S ALL BASED ON SCIENCE

It is quite common to talk about the American and European chemical regulations as fundamentally different systems. REACH requires companies to create at least a minimum dataset for their substance upfront, whereas US companies are not required to generate any data until the government has identified their substance as a priority.

However, according to Mr Jones, this is an oversimplification and we should focus more on what the two systems have in common – which is the underlying premise of risk assessment based on science. "I have always seen this as an opportunity for collaboration. Although we may end up with different risk management measures because of the differences in the laws and their interpretations, the science that underlies the decision is the same," he points out.

Apart from the chemical safety evaluation, Mr Jones says that the Americans have learnt a lot about the restrictions that have been put in place in Europe. "Since Europe is ahead of us in restricting chemical use, it is very helpful to learn what is actually feasible from, for example, the point of view of the cost effectiveness of alternatives".

ROBUST STUDY SUMMARIES ARE NOT ENOUGH

Sharing data is one of the areas where the two regulatory systems could support each other more. As an example, Mr Jones mentions sharing more than just the robust study summaries. This would help risk assessment and add credibility to the decisions taken.

"In the US, we have long been suspicious of simply relying on the robust study summary as the basis of any decision that we make. We learnt long ago that the way companies report study results doesn't always match what would happen if an independent authority did the evaluation," he points out.

Given that companies own the data, Mr Jones calls for closer cooperation with industry to make it possible for different regulatory actors to get access to all the relevant information, not just the robust study summaries. "I think that these are manageable issues. Nobody wants companies to redo all the studies. There is enough common ground to help solve the problem," he concludes.

Further information:

United States Environmental Protection Agency
https://www.epa.gov/

The Frank R. Lautenberg Chemical Safety for the 21st Century Act
https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act

Chemicals under TSCA
https://www.epa.gov/chemicals-under-tsca

DID YOU KNOW?

Jim Jones was appointed in December 2011 as the Assistant Administrator for Chemical Safety at the US Environmental Protection Agency (EPA) by former US President Barack Obama. He continued in the post until the end of Obama's presidency on 20 January 2017.

Before that political appointment, he was a civil servant for 25 years, working most of the time on the chemical safety of pesticides and commercial chemicals.

After his departure from the US EPA, he has been working as a consultant, focusing on chemical safety issues, and since July 2017 as the Executive Vice President of Strategic Alliances & Industry Relations at the Consumer Specialty Products Association.

Human biomonitoring: which unexpected chemicals are in our bodies?

TEXT BY PAUL TROUTH

We are all exposed to a complex mixture of chemicals at home, at work, in the products we buy, the food we eat and in the water we drink. A new joint initiative by the European Commission and 26 countries, co-funded under Horizon 2020, will use human biomonitoring to better understand how we are being exposed to chemicals and how our health might be impacted.

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Biomonitoring measures the body burden of toxic chemicals, their metabolites and markers of subsequent health effects in human bodily fluids or tissue. This is usually done by taking samples of blood or urine and measuring the presence of chemicals.

Over the next five years, the European Human Biomonitoring Initiative (HBM4EU) will generate information on our exposure to chemicals as well as the health effects caused by this exposure.

Biomonitoring measures the body burden of toxic chemicals, their metabolites and markers of subsequent health effects in human bodily fluids or tissue. This is usually done by taking samples of blood or urine and measuring the presence of chemicals. This work could result in some important developments:

- Giving information to medical practitioners to help them select the right medical treatments for their patients.
- Helping authorities to advise the public about what they need to do to reduce their exposure.
- Understanding the link between chemical exposure and health.

The data generated will be of interest to policy makers and regulators, scientists, journalists, companies manufacturing and using the chemicals involved and the citizens of Europe.

CHEMICAL EXPOSURE AND HEALTH

For many chemicals, the health impacts of exposure and the ways in which people become exposed remain uncertain. There is even more uncertainty about the impact of exposure to mixtures of chemicals (the cocktail effect) and emerging substances. Increasing the knowledge we have on this is crucial to continue providing a high level of scientific input into policy making.

The results of the biomonitoring will be combined with health information to gain a better understanding of exposure-response relationships. The initiative will develop and use modelling tools that will help identify the most likely sources of exposure to certain groups of chemicals.

Health impacts across different age groups and genders will be looked at, and socio-economic status, environmental conditions, lifestyle and diet will also be taken into account. The information generated from the biomonitoring will be used to investigate any causal links between the chemicals we are exposed to and the impact they have on our health.

HARMONISED BIOMONITORING ACTIVITIES IN EUROPE

At present, there is little comparable information from the Member States on our exposure to chemicals. This is a major obstacle in the pursuit of reliably assessing and managing chemical risks.

The HBM4EU initiative will result in harmonised data on the levels of human exposure to chemicals and mixtures across Europe.

The research will tackle current policy questions and then form a scientific basis to inform policy makers and help them steer decisions towards prioritising the safe use of chemicals and protecting human health.

The close collaboration of scientists and policy makers can ensure

that the research truly reflects and addresses current societal concerns.

PRIORITY SUBSTANCES

The initiative will focus on different substances during the five-year period. This prioritisation will take account of whether a substance is known to be of concern to human health and whether there is existing evidence of exposure at EU level.

ECHA is closely following the project and is helping to identify and prioritise substances and substance groups for biomonitoring.

The first prioritisation round resulted in nine groups of substances that will be the focus in 2017 and 2018. The substance groups are:

- phthalates and Hexamoll® DINCH – phthalates are mainly used as plasticisers (substances added to plastic to make them more flexible, transparent, durable or sustainable). Hexamoll® DINCH is a non-phthalate plasticiser;
- bisphenols – a group of widely-used chemicals used in certain types of plastic (polycarbonate) and synthetic resin (epoxy resin). They can be found in products made of clear, hard plastic, such as water bottles, DVDs and credit cards;
- per-/polyfluorinated compounds (PFCs) – used universally in the production of teflon and related fluorinated polymers. They have been used to make fabrics water and stain resistant and also in fire-fighting foams;
- flame retardants – added to manufactured materials, such as plastics and textiles, and surface finishes and coatings. They inhibit or delay the spread of fire by suppressing the chemical reactions in the flames or by forming a protective layer on the surface of a material;


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- cadmium and chromium – cadmium is a common component of electric batteries, pigments, coatings and electroplating; chromium is primarily used to form metal alloys, but is also used as a wood preservative, for tanning leather, and as a refractory material;
- polycyclic aromatic hydrocarbons (PAHs) – found naturally in the environment and are common by-products of combustion processes. PAHs are a natural component of most fossil fuels. Most PAHs in ambient air are due to man-made processes including burning fuels such as coal, wood, petroleum, petroleum products, or oil; burning refuse, used tires, polypropylene, or polystyrene; producing coke; and motor vehicle exhausts.
- anilines – a group of organic bases used to make dyes, drugs, explosives, plastics, photographic and rubber chemicals;
- chemical mixtures; and
- emerging substances.

More rounds will be conducted during the five-year project to identify further substance groups for 2019-2020.

Further information:

European Human Biomonitoring Initiative (HBM4EU)
https://www.hbm4eu.eu/

About HBM4EU
https://www.hbm4eu.eu/wp-content/uploads/2017/03/English.pdf

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

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

Horizon 2020
https://ec.europa.eu/programmes/horizon2020/

THE PROJECT

The European Human Biomonitoring Initiative is a joint project between 26 countries and the European Commission to provide evidence of the actual exposure of European citizens to chemicals and their possible health effects.

The countries involved include 22 EU Member States, Iceland, Israel, Norway and Switzerland.

The initiative is currently compiling a list of European laboratories with experience in the chemical analysis of human samples, development of analytical methods in biological samples and organisation of ICI/EQUAS schemes with biological samples. The aim is to produce an inventory of laboratories for a future network of reference human biomonitoring laboratories. If you represent an interested laboratory, contact hbm4eu@isciii.es for more details.

Guest column | Charles Laroche, EPAA

Change of mindset needed to increase use of non-animal methodologies for safety assessment

When it comes to safety assessment of chemicals, we need to find a balance between ethics and science. We need to make sure that the pace of development, acceptance of new methodologies by regulators and promotion of education all go hand-in-hand to make most of the momentum started in Europe that is being embraced worldwide.

Europe has pioneered the promotion of alternative approaches to testing on animals. European regulations were the first to require fewer animal tests for assessing safety and no *in vivo* tests at all if alternatives are available. In fact, the EU invests massively in developing, validating and accepting new alternative approaches. I am very proud to have been one of the founders of the **European Partnership for Alternative Approaches to Animal Testing** (EPAA) in 2005, which is a public private partnership between companies and the European Commission.

Charles Laroche.

The goal of the EPAA is to share information on alternatives to accelerate their validation and acceptance. For instance, our current portfolio includes six projects covering different endpoints and industry sectors.

One of the largest is the skin sensitisation project that focuses on comparing new *in vitro* skin sensitisation models based on 3D-epidermis with a set of difficult to test reference chemicals. Since the first step in safety evaluation of chemicals and cosmetics is the assessment of the skin sensitisation potential (hazard identification), finding ways to do this without using animals has been the focus of intensive work in industry and academia. Developments here would have a significant effect on the numbers of animals needed.

This work has resulted in validated non-animal tests that are accepted as OECD Test Guidelines. The REACH Committee has approved a revision of Annex VII to REACH with the result that validated non-animal test results are now the default information requirement for assessing the skin sensitisation potential of chemicals.

In addition, three *in chemico/in vitro* methods based on cell culture and/or aqueous media have been validated by the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) and have also been adopted by the OECD. However, these methods still have limitations in terms of predicting potency, which is a key element for risk assessment and to test certain types of substances.

Therefore, further work on these models is needed. For example, 3D skin tissue models are being developed to better mimic the skin's structure and how it works allowing the substances to be applied to this more accurate skin model. The objective of this EPAA project is to evaluate the three most advanced 3D skin models for their reliability for skin sensitisation prediction for substances that are difficult to test. We are expecting to have the preliminary results of this project ready within the coming months.

These European regulations and developments are inspiring many similar initiatives overseas, which is a great thing. Meanwhile, the EPAA partners will further work to strengthen the European lead in more effective assessment for safer products while bringing benefits for animal welfare.

Mr Charles Laroche is the Head of the International Fragrance Association (IFRA) Europe as well as the Industry Chair and Founder of the European Partnership for Alternative Approaches to Animal Testing (EPAA).

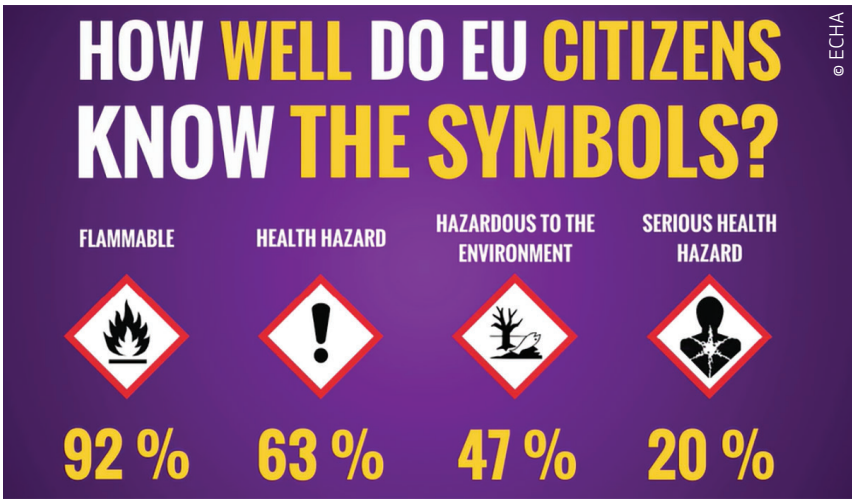
EPAA is a voluntary collaboration between the European Commission, European trade associations and companies from seven industry sectors. The partners work to speed up the development, validation and acceptance of alternative approaches to animal use in regulatory testing.

http://ec.europa.eu/growth/epaa

Safer chemicals and products make great business sense

TEXT BY JAKOB AAHAUGE

Looking for a marketing edge in challenging times? Don't overlook how important safer chemicals and products are to an increasing number of consumers. A new European study of almost 28 000 people in 28 countries shows that 65 % are concerned about being exposed to hazardous chemicals. That's a big market.



The Eurobarometer study shows that some of the new pictograms, for example, the one for 'flammability' are familiar to most of the respondents. Others, such as the 'serious health hazard' were not that well recognised.

Not only are consumers concerned about the safety of chemicals, but the media are focusing on it, too. Of course, the media focus tends to be on substances that may cause harm – all the more reason to make sure that the substances you work with have the lowest possible hazard profile.

So what does the Eurobarometer study on chemical safety show?

65 % of EU citizens said that they are concerned, to different extents, about being exposed to hazardous chemicals.

- 26% were very concerned; and
- 39% were a little concerned.

The level of concern varies according to the respondents' Member State, with those in northern Europe generally feeling more informed and less concerned than those in southern Europe. Having said that, in every Member State, at least half of the respondents showed some level of concern.

The data behind the survey results are pretty solid. Almost 28 000 EU citizens were interviewed face-to-face and in their native language.

ARE HAZARD PICTOGRAMS HELPFUL?

The survey also looked at citizens' awareness of the hazard pictograms. Despite the fact that citizens may have had limited opportunity to become familiar with the new pictograms, some are already very familiar with them.

- 92 % have seen the 'flammability' pictogram and almost all of them (96 %) knew its meaning.
- At the other end of the scale, only 20 % recognised the 'serious health hazard' pictogram.

Citizens also act on the information you provide on your labels:

- 76 % read the safety instructions,
- 57 % read the instructions on the label, and
- 19 % also search for further information.

Only 10 % said that they use the product as they would any other product. 9 % would not use a product with a hazard pictogram.

ARE CITIZENS MORE POSITIVE ABOUT EU PRODUCTS?

Almost half of the respondents, 47 %, thought that products manufactured in the EU are safer than those produced elsewhere. Only 5 % thought that products imported from outside the EU contain safer chemicals.

Interestingly, as many as 30 % had little confidence in either – believing that neither products manufactured inside or outside the EU contain safe chemicals.

CITIZENS SEE AN IMPROVEMENT

Respondents to the survey were also asked whether they thought the safety of products containing chemicals has improved or deteriorated, compared to 10 to 15 years ago.

- 44 % think that the safety of chemicals in products has improved over the last 10 to 15 years;
- 33 % feel it is more of less the same; while
- 16 % feel that it has deteriorated.

CITIZENS' APPS ARE INCREASING TRANSPARENCY

Checking products for harmful substances is getting easier. Not only do citizens have the legal right to ask about substances of very high concern (SVHCs) in the products they buy, but free apps are also being developed to make that information much more accessible.

There are already some apps that enable citizens to check if a product contains any SVHCs.

The apps use the list of SVHCs and combine it with the product's barcode. They also help consumers contact the producers to check whether the product contains any hazardous chemicals. The question is sent to the owner of the barcode, the supplier, who then has to answer within 45 days according to REACH.

The apps also host databases that store the answers and make them immediately available to the next consumer asking the same question – saving them 45 days of waiting.

The Danish app Tjek kemien also sends a notification to the supplier giving them the option to update the answer.

The German Federal Environment Agency's app Scan4Chem works in a similar way. By simply scanning the barcode of the article an enquiry is automatically sent to the responsible producer or importer.

This is only the beginning. A new app that covers the whole of the EU has been awarded EU funding and is on the drawing board, but it might take a few years before that is ready to download.

Either way, the message is clear – your marketing advantage lies with safer chemicals.

The smart players are staying ahead of the game and making sure that their chemicals are as safe as they can be. Make sure you do the same.

Further information:

The Eurobarometer study
http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2111

Video: Hazardous chemicals - do you know how to use them safely?
https://youtu.be/Pg8uPeE_K4w

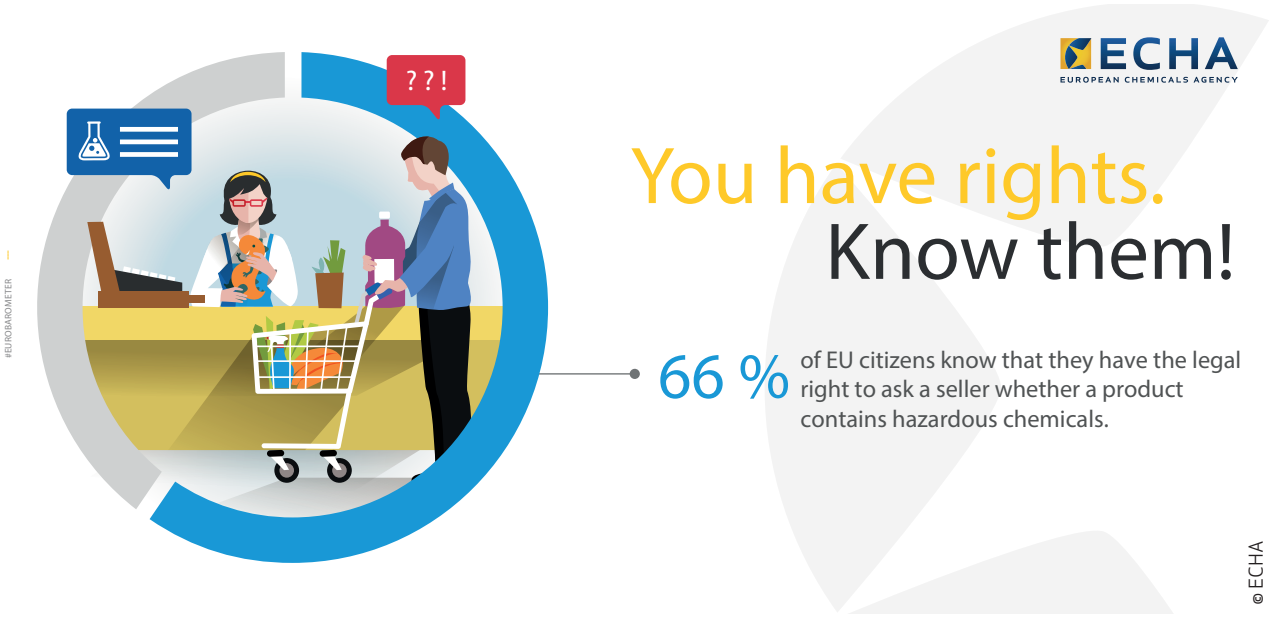
Danish app, Tjek kemien (in Danish)
http://tjekkemien.dk/

German app, Scan4Chem (in German)
https://www.umweltbundesamt.de/tags/scan4chem

REACH for consumers, Umwelt Bundesamt Germany
https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/reach-for-consumers

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

Addressing Chemicals of Concern
https://echa.europa.eu/addressing-chemicals-of-concern



There are some apps available that enable citizens to check if a product contains any hazardous chemicals. You also have the legal right to ask a seller whether the product you are planning to buy contains hazardous chemicals.