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The next five years are crucial

I am very excited and fortunate to be leading the European Chemicals Agency for the next five years. Excited, because there is still much to do to implement the legislation entrusted to us and because there is a lot happening in the EU and internationally that we can contribute to. Fortunate, because I have inherited a very capable staff working for this Agency, which allows me to look at my five-year tenure with confidence.

In 2015, the world set 17 very ambitious and necessary goals to achieve **sustainable development by 2030**. Clear targets for managing chemicals and waste are integral to achieving these goals. By developing and implementing chemicals and waste policies, the EU and its Member States will contribute greatly to successfully meeting the ambitious development targets.

ECHA implements the EU's chemicals legislation, namely REACH, CLP, Biocides and PIC. As such, the Agency has a lot of **scientific and technical competence** with which to contribute to further developing EU chemicals policies and applying them to the international chemicals agenda.

Our core competence is implementing the scientific and technical aspects of the legislation. This cannot be done unless the Agency has everything it needs. Thankfully, the infrastructure is in place – from the building to human resources, from finance to IT, and from administration to scientific expertise – so the legislation can continue to be implemented successfully.

The REACH Review by the European Commission sums up our strengths and shows the areas where we need to improve. I read from it that we are doing the right things, but we still need to work on doing things right.

We are being asked to be more efficient in evaluation, authorisation and with restrictions. Besides looking closer at procedures to see where we can simplify things, for me this means being better at identifying the key information that is driving decisions and opinions, and then focusing our efforts on those key areas. And lessons learnt from REACH should then be considered in relation to biocides and CLP (and, of course, also vice versa).

Our continuous implementation of these regulations helps to build our competence, which in turn will enable us to take on new tasks. A look back shows this: we were set up in 2007 to implement tasks under REACH and CLP, but then over the years we have been entrusted with biocides and with PIC. At the end of last year, we were also given **certain chemical elements of the Waste Framework Directive**. And this year, the negotiations on the **Persistent Organic Pollutants (POP) Regulation** will start, probably resulting in further tasks for us.

Despite these opportunities, I of course know that we will deal with many challenges, too. One that I am less enthusiastic about is the UK's withdrawal from the EU. There are many challenges that will stem from whatever transitional and final agreement is reached, but despite these, I am confident that we will be able to face them.

The next five years will be crucial both in terms of further developing the chemicals legislation that we manage and in starting to put the **'beyond 2020 chemicals and waste agenda'** into action. Both are necessary for achieving the chemicals and waste targets set by the sustainable development goals, and I think in that endeavour, ECHA has much to contribute.

Bjorn Hansen
Executive Director

"We are doing the right things, but we still need to work on doing things right."

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Promoting substitution to safer chemicals through innovation

TEXT BY PAUL TROUTH

Substituting hazardous substances with safer alternatives, contributes to a non-toxic environment, a circular economy and promotes innovation, as well as sustainable production and consumption. ECHA's new substitution strategy aims to support companies to replace substances of concern with safer substances and technologies.

MOVING AWAY FROM CHEMICALS OF CONCERN

REACH, CLP and the Biocidal Products regulations are designed to put pressure on and provide incentives for industry to try to replace hazardous substances with less harmful ones. By implementing these regulations successfully, ECHA directly and indirectly supports substitution.

ECHA's new strategy aims to boost the substitution of chemicals of concern throughout the EU in different ways. It aims to improve access to ECHA data and increase the capacity of Member States and stakeholders to carry out analyses of alternatives by offering support for innovation and by providing opportunities for networking.

Successful substitution is underpinned by research and development (R&D). So, the strategy looks at ways to help companies innovate and invest in R&D. Since the strategy is linked to current EU priorities on a circular economy, a non-toxic environment and sustainable production and use of chemicals, it calls for coordinated, EU-wide actions that take into account the life cycle of products.

A BUSINESS OPPORTUNITY

A stronger foundation for substituting chemicals of concern in the EU is needed. This calls for a change in mindset where substitution is seen as a business opportunity that brings benefits to human health and the environment, rather than as a response to regulatory action.

In this respect, it is an essential building block for reaching the United Nation's 2020 and 2030 sustainable development goals. This mindset change should take place throughout the supply chain, involving retailers and end users of the products, but it should also take place within governments and agencies, too.

SUBSTITUTION AS PART OF A BUSINESS MODEL

While the EU chemicals legislation puts regulatory pressure on industry to substitute hazardous substances with safer alternatives – including substances, technologies or organisational measures – it also provides incentives for companies to do so.

To understand the viability of their chemicals portfolios, companies must know the properties and uses of their substances. This knowledge allows them to integrate substitution as an essential part of their business models. By staying at the forefront of the latest technological advances and developments, European businesses can be more competitive. Furthermore, with retailers and consumers increasingly demanding safer products, sustainable chemistry is also progressively becoming a vital element of business planning for investors.

This is where ECHA's substitution strategy comes in – by supporting stakeholders to move in this direction through four actions areas.

BUILDING UP CAPACITY IN THE SUPPLY CHAIN

1 The first action area is **capacity building**. There are a number of challenges to substitution, including achieving performance and cost requirements, understanding available options, and evaluating them.

As such, successful supply chain collaboration for these challenges is essential and requires increased skills and knowledge on how to substitute in different parts of the whole chain. There is an imbalance in knowledge at different levels of the supply chain. While

Substitution contributes to a non-toxic environment, a circular economy, and promotes innovation as well as sustainable production and consumption.

substance-level knowhow is greater among upstream manufacturers, downstream users are more likely to have information about different technological possibilities for innovation and substituting hazardous chemicals.

To address this, ECHA plans to collaborate with Member State and EU-level authorities, industry associations and NGOs to organise collaborative workshops on specific substitution challenges that companies face.

The workshops aim to help improve the capacity of companies and authorities concerning analysis of alternatives, innovation and substitution. They will also be an opportunity for various actors to discuss substitution issues specific to their supply chain. The ambition is to understand the needs and make progress in identifying and adopting safer alternatives. The workshops can be held at national level in the local language or at EU level, depending on the need.

ECHA will develop a standard package of methods and content, which can then be used as a basis for organising different workshops.

GETTING ACCESS TO FUNDING AND TECHNICAL SUPPORT

2 The second action area concerns **access to funding and technical support**. While there is some funding available for sustainable chemistry projects at EU and Member State levels, specific funding for substituting hazardous chemicals is scarce.

On top of this, even though research and technical institutions, and suppliers of alternatives often have the knowledge to provide technical support, this is rarely known to those companies facing substitution issues. Acknowledging this, ECHA will work closely with the European Commission, Member States and stakeholders to map the current funding mechanisms and institutions and make this information available to facilitate R&D activities for substitution purposes.

ECHA's strategy supports substitution by building supply chain capacity, supporting access to funding, making better use of REACH and CLP data, and facilitating networking.

Recognising that ECHA does not provide any funding, the Agency will consider ways of nudging European funding institutions to pay attention to chemicals being used in new innovations (so that these are preferably of no or low hazard) when considering funding applications.

BETTER USE OF REACH AND CLP DATA

3 Sustainable substitution requires a proper understanding of the hazards and risks associated with the substances being substituted. To avoid regrettable substitution, the hazards and risks of alternatives also need to be known. For this, the third action area relates to **making better use of REACH and CLP data**.

Over the years, ECHA has worked to improve access to its databases. For instance, information from the registration dossiers and classification and labelling notifications is publicly available and directly accessible from ECHA's website. This serves stakeholders looking to make well-informed decisions about the substances they manufacture and use.

As part of the strategy, ECHA will see how to improve access to data relevant for substitution purposes.

For registration data, it may be possible to enhance the search functionality by including uses as well as sectors of use. However, the use descriptions in the registration dossiers are currently rather general, so ECHA would need to see how registrants could provide complementary information in their dossiers that would be useful for downstream users assessing potential alternatives.

For data in applications for authorisation and restrictions, information on the analysis of alternatives from the dossiers, as well as key information derived from the public consultations, could also be searchable on ECHA's website. ECHA will also discuss with Member States and stakeholders to see what additional data would be useful for them and how existing information could be communicated in a more helpful manner.

MULTI-STAKEHOLDER SUBSTITUTION NETWORKS

4 The fourth and final action area relates to **networking** to routinely and effectively connect and collaborate on substi-

tution challenges and opportunities. Creating a network for innovation and substitution could help to advance informed substitution. The Network of REACH Socio-economic Analysis and Analysis of Alternatives practitioners (NeRSAP) has been created by ECHA and industry stakeholders to make such connections. However, more networking is called for.

Networks can be authority-centred, sector-specific or supply chain-specific. They can also be multi-stakeholder networks, consisting of different sectors, different actors in the supply chain as well as different authorities at Member State and EU level.
At ECHA's substitution workshop on 9 to 10 October 2017, the participants considered that a new multi-stakeholder network supporting innovation and substitution would be the best way to progress in the EU.

The network would include ECHA, the Commission, Member State competent authorities, industry organisations, NGOs, research organisations, academia, consumer associations and certain individual companies and would inform and exchange information on various substitution-related activities.

Several channels will be used for this purpose. ECHA's web pages on substitution will be progressively expanded with additional case studies and material from the supply chain workshops, a series of webinars on substance-specific issues and training on analysis of alternatives, and news exchange on social media with a new LinkedIn group.

SUCCESS RELIES ON ALL PARTIES

ECHA cannot promote substitution alone. All actors need to chip in. The substitution strategy can only succeed if all concerned parties get involved. Being proactive, contributing, and having open and solution-oriented exchanges between stakeholders are the key to meaningfully moving away from the use of chemicals of concern.

Further information:

Substitution strategy
https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf/bce91d57-9dfc-2a46-4afd-5998dbb88500

Substituting hazardous chemicals
https://echa.europa.eu/regulations/substituting-hazardous-chemicals

LinkedIn group
https://linkedin.com/groups/13554908

SWEDISH SUBSTITUTION CENTRE

Within the work of developing and submitting proposals on how to achieve a non-toxic environment, the **Swedish Chemicals Agency (KEMI)** proposed to set up a centre that would bring benefits for individual companies as well as society. "We identified that REACH and other chemicals legislation provides the conditions that are necessary to reach a non-toxic environment, but that these measures are not enough," says *Ms Åsa Thors*, from the EU Coordination Unit at KEMI.

"One of the actions we proposed was to set up a centre for knowledge about sustainable production, the use of chemicals and green chemistry. The idea was that the centre would bring benefits for individual companies as well as for society as a whole such as new business opportunities, reduced volumes of waste and decreased energy consumption. Companies using chemical products are in need of support and further knowledge to increase and enhance green product development," she explains.

Back in November 2017, the Swedish government confirmed plans for such a centre. It will located at the **Research Institutes of Sweden (RISE)** in Borås and will help companies, industry associations, authorities and academia to share their knowledge. "The centre will offer support in three parts – communication, consultation and education. It will help companies and other parties climb the first three steps of the substitution staircase – identifying unwanted agents, creating an inventory of alternative solutions, and assessing and choosing an alternative solution," says *Ms Pernilla Walkenström*, Docent at RISE.

"We plan to create an IT-based communication platform that can be used by members, and for consultation, we will advise members directly. We will also work to help fundraising for the more time-consuming R&D-driven activities," she adds.

KEMI
http://kemi.se/en

RISE
https://www.ri.se/en

Improving compliance with restrictions

TEXT BY JAKOB AAHAUGE

ECHA's Enforcement Forum's latest project (REF-4) has shown serious breaches in compliance with restrictions, for example, for asbestos, plasticisers and mercury in consumer products. We look at the results of the project and what lessons can be learnt by enforcement authorities and companies.

The aim of the project was to understand the degree to which restrictions are being complied with and, where necessary, to follow up with enforcement actions. It covered 14 entries from the list of substances restricted under REACH (Annex XVII).

The overall goal is to improve the level of compliance with restrictions and, in doing so, protect our health and the environment.

WHAT WAS FOUND?

5 625 inspections were carried out in total for more than 1 000 mixtures, nearly 4 600 articles and 17 substances. The average non-compliance rate was 18 %.

Given that restrictions are put in place for uses of chemicals that pose the highest risk to health or the environment, this number is too high. Enforcement authorities tend to work on cases where they are likely to see the most non-compliance and, for this reason, the results are not deemed to cover all related products on the European market.

The highest non-compliance rates were for **phthalates** in toys, **asbestos fibres** in products, as well as **mercury** in measuring devices – an entry inspected outside the scope of the main project.

There were also high levels of non-compliance for cadmium in brazing fillers and jewellery, chromium (VI) in leather articles, nickel in metal parts of clothing, and polycyclic aromatic hydrocarbons (PAHs).

REACH restrictions apply to toys and childcare products with phthalates in concentrations above 0.1 % by weight of the plasticised material that can be placed in children's mouths.

PLASTICISERS IN TOYS AND CHROMIUM IN LEATHER

The restriction of phthalates was done to protect children from the harmful effects of chemicals. Some phthalates are suspected of being toxic for reproduction and endocrine-disrupting. Under REACH, restrictions apply to toys and childcare products containing phthalates in concentrations above 0.1 % by weight of the plasticised material that can be placed in the mouth by children.

As such, it is alarming that the presence of phthalates in toys is so high – almost 20 % of more than 460 inspected products contained higher levels of the phthalates DEHP, DBP and BBP than they should, and 10 % of more than 300 products checked contained too high amounts of the phthalates DINP, DIDP and DNOP.

Inspectors also found overly high levels of chromium VI in leather articles. Chromium VI is restricted in leather articles that touch the skin. The articles cannot be placed on the market if chromium VI is present in concentrations equal or greater to 3 mg/kg. Almost 500 leather articles were tested and more than 13 % breached the restriction.

ASBESTOS IN SECOND-HAND PRODUCTS

Asbestos fibres have been restricted in the EU for many years. They can cause cancer of the lungs, larynx and ovaries, and also lung fibrosis. So it is surprising that asbestos was found in nearly 14 % of products checked. The fibres were found in 20 catalytic heaters, three thermos flasks, two brake pads, two cement materials, a sky lantern and a jug flask. In the EU, producing, placing on the market and using these fibres and any articles containing them is banned.

One reason that the fibres may have been found is that many of the articles containing them were second-hand and therefore probably produced before the restriction came into force. However, even if this is the case, selling these products is still illegal if they do not meet the requirements in force today. There are some exemptions to the restriction. If articles containing the fibres were already installed

or in service before 1 January 2005, then their use is exempted from the restriction.

MERCURY IN MEASURING DEVICES

UK inspectors checked almost 400 measuring devices and nearly 90 % were found to contain mercury above the allowed limit. Mercury is toxic and inhalation of mercury vapours can cause harm to the nervous, digestive and immune systems. The high non-compliance could be because the UK inspectors were using alerts on online auction sites that allowed them to specifically target articles where mercury is indicated as being present and avoid those that are categorised as 'mercury-free'.

While the devices were only inspected by United Kingdom enforcement authorities, the high proportion of devices that were found to have mercury above the limit suggests that other countries should do similar checks.

RESTRICTED HEAVY METALS IN JEWELLERY

Illegal levels of heavy metals are still being found in jewellery used in the EU. Nearly 7 % of inspected items contained lead, 8 % contained nickel, and more than 12 % contained cadmium above the respective restriction limits. The risks from heavy metals vary. Nickel can cause skin allergies, cadmium can cause osteoporosis, cancer, and is also toxic to the environment, and lead can cause damage to the nervous system and impair intellectual development.

These rates suggest that the presence of heavy metals in the products is not accidental, but either a result of producers consciously using the raw material during manufacture or lacking sufficient knowledge about what their materials contain.

LESSONS TO BE LEARNT BY ENFORCEMENT AUTHORITIES

The key learning that national enforcement authorities can get from the report is that they should target the kinds of products for which regulatory action can bring the **most benefit to health and the most protection to the environment**. That said, their activities on restrictions should focus on those substances where the highest rates of non-compliance were found: asbestos, cadmium, nickel, phthalates, mercury, chromium (VI), heavy metals in jewellery and PAH compounds.

Enforcers could also target their activities at **products that do not contain a marking of origin on their label**, or where the origin cannot otherwise be found, as the non-compliance rates were extremely high (39 %).

To prove non-compliance by **testing the chemicals onsite**, companies and enforcing authorities would need to put systems in place to carry out a chemical analysis. The Forum has prepared a collection of analytical methods to be used as a reference when checking compliance with REACH restrictions.

Developing **combined nomenclature (CN) codes** – used in export declarations for trade in Europe – for all substances, mixtures or articles restricted under REACH would have a positive effect on the related checks and the involvement of customs, as would streamlined procedures to help enforcement authorities get information from customs.

To improve these, more common projects between the enforcement authorities and customs are needed.

WHAT COMPANIES CAN DO

All companies placing chemical products or articles on the EU market have to comply with REACH restrictions. This means that the

SUBSTANCES	PRODUCTS TO BE TESTED
Benzene	glues for consumers and professionals
Asbestos fibres	articles
Cadmium and its compounds	plastic materials/packaging and other articles, brazing fillers and jewellery
Nickel and its compounds	jewellery and metal parts such as buttons and zips
Chloroform	glues for consumers and professionals
Azocolourants and azodyes	textile and leather articles
Diphenylether, octabromo derivative C12H2Br8O	substances, mixtures and articles
Chromium VI compounds	leather articles and cement
Toluene	adhesives and spray paints for supply to the general public
Trichlorobenzene	substances and mixtures
Polycyclic aromatic hydrocarbons	articles for supply to the general public
Phthalates	toys and childcare articles
Lead and its compounds	jewellery

The Forum project covered 14 restriction entries. Mercury was an entry inspected outside the scope of the main project.

suppliers of products in all steps of the supply chain are responsible. So, if you place products on the market, you should be aware of the chemicals they contain and how they are supplied and by whom.

This may mean proactively testing the products and establishing agreements with suppliers to make sure that the chemical composition of the products in the supply chain is in line with chemicals legislation. Companies should also put systems in place in case a non-compliant substance, mixture or article is found in their portfolio, so they can quickly act to correct the situation.

Companies could also check the RAPEX alert system – an EU portal of products found on the market that pose a serious risk to health or the environment – to get information on non-compliant products found on the market. Restrictions are put in place so that the risks from substances that are harmful for human health and the environment are under control. Preventing these risks is a **legislative and moral responsibility** and should be taken seriously at every step of the supply chain. Given the findings of the project report, however, there still seems to be a lot to be done.

Further information:

Enforcement Forum
https://echa.europa.eu/about-us/who-we-are/enforcement-forum

REF-4 project report
https://echa.europa.eu/documents/10162/13577/ref_4_report_en.pdf/b53f5cd9-64a4-c120-1953-e9e-176b9c282

DID YOU KNOW?

The EU Commission runs an alert system, the Rapid Alert System (RAPEX), which enables quick exchange of information between the Commission and 31 European countries about non-compliant non-food products that pose a risk to the health and safety of consumers.

Companies should regularly check this system to get information on the non-compliant products that can be found on the market.

RAPEX
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications

Valmet – generating business value through regulatory compliance

INTERVIEW BY PAUL TROUTH

Tracking your company's obligations under chemical regulations can be quite complex. In the EU, it is important to know how your duties under REACH overlap with obligations under national laws. If your company has multiple roles in the supply chain, this can be even more complicated. We spoke to *Arto Huuskonen* and *Victoria Larsson* from Valmet, a global developer and supplier for the pulp, paper and energy industries, to find out more about the challenges their company faces in collecting reliable data.

ALIGNING REACH AND THE SINGLE MARKET

The complex regulatory landscape can make it difficult for companies to understand how to follow national legislation and still comply with their obligations under REACH. There are national duties for managing chemicals in many Member States that overlap with REACH requirements. And substances in articles are regulated by various EU regulations that can often set different concentration limits and even give different ways of calculating concentrations.

"Let's take food contact materials as an example. Substances are regulated under REACH across the EU, but there are also EU-wide regulations on plastics that affect plastic food contact materials. There are, however, no EU-wide regulations for food contact materials made of paper. Some Member States have created national legislation for these, but this differs in each Member State. It quickly becomes difficult to know which regulation to follow in all situations," says Mr Arto Huuskonen, the health, safety and environment (HSE) manager for the automation business line at Valmet.

"There needs to be an alignment between the single market and REACH, so any national regulations overlapping with REACH should be removed to secure the single market's functioning," he says.

WORKING IN A GLOBAL CONTEXT

Under REACH, Valmet has three roles. It is, first and foremost, a **downstream user** of chemicals with operations in more than 30 countries. But it also operates as an

importer of key raw materials and as an **article manufacturer** supplying more than 100 000 components.

Mr Huuskonen argues that REACH has limited the availability of some specialty chemicals, and that this has led to some downstream users needing to take on the importer role.

"We use some chemicals with limited applications, such as those used for paper machine roll coverings. Because of the obligations that REACH places on importers, some manufacturers have stopped selling some niche chemicals to Europe. So, companies with global manufacturing chains like ours are left to choose between importing the chemicals themselves or changing the recipes. Both options have their own difficulties and costs," Mr Huuskonen tells.

"Even if you are able to get some chemicals you need into Europe, you may still find that there are a lot of deficiencies in the safety data sheets," he adds.

A DEVELOPMENT PROGRAMME FOR SUPPLIERS

Valmet has around 10 000 suppliers in over 50 countries, delivering hundreds of thousands of components. "Sometimes, suppliers' knowledge on what is required under REACH can be limited. So, to make collecting data feasible, we carefully scope the suppliers we use," Mr Huuskonen tells.

The company assesses how likely it is that components sourced from its suppliers may contain substances of very high concern (SVHCs). The data is collected primarily to improve chemical safety assessment and customer communication, but also to identify possible substitution needs and opportunities. It also enables better compliance with regard to SVHC notification.

This information is used to gauge how much data needs to be collected and what kind of quality assurance needs to be run.

From left: Victoria Larsson and Arto Huuskonen.

"Most of the components we buy contain metal parts, such as steel tubes and plates, which we consider to pose a lower risk than parts made of certain plastics. Each of our purchases is given a risk score and those suppliers associated with higher risk categories are selected for more in-depth data collection," Mr Huuskonen adds.

To successfully navigate the evolving legislation in Europe and worldwide, a development programme has been set up for Valmet's suppliers, to raise their awareness of what is required on a global level. "REACH-like chemical regulation is still a novel concept worldwide. Our traditional management focus has been to look at occupational health and safety regulations, with our attention on the concentrations that workers are exposed to," says *Ms Victoria Larsson*, Valmet's global HSE manager.

If the programme identifies a good practice in one unit, the company can also apply it globally. It has also helped Valmet to identify front-runner jurisdictions where regulation is more advanced than in some other countries. "We try to follow these regulations more closely so that we can stay up to date with the most strict and applicable requirements. Planning compliance according to the strictest regulations creates a good baseline for compliance globally," Ms Larsson stresses.

'ZERO HARM, WHEREVER WE WORK'

One of Valmet's aims is '**Zero harm, wherever we work**'. The company sets out minimum safety standards designed to meet the requirements of the main global HSE laws so that safety is always a priority, especially when working with hazardous substances.

"In a global company, it is important to have a common baseline for safety standards. Our starting point is, of course, to know which chemicals are used and what their potential hazards are across all our operations. For this, the substances need to be fully risk assessed before starting work so they can be correctly handled, stored and marked," says Ms Larsson.

While the standards are adhered to in Valmet's own workshops, there is also a need to think about the potential for exposure in their customers' mills and plants.

"There are obviously different risks of chemical exposure in those environments, so we also try to cover these in our standards. It always comes back to doing a thorough

risk assessment so that we know for sure that we have identified all the potential hazards," Ms Larsson asserts.

HARMONISING REACH INTERPRETATIONS

According to Mr Huuskonen, stabilising interpretations of REACH could lessen the confusion of companies, especially those operating in more than one Member State.

"More than a decade since REACH entered into force, national helpdesks still offer different advice even on how to define a chemical. A stable interpretation of REACH and harmonising the support provided by helpdesks and authorities at a national level would help companies," says Mr Huuskonen and continues, "but it would also require clear legal texts with sufficient supporting documents and giving EU agencies a bigger mandate in their own fields of expertise. So ECHA, for example, should have a stronger role in managing chemicals within the EU, not only based on how REACH should be interpreted but also based on other related regulations".

LESS FREQUENT CHANGES TO REACH

In Valmet's view, stabilising REACH's legal framework – so less frequent but more significant changes take place – could also benefit companies. Updates to the Candidate List, for example, happen every six months, which in their view is too often, as companies constantly have to cope with change.

"For companies supplying complex articles, it could take six months to even identify if the substance of concern is in their supply chain, let alone do anything about it. The frequency of updates means there is a constant need to chase data from suppliers, only to find that once it is obtained, it is probably already outdated," Mr Huuskonen maintains.

According to Valmet, ECHA should have a stronger role in managing chemicals in the EU, not only in how REACH should be interpreted but also for other related regulations.

"Suppliers feel that they get requests for information about substances of very high concern too often and they are therefore less willing to react. Less frequent updates could create a better outcome in terms of getting good data from manufacturers. It is, however, a careful balancing act. If a risk from a substance is identified, there shouldn't be a two-year wait before something is done about it," he adds.

RATIONALISING DATA

While both Mr Huuskonen and Ms Larsson think that there are useful tools under REACH to help companies manage the hazards of individual chemicals in the supply chain, they also feel that there is room for improvement. "When companies have to deal with several substances at the same time, with multiple roles in the supply chain and with manufacturing processes that are complex, the tools are deficient and the requirements become overly bureaucratic," Mr Huuskonen says.

To address this, data flows should be simplified to take the complexity of manufacturing processes, supply chains and the final products into account. "To ease decision making, only data essential for ensuring safety and environmental protection should be readily accessible and flow throughout the supply chain. The rest should be stored to be used when needed, but not mandatorily communicated, as this only lessens the emphasis given to critical data," he concludes.

Valmet is a global developer and supplier of technologies, automation and services for the pulp, paper and energy industries. The company's solutions include complex machinery, equipment, automation electronics, wear and spare parts, and associated expert services. Under REACH, Valmet operates primarily as a downstream user of chemicals, but also as an importer and article manufacturer.

Valmet has research and development units operating across several continents that require a notable amount of chemicals either as raw materials or auxiliary substances. The raw materials contain various metals used in the company's foundries, as well as monomer and polymers for manufacturing paper and tissue machine roll covers and fabrics.

http://valmet.com

Further information:

Communication in the supply chain
https://echa.europa.eu/communication-in-the-supply-chain

Valmet guidance on restricted materials in products
http://valmet.com/globalassets/sustainability/documents/supply-chain-policy/valmet-guidance-on-hazardous-substances.pdf

Poison centres: changes to placing hazardous mixtures on the market

TEXT BY JAKOB AAHAUGE

If you or someone you know has ever been accidentally exposed to a chemical product, you can pick up the phone and call a poison centre to ask for medical advice. The first question they may ask you is: what exactly is in the product? We look at why answering this question might become a lot easier in the future.

Poison centres help to ensure the safe use of chemicals and offer preventive and remedial measures if somebody has been exposed to a poisoning agent. They give medical advice to general consumers and physicians on health emergencies arising from exposure to hazardous chemicals or to other toxic agents. They also provide an assessment of whether a particular exposure is hazardous, and give information on whether treatment is needed, and if so, what kind.

A NEW CHARACTER CODE FOR PRODUCT LABELS

While you may know the brand name of the product, it is not always straightforward for poison centres to give you the best possible medical advice based on this information alone, as the product labels currently only provide limited information.

To improve this situation, a new 16-digit character code known as a **unique formula identifier** (UFI) will be required on the labels of products containing hazardous mixtures from 1 January 2020.

The aim is to help poison centres identify the exact poisoning agent so a more immediate health response can be given if someone is poisoned. Placing the UFI on the labels of your products is already possible, but it will only be mandatory from 1 January 2020.

The UFI provides a link between the product placed on the market and the information on the composition that companies have to make available to poison centres, such as the trade name of the product, its colour, packaging, product category and toxicological information.

WHO HAS TO SUBMIT INFORMATION?

Before placing mixtures on the market, importers and downstream users must submit information on the mixtures classified for any health or physical hazard to the body appointed to receive this information in each Member State.

The information has to be provided to Member State appointed bodies and poison centres so that consumers, physicians and other professional users can contact them and get the best possible advice for medical treatment.

Other operators that rebrand or repackage mixtures may also need to make such notifications.

WHAT ARE THE NOTIFICATION DEADLINES?

Currently, national requirements on notifying hazardous mixtures vary between Member States. The introduction of Annex VIII to CLP harmonises the information requirements relating to emergency health response and preventative measures across the EU.

The new obligations for notifying hazardous mixtures before placing them on the market, such as adding the UFI on the label, submitting the full chemical composition (including the non-hazardous components) and assigning a product category from a harmonised product categorisation system, have different deadlines depending on the use.

The phased deadlines are by **1 January**:

- **2020** for consumer uses;
- **2021** for professional uses;
- **2024** for industrial uses only.

Mixtures that were already on the market when this obligation started being imposed will need to be re-notified by the end of the transition period, on **1 January 2025**.

WHAT YOU NEED TO NOTIFY

Companies will need to notify product information such as:

- the UFI;
- contact details;
- product identifiers and details such as the trade name, colour and packaging type;
- the product category;
- toxicological information such as the likely route of exposure and the symptoms caused by exposure to the chemical; and
- the hazard classification label elements such as the health and physical hazards, the pictogram codes, signal words, and hazard statement and precautionary statement codes.

By 2025, all relevant products on the market are expected to be notified and have the UFI on their labels.

Make sure you know your supply chain – it might affect the deadline obligation for your mixture. In cases where an industrial mixture is eventually included in a mixture for a consumer product, you will need to meet the earlier deadline of 2020.

HOW TO NOTIFY

ECHA will provide the harmonised format necessary for the notifications. The Agency has also started to develop a **poison centre notification (PCN) portal** that will enable companies to submit the information centrally, and dispatch the notifications to the appointed bodies and poison centres of the (relevant) Member States where the product is placed on the market.

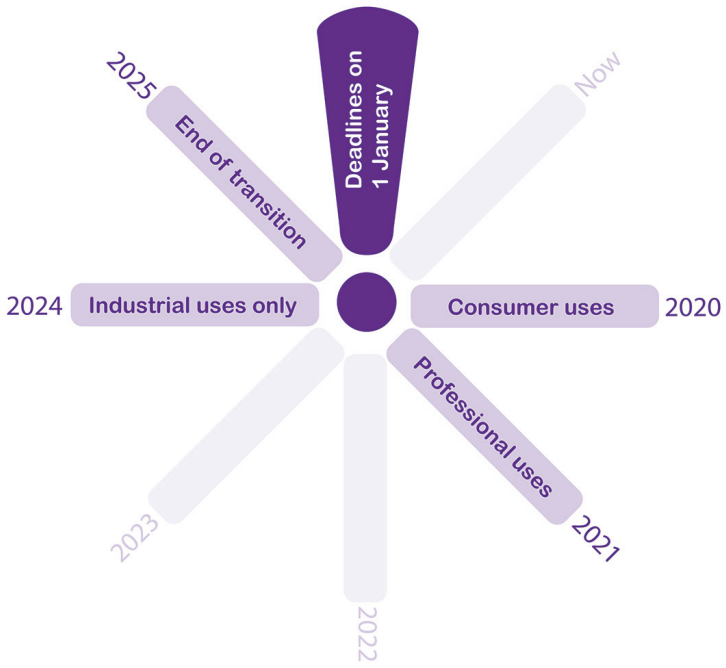
There are other tools available or under development that will help industry prepare and submit their notifications.

The **UFI Generator** has been finalised, so companies can already start using it to generate their UFIs and prepare internally before the first deadline on 1 January 2020.

A developers' manual is also available for companies that prefer to develop their own UFI generator and integrate it in their IT systems.

The **poison centres notification (PCN) format** that defines the data requirements and structure for the submission of information to the appointed bodies and the related editor are currently being developed, as well as a harmonised **product categorisation system (EuPCS)** that details the different product categories based on their main intended use.

These tools will be available on ECHA's website in early 2018.



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Deadlines to notify hazardous substances are on 1 January 2020 for consumer uses, 2021 for professional uses, and 2024 for industrial uses only. The transition period ends on 1 January 2025.

WHY A CENTRAL NOTIFICATION PORTAL?

There are a number of benefits for industry and Member States in developing a central notification portal.

For industry, the portal will limit the administrative burden and reduce the costs of submitting information by decreasing interactions with Member State appointed bodies. It will also secure confidential business information through the supply chain by reducing the number of channels of data transmission, reduce the number of errors by offering validation tools and support multilingualism by allowing companies to submit in their own language while ensuring that information to the appointed bodies is in their language.

For Member States, the central notification portal will reduce the need for IT development in each Member State thereby reducing the overall costs.

A central portal also offers the possibility to work as an information hub for cases where mixtures are notified in one Member State but marketed in a different Member State as part of another mixture.

The scope of this central notification portal and the functionalities that it may offer to both industry and Member States are still under discussion. A first version with some basic options is expected to be available in 2019.

Further information:

ECHA's Poison Centres website
https://poisoncentres.echa.europa.eu/home

List of European appointed bodies
http://ec.europa.eu/DocsRoom/documents/5219/attachments/1/translations

UFI Generator
https://poisoncentres.echa.europa.eu/ufi-generator

Central notification portal
https://poisoncentres.echa.europa.eu/poison-centres-notification-portal

Incentives needed for biocides innovation

INTERVIEW BY VEERA SAARI

Legislation on biocides was designed to create a demand for safer alternatives by removing the most toxic substances from use. Substances have been restricted, but is there enough innovation underway? We mapped the measures that are already in place to support innovation in biocides.

LEGISLATION-BUILT DEMAND

The most toxic active substances are not approved for use. This is to protect human and animal health, and the environment. A substance that, for example, has endocrine-disrupting properties or is classified as carcinogenic is not approved unless:

- it can be shown that the risk from exposure to it is negligible;
- it is essential to prevent a serious danger to human or animal health or the environment, or
- if not approving it would have a disproportionate negative impact on society.

"The paints industry selects substances for their best technical, efficacy, toxicological and cost profiles," says Mr *Didier Leroy*, Technical Manager at the European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE). "Restricting any of the substances in legislation clearly leads to a need to substitute them with options that have a better 'regulatory profile'. Nowadays, regulatory pressure is a key driver for substitution, but sometimes there are no suitable alternatives available."

As an example of substitution, Mr Leroy mentions the EU's Paints Directive that concerns emissions of volatile organic compounds from decorative paints. "In my own industry, 85 % of decorative paints are now water-based thanks to the legislation. But, water-based paints need preservatives to survive, and this is where our need for biocides comes in."

As a downstream user, Mr Leroy says the predictability of authorities' decisions on substances could be improved, as this would allow companies to better adapt their business. "For better predictability, we would like to see the authorities evaluate and give their outcome on substances for particular uses in batches, by product-type. This way, they could take a weighted decision in the end to make sure that sufficient tools remain available to preserve products."

Predictability would also help companies decide whether to invest in research and innovation, Mr Leroy stresses. "If the outcome of a big investment and years' of development work is not certain, companies might be reluctant to act on new ideas." So far, out of **246** fully assessed dossiers, **236** active substances have been approved at EU-level for different product-types, like disinfectants, preservatives and pest control products. In **10** cases, substances have not been approved.

CUSTOMER-BUILT DEMAND

From a customer's point of view, innovation is needed. "We see a continuous reduction in available solutions for preserving our products," Mr Leroy underlines. "Substances are starting to drop out from the market because they have not been approved for use, but at the moment, we see little innovation taking place and few new solutions being developed to replace them. There is a clear demand for new biocides, or even solutions without any biocides."

Didier Leroy.

"As a downstream user, we rely on manufacturers to buy our substances from, and there are not that many biocides suppliers on the market," he stresses.

Mr Leroy says it is not easy for companies to enter the biocides market without any previous knowledge and financial support. "Smaller companies are interested, but they need more guidance on how to manage the legal processes."

CONSUMER-BUILT DEMAND

Consumer pressure to find less harmful options is growing. Dur-

ing 2018, ECHA will be working to make its database on biocidal products more user-friendly. Citizens will have access to more data on biocides than before. For example, you can pick up a biocidal product in a shop and search the database with the name on that product. You will see who holds the authorisation and in which EU countries. You will also be able to compare the product with others to find options that might be more favourable to health and the environment.

WHERE TO LOOK FOR ALTERNATIVES

Active substances that could cause concern are identified on an ongoing basis as candidates for substitution. The EU system for biocides has steps in place to encourage replacing these substances, and products containing them, with more favourable options.

Before substances that are identified as candidates for substitution can be approved for use, a call is launched on ECHA's website to find alternatives. So far, there have been 35 such calls for information. If no alternatives are found, these substances can be approved, but the decision will have to be re-evaluated in seven years' time at the latest. The list of candidates for substitution is therefore a good place to start when looking for areas where innovation is needed.

For biocidal products, the EU system has also added an extra step. If a biocidal product contains an active substance of concern, it can be authorised for use only after the authorities have looked for alternative products on the market. If more favourable alternatives exist, the use of the product can be prohibited or certain uses can be restricted. If there are new or lesser-known alternatives available on the market, ECHA's public calls for information are the perfect opportunity to let authorities and companies know about them.

LOOKING FOR INCENTIVES?

APPLY FOR FUNDING - Have you considered applying for funding to help your research? Several options are available both at EU and national level. There are two grant types you can explore: grants for substitution and innovation or loans and guarantees adapted to the needs of small and medium-sized companies.

The **EU's Horizon 2020 programme** is funding projects in the field of biocides. With a quick search in their database, you can find hundreds of projects.

To help you get started, contact your local **Enterprise Europe Network (EEN)** partner, who will be able to consult the network's database for offers in more than 50 countries.

FAST-TRACK TO THE MARKET - Does your product contain a new active substance? You can fast-track to the EU market even though your substance has not yet been approved. You can be granted a provisional, three-year authorisation to access the entire EU market. This can be extended for one additional year. A requirement is that the EU country currently evaluating your substance gives a recommendation for approval for the substance.

GET A SIMPLER AUTHORISATION - Does your product contain an active substance that is more favourable for health and the environment? You are entitled to **simpler authorisation**. This means your application is processed faster and there is less bureaucracy involved. Your product can be made available in all EU countries by simply notifying the relevant countries' authorities. No applications are needed.

To get this simpler authorisation, your product can only contain active substances that are considered less harmful. These substances are listed in **Annex I to the Biocidal Products Regulation (BPR)**.

PROTECT YOUR INNOVATION - Invested time and money in developing a new active substance or product? It might be important for you that the data is kept confidential. As an incentive for developing new substances and products, longer periods of data protection are granted.

When you apply for the approval of an existing active substance, the data on your substance will be protected for 10 years. For a new active substance, the period of data protection is extended to 15 years. The same applies to products containing a new active substance. When you apply for an authorisation for a product that contains a new substance, the data you provide will be protected for 15 years.

Further information:

Candidates for substitution
https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations

Approval of active substances
https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances

Guide for small companies
https://echa.europa.eu/documents/10162/21332507/guide_chemical_safety_sme_en.pdf/09a01b3e-6a31-4311-8eae-8363730a23b3

Authorisation of biocidal products
http://echa.europa.eu/regulations/biocidal-products-regulation/annex-i-amendment

Do you know the symbols on products? Learn them to prevent accidents

INTERVIEWS BY SATU KIMMO

Every year, thousands of children in Europe have accidents with household products. Some of these could be avoided by paying attention to and knowing the packaging symbols. Here we look at how Belgian and Spanish authorities are running campaigns to try to reduce the number of accidents.

If you ever pick up a package in a shop and look at its label, you will see a small red diamond-shaped symbol that draws your attention to the possible harm caused by misusing the product. The label also gives information about the damage that the substances or mixtures in the product can cause you or the environment, as well as safety advice on what to do if you are exposed to the substance.

Since the products need to be handled with care, it is important to educate people about their dangers, and this is exactly what both the Belgian and Spanish campaigns aim to do.

SAVE THE EMOJI GAME IN BELGIUM

In Belgium, the advertising agency BUBKA has created an emoji game ***Red de emoji/Sauve l'emoji*** (Save the Emoji). The project was commissioned by the national authority, the FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu (Federal Public Service – Health, Food Chain Safety and the Environment). "The game is part of a bigger communications campaign to educate people about the importance of the safe use of chemicals," explains *Ms Jona De Leye*, Communications Officer at the FOD.

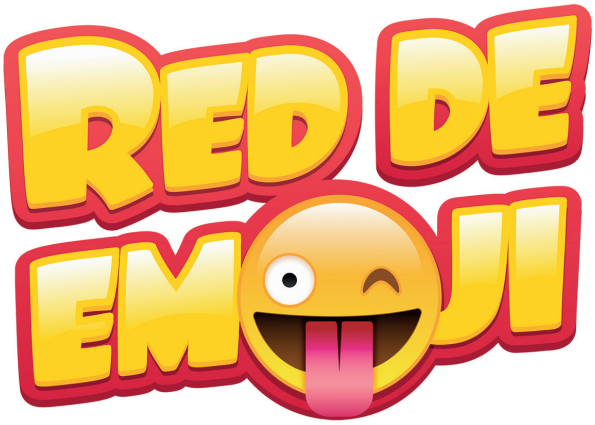
From left: Thomas Faes and Jona De Leye.

REACHING THE YOUTH

Each year, more than 5 000 young people in Belgium are injured in accidents involving chemical products. "Something needed to be done to prevent the accidents and we thought that the best way to reach out to young people is by giving them information in a language they understand best," says *Mr Thomas Faes*, Account Manager at BUBKA.

Even though most accidents actually occur to children between the ages of 1 and 4, the government targeted 10 to 14 year-olds. "This is the age when they become aware of the products and are already capable of giving instructions to their younger siblings and recommendations to their parents," explains Ms De Leye.

"After some research, it was clear that the best way to reach that age group was to use a means of communication that they are already familiar with – emojis, texting and instant messaging – to infiltrate their everyday lives. That is how we developed the idea of an emoji game," adds Mr Faes.



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Save the Emoji is part of a campaign in Belgium to educate about the safe use of chemicals.

HOW DOES THE GAME WORK?

"We wanted to raise awareness about the nine symbols and the dangers they describe. Players need to save the emoji by dragging the correct symbol to the correct product," explains Mr Faes.

Young people learn by playing, so to make the game even more attractive, a prize factor was added to encourage them to repeatedly play the game. "The more the youth play the game and keep playing it, the better they will learn the symbols. And then they can educate their families when they see the same symbols on the products their parents buy," he adds.

BUBKA also targeted their advertising at people who follow some popular vloggers on YouTube, as many in the targeted age group are fans of the vloggers. The idea was to attract more players and spread awareness about the game even further.

Ms De Leye tells us that they plan to continue the campaign and aim to further promote the game in schools, by visiting them and providing educational material about the safe use of chemicals and the symbols. Future plans also include targeting households with small children, as well as people doing home repair work involving chemicals.

By looking at the statistics, the game has been played almost 20 000 times during the first 9 weeks of the campaign. However, it remains to be seen how successful the game will be at teaching the youth. "That is something we will hopefully see in the yearly statistics for chemicals-related accidents. We certainly hope to see a decrease, but if the game manages to prevent even one accident, it will be a success! But, of course, the goal is to make a difference both in the short term and the long term," says Mr Faes.

★ ★ ★ ★ ★

OJO A LA ETIQUETA CAMPAIGN IN SPAIN

In Spain, the Business Federation of the Spanish Chemical Industry (Feique) and the Consumers and Users Confederation (CECU) have collaborated with the Toxicological Information Service (SIT) that operates as the national poison centre to develop a separate campaign on classification, labelling and packaging that also targets youngsters. The project has been funded by the Spanish Agency of Consumption, Food Safety and Nutrition, which is attached to the Ministry of Health (AECOSAN-MSSSI).

The ***Ojo a la Etiqueta: por la seguridad de los más pequeños*** campaign (Take a look at the label: for the safety of the youngest) aims to reduce the number of exposures and intoxications among children in Spain. It informs those taking care of children about the importance of reading the product labels, following the instructions, and using and storing products safely.

The campaign provides information about the national poison centre that is open 24/7 to respond to questions and give advice. "In the event of a poisoning with a toxic

Maria Eugenia Anta.

product, keeping calm and calling the poison centre can prevent unnecessary visits to health emergency services," says *Mrs Maria Eugenia Anta*, Director of Internationalisation and Product Stewardship at Feique.

MOBILE APP FOR YOUNGSTERS

The Spanish campaign includes a simple and intuitive mobile app that offers basic advice on what to do if there is a poisoning, including the direct contact information for the poison centre. "Youngsters often favour using new technologies so we created an app to reach them," Mrs Anta explains. "We want to educate them on the importance of the symbols and their meanings, and, of course, to prevent accidents," she adds.

Ojo a la Etiqueta aims to reduce exposure to hazardous chemicals among children in Spain by informing about the importance of reading the labels and following their instructions.

SPREADING THE INFORMATION

Several other products for the campaign are available from the campaign's website including:

- a cardholder (with basic information and the poison centre's phone number) that can be attached to the back of smartphones;
- 10 downloadable training sheets with information on labelling, pictograms and home safety (including how to store, use and recycle products) and disproving false myths related to first aid;
- a calendar for 2018, each month presenting different information and tips related to labels, pictograms, safe use and storage, and the poison centre; and
- a brochure containing the main information about the campaign.

CECU also visits schools, if requested, to spread the campaign information to teachers and pupils.

To measure the success of the campaign, a range of statistics will be collected and checked – on media coverage, contact requests from schools, the number of app downloads and web page visits, as well as reports from the Twitter hashtag #OjoALaEtiqueta.

"We expect the Spanish poison centre's report for 2017 to show more calls asking for information and fewer about actual poisoning cases. This will hopefully mean that fewer unnecessary visits to health centres have occurred, which will be an indication of the campaign's success," Mrs Anta concludes.

Further information:

Take the CLP Quiz
https://echa.europa.eu/clp-quiz

Red de emoji (in Dutch)
http://reddeemoji.be

Sauve l'emoji (in French)
http://sauvelemoji.be

Ojo a la Etiqueta material (in Spanish)
https://cecu.es/ojo-a-la-etiqueta/index.php/materiales-formativos

PLAY IT SAFE

To play it safe with chemicals, store them in the original container and keep them out of the reach of children.

Follow the instructions on the label and avoid exposure to your skins, eyes and lungs.

Also, consider the environment before disposing the chemicals and their packaging. If a poisoning accident occurs, call 112 or contact your national poison centre.

https://poisoncentres.echa.europa.eu

How chemicals can result in autism and IQ loss in developing children

INTERVIEW BY ELENA MEZZADRI

Nowadays, there is concern about endocrine-disrupting chemicals, especially their interference on the thyroid gland. The impact on thyroid hormone levels, especially for pregnant women during the first three months of pregnancy, may result in neurodevelopmental diseases, autism and IQ loss in the unborn child. We spoke to *Barbara Demeneix*, Professor from the French National Museum of Natural History, to ask why these chemicals affect the signalling of thyroid hormones and what we can do to protect our children.

THE ENVIRONMENT AFFECTS OUR GENES

Exposure to endocrine disruptors occurs on a daily basis. We should all pay attention to it, but especially pregnant women. This is because the levels of thyroid hormone that mothers have is crucial for brain development in the unborn child. Without the right amount of the hormone at the right time, the child has an increased chance of autism and reduced IQ. The problem is that many chemicals to which we are all exposed can interfere with thyroid hormone signalling.

Autism is a developmental and neurological disease that is present from early childhood and is characterised by difficulties in communicating, forming social relationships with other people, and using language and abstract concepts.

While cretinism (which in severe cases was characterised by an IQ of around 35) has been virtually eradicated worldwide due to therapies that correct thyroid dysfunction (such as postnatal T4 therapy), there is concern that IQ loss and autism risk are increased by exposure to thyroid disrupting chemicals and iodine deficiency, especially during pregnancy.

Studies in the United States have shown a steep increase in the number of children diagnosed with autism since the early 2000s. The same dataset also shows a plateau from 2010 to 2012. Many of the children diagnosed with autism also have intellectual deficiency. So, why have the numbers risen so steeply and what happened to make them

plateau? A number of arguments have been put forward to explain the increase, including better diagnosis and increased awareness.

"But changes in diagnostic methods did not occur between 1994 and 2010," Professor Demeneix points out. In fact, major changes did not occur until the fifth edition of the American Psychiatric Association's (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM-5) was adopted in 2013. DSM-5 introduced the concept of autism spectrum disorder, which encompasses autistic disorder (autism), Asperger's disorder, childhood disintegrative disorder and pervasive developmental disorder from DSM-IV.

"At the beginning of the 2000s, there was a general increase in awareness of autism, as it was being extensively discussed in the media. So, the contribution of increased awareness could have first increased and then stagnated during the plateau period from 2010 to 2012," she tells.

A more plausible reason for the plateau could be that there is now better regulation of certain chemicals. "It is not illogical that the environment has an impact on us and on how our genes are transcribed. For example, if we look at the levels of lead in the environment, it is clear that they have decreased in large part due to more comprehensive regulation. For other compounds, it is slightly more difficult to assess, so it would be worth comparing levels of certain perfluorinated compounds and manmade polychlorinated biphenyls (PCBs) before and after they were phased out," she adds.

A BIOLOGICALLY PLAUSIBLE MECHANISM

Anything interfering with the levels of maternal thyroid hormone will have a long-term impact on the formation and development of organs and neurons in the foetus.

Professor Demeneix suggests that Austin Bradford Hill's nine criteria to establish epidemiologic evidence of a causational relationship are pertinent. Many of the criteria can be aptly applied to show that endocrine disruptors can be linked to biological mechanisms that could cause autism and IQ loss.

"First, there are consistent findings on endocrine-disrupting effects across different populations and places as well as **coherence between epidemiology and laboratory findings** through experimental evidence," Professor Demeneix argues.

"Second, the **temporality criterion** requires exposure before diagnosis, as is the case of neurodevelopmental diseases generated after exposure to endocrine disruptors," she tells.

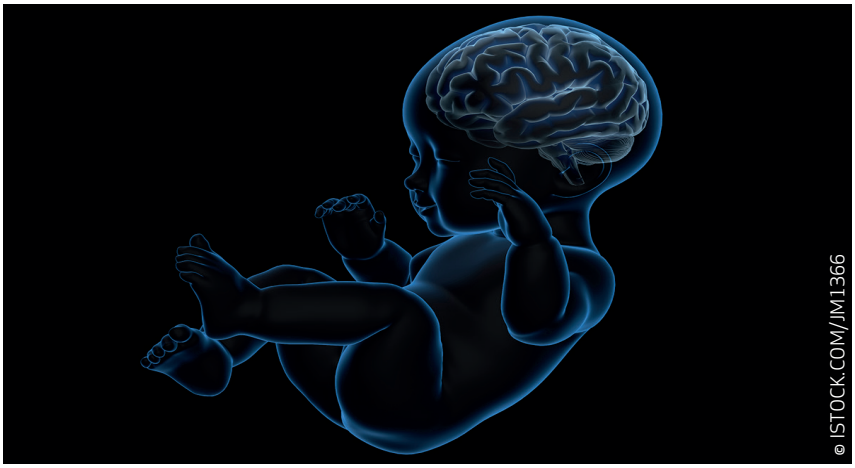
"Third, the **biological gradient** suggests that greater exposure usually leads to greater effects; however, this is not always the case with endocrine disruption, as effects can be seen at low doses and the presence of mixtures of chemicals makes assessing individual effects difficult. Last but not least, there is a plausible mechanism between endocrine disruptors and their interference with thyroid hormone signalling. "Combining the facts

Barbara Demeneix.

that first, maternal hypothyroidism increases the risks of autism and second, that exposure to many chemicals reduces circulating thyroid hormones provides a strong case for **biological plausibility**," Professor Demeneix explains.

MATERNAL THYROID FUNCTION AFFECTS DEVELOPMENT

One of the major findings on thyroid hormones in the last two decades is the significance of the need for strict control of maternal levels in the first three months of pregnancy. Recent data has proven that these maternal levels of thyroid hormone in the first 10 to 12 weeks of pregnancy are determinant for the child's brain development.



Thyroid hormone levels of mothers are crucial for brain development in the unborn child. Without the right amount at the right time, the chances of autism and reduced IQ increase.

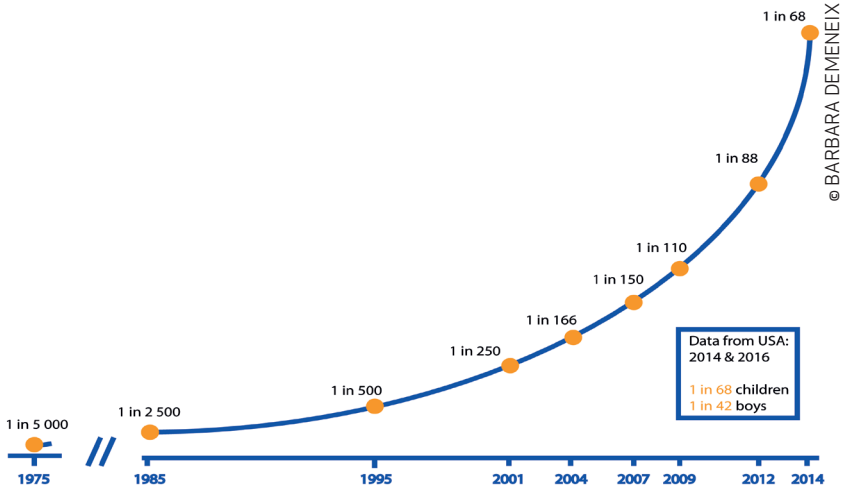
During this period, the foetal thyroid gland isn't fully functional yet, so the foetus depends on the mother's supply of thyroid hormones. "If there is any maternal lack of thyroid hormones, the foetus will not be able to compensate for it. This is the time when the baby is being formed, which is why women are advised not to take any medication in these first three months," says Professor Demeneix.

Consequently, low levels of maternal thyroid hormone will negatively affect the child's neurodevelopment. "In fact, both high or low maternal levels of thyroid hormone (even within normal values) increase the risk of having a child with an IQ less than 85. Clinical hypothyroidism during pregnancy increases the risk of autism, too. As thyroid problems are difficult to treat during pregnancy, it is important for women to get their iodine levels and thyroid status checked before becoming pregnant".

BOYS MORE LIKELY TO SUFFER

The data collected in 2010 and 2012 shows that 1 in 68 children were diagnosed with autism in the USA. For boys, this figure was as high as 1 in 48. For attention deficit/hyperactivity disorder (ADHD), current figures suggest that 14 % of American boys are affected. So, why are boys more likely to suffer from neurodevelopmental problems?

According to Professor Demeneix, there are several theories for this. "It could be that boys are more affected because they lack the second X chromosome, which is linked to many related diseases affecting the brain. They could also be more affected by an overproduction of testosterone either by the foetus or the mother."
"A third idea is that, as testosterone aromatises to oestrogen in the brain, it has a different effect on different areas of the brain. Aromatase is an enzyme that is very sensitive to endocrine disruption," she continues.



Unexplained increases in neurodevelopmental disease. The data for 2014 and 2016 from the USA were actually, in each case, collected four years earlier.

"A fourth, less likely factor, could be that male and female foetuses take up endocrine disruptors differently."

There could also be a factor related to the societal expectations of girls versus boys. "Indeed, we often expect more controlled and less disturbing behaviour from girls than we do from boys, but these sociological factors are more difficult to assess," Professor Demeneix states.

WHAT ACTIONS COULD BE TAKEN

With so many chemicals still on the market there is a need for rigourous testing as well as regulating them accordingly. "There has been a preoccupation on concentrating on mechanisms of action that has resulted in many chemicals not being classified as endocrine disruptors," Professor Demeneix tells.

Endocrine-disrupting chemicals can be found in flame retardants, toiletries, surfactants, plastics, textile products and also pesticides. There are things that you can try to do in your everyday life to limit the amounts of such chemicals that you are exposed to. "Eating organic food can reduce your pesticide exposure. Also, you should air your home regularly and it is also very important to avoid smoking, either actively or passively, since this can alter thyroid hormone levels in early pregnancy," she advises.

Barbara Demeneix is a professor currently working at the French National Centre for Scientific Research (CNRS) at the National Museum of Natural History in Paris, France. Her research has focused on the evolution of thyroid hormone signalling and has sought to understand how thyroid hormones activate or repress gene activity in different tissues at various developmental states and in changing physiological conditions.

She is the author of 'Toxic Cocktail: How chemical pollution is poisoning our brains' (Oxford University Press, 2017) which explores in detail how children born to women exposed to thyroid-disrupting chemicals have lower IQs and more neurodevelopmental disorders including autism and ADHD, among others.

Further information:

Endocrine disruptors
https://echa.europa.eu/chemicals-in-our-life/hot-topics/endocrine-disruptors

Video: How chemicals can result in autism and IQ loss in developing children
https://www.youtube.com/watch?v=LgPlKXBw4G4

Guest column | Scientific Consulting Company (SCC) GmbH

Mastering challenging chemical risk assessments using Chesar

Chesar is ECHA's tool developed to support companies in carrying out **chemical safety assessments** (CSAs) and generating **chemical safety reports** (CSRs). Some substances, however, do not permit an easy and straightforward standard approach for risk assessment. An exemplary approach is shown to demonstrate how to successfully deal with complex cases by integrating other approaches and data as complementary input into Chesar.

As a consultant, we are often asked for support in performing difficult risk assessments. For example, inorganic substances such as copper salts may present challenges for risk assessment due to their special requirements with regard to environmental exposure.

For copper salts, we faced the problem that according to the respective guidance document, the four values that are necessary for environmental risk assessment for inorganic substances (the bioaccumulation factor and three adsorption coefficients – Kp values – which indicate how a substance partitions between solids and water) are not sufficient to obtain exposure estimates for all relevant routes with Chesar.

Actually, Chesar requires additional Kp values to be entered. Since not all the values had been determined, creative thinking was required to resolve the issue. We did so by using a stepwise calculation and integrating other data. At first, the existing Kp values and other known data for copper salts were entered into the **European Union System for the Evaluation of Substances (EUSES)** program. EUSES provided predictions for certain parameters, but we could not calculate the environmental concentrations as, even with the extra predicted parameters, not all necessary parameters needed by EUSES were available.

Instead, we used existing and predicted values together with distribution in the sewage treatment plant to calculate the environmental concentrations according to the equations outlined in chapter R.16 of ECHA's *Guidance on Information Requirements and Chemical Safety Assessment*. We then manually entered the values into Chesar to calculate the respective risk characterisation ratios (RCRs) and complete the environmental risk assessment.

Thomas Roth.

It has to be kept in mind that Chesar output depends on the implemented background calculations set by EUSES or the **European Centre for Ecotoxicology and Toxicology of Chemicals' targeted risk assessment** (ECETOC TRA). Both applications thereby define the key limitations of Chesar.

This was also explained during an advanced users' Chesar workshop that ECHA organised in Helsinki in October 2017. The workshop was a good opportunity to exchange knowledge and collectively benefit from ECHA's experience as well as that of other participants. We had the chance to discuss and listen to special situations and complex cases, and were able to share the copper salts case study. For inorganic substances and their adsorption coefficients, it was confirmed that for this specific case, the information requirements as defined in the guidance documents do not match the required values needed for calculations in Chesar. ECHA promised to address this issue in one of the next updates.

ECHA also encouraged users to directly engage with them through the helpdesk should any problems evolve during risk assessment. Based on our experience, the helpdesk answers related to Chesar are provided in a very timely manner. Direct input by industry experts to the software specialists, for example, during expert workshops helps to improve the handling of complicated risk assessments. This is indispensable for further improvement of the tool by the ECHA Chesar team.

Dr Thomas Roth is the Head of the Chemicals/REACH business unit at the Scientific Consulting Company (SCC GmbH), which also includes responsibility for consumer products, cosmetics, food contact materials, feed and food additives. He has a PhD in food chemistry and is a certified expert for toxicology.

SCC GmbH is one of Europe's largest privately-owned and independent consulting companies, supporting global customers in registration of chemicals, agrochemicals, biopesticides, biocides, cosmetics, consumer products, and feed and food additives.

http://www.scc-gmbh.de

What EU agencies can learn about being transparent - Q&A with the EU Ombudsman

INTERVIEW BY HANNA-KAISA TORKKELI

Public trust in the work of EU agencies is extremely important to their reputation. This is especially true for agencies dealing with scientific assessments that form a basis for decision making on, for example, the safety of food, the medicines we take or the chemicals we are exposed to. We spoke with the EU Ombudsman *Emily O'Reilly* to hear her views on how EU agencies can gain public trust.

WHAT ARE THE MOST IMPORTANT ASPECTS OF GAINING THE PUBLIC'S TRUST IN EU DECISION MAKING?

A useful starting point is to assume that the public has a right to know what an institution is doing, how and why. Such information should proactively be made public unless there is a good reason for it not to be.

In general, EU institutions have high transparency standards. However, as EU policies affect many aspects of people's lives and the EU is often perceived as remote, it must work harder to win the public's trust.

Trust in EU decision making can be improved by making the process easier to follow. Ordinary citizens simply do not know what their government's position on a piece of legislation is as discussions on it evolve. If citizens do not have an innate sense of how we travelled from point A to point B, they are less likely to trust the institutions that managed that journey.

Citizens should also be given the tools to inform themselves. It is not enough to simply unleash a mass of information onto a website and consider the job done. The information has to be structured, it has to be in one place and it needs to be regularly updated.

Another aspect is understandable communication. When people read acronyms and eurospeak that they do not understand, they risk becoming apathetic or even hostile towards the institutions.

HOW CAN EU AGENCIES MAKE THEIR POLICY MAKING MORE TRANSPARENT AND TRUSTWORTHY?

I am impressed by how seriously ECHA, the European Food Safety Authority (EFSA) and others already take transparency for building up trust with the public.

ECHA's website, for example, is informative and well laid out and I can see that a lot of effort has gone into explaining complex terms in a clear manner.

I am also impressed by the fact that European Ombudsman cases concerning ECHA are listed on the website and that the declarations of interest of senior ECHA figures are listed. These kinds of steps increase public trust.

Broadly speaking, it is always good to consider your own institution or agency through the eyes of the public. Could an action or situation give the impression that there is a conflict of interest, that a decision may have been unduly influenced, or that something is being hidden?

It is better – and much easier – to anticipate potential problems than to try to dispel the effects of negative publicity afterwards.

Emily O'Reilly.

HOW DO YOU SEE THE BALANCE BETWEEN PUBLIC AND CONFIDENTIAL INFORMATION?

In my work, I regularly come across instances where information is not disclosed because it is deemed confidential business information.

There are occasions when some information cannot be released on data privacy or business confidentially grounds. This is reasonable. What is not reasonable is using these grounds as a basis for blanket refusal of access to information.

I believe a middle ground still has to be found. Given agencies' regulatory responsibilities, the point of departure for discussion has to be that citizens have a right to know on what basis decisions are made.

The European Commission announced in December that it will come forward with a legislative proposal this year to increase transparency in scientific assessments. My office will continue to follow this issue.

HOW DO YOU SEE ECHA'S ROLE TOWARDS CONSUMERS? REACH DOES NOT INCLUDE MANY REFERENCES TO CONSUMER AWARENESS AND THE ROLE HAS BEEN GIVEN MORE TO THE NATIONAL AUTHORITIES.

While much of ECHA's work may be invisible to the public, its consequences are very real. I commend ECHA for setting up a database with information about thousands of chemicals, which is also open to the public. I also welcome the fact that there are web pages dedicated to explaining who is responsible for chemical safety and what is done about hazardous chemicals.

It is important for all agencies to establish an internal culture that recognises that their ultimate responsibility is to the consumer. In my experience, the public wants to trust that regulatory authorities are upholding the highest standards in ethics, accountability and transparency. It is not enough, however, for a public authority to say this is the case, they must also demonstrate that this is the case.

AFTER BREXIT, THE EU'S REPUTATION HAS TAKEN A HIT. WHAT CAN WE DO TO IMPROVE PUBLIC PERCEPTION OF THE EU?

I think that the UK's decision put the EU, and what it means to be a Member State, into sharp focus. In the immediate aftermath of the referendum, European politics and EU politicians regularly occupied the front pages of newspapers.

Citizens heard about what the EU actually does on social media, in newspapers and on radio. European politics was beginning to sound a lot like normal national politics. And polls showed that support for the EU increased in most Member States after the referendum. Having said that, more could be done to improve the public's perception of the EU. The first important aspect is education.

Public perception of the EU is built on what people understand about it or what they hear about it. But it is often difficult for citizens to **know** the EU like they know their own national institutions. EU institutions feel far away, are often physically far away and are built on a system that is not analogous with national systems. More systematic teaching about the EU and its history in schools would remove some of this feeling of **otherness**.

The second important point is that the EU should get credit for popular initiatives or laws. At the moment, the tendency is to blame the EU for less popular policies, even though, as we all know, Member States are involved in shaping them. National governments, meanwhile, tend to **own** the more popular ones.

Further information:

EU Ombudsman
https://www.ombudsman.europa.eu/en/home.faces

Event summary: EU Agencies - how to manage the risk of reputational damage
https://www.ombudsman.europa.eu/activities/report.faces/en/84866/html.bookmark

Transparency at ECHA
https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/transparency

More progress needed to replace animal tests

INTERVIEW BY TIIU BRAUTIGAM

ECHA's report on how non-animal approaches can be applied sees promising development on alternatives to animal testing, but proposes a continuous and active dialogue between the research community and regulatory authorities to ensure further progress.

The report describes how non-animal approaches can be applied to REACH, CLP and the Biocidal Products regulations and reviews their current status as well as needs for future development. Overall, non-animal approaches are increasingly being developed and used.

Testing chemicals on animals should be carried out as the last resort, only after all other scientifically reliable methods have been explored.

To further develop non-animal approaches, dialogue between researchers and regulatory authorities is needed. "We must ensure that innovations can be considered for regulatory use without delay. We propose an inventory of non-animal approaches, covering different stages of development and regulatory applicability. This would help to identify current gaps and determine future steps to enhance their use," says Dr *Hannele Huuskonen*, Senior Scientific Officer in the Evaluation Directorate at ECHA.

SIGNIFICANT SCIENTIFIC PROGRESS

Over the last 10 years, there has been significant progress in developing non-animal approaches.

"There are various methods and promising tools that have increased our understanding of biological and (eco)toxicological mechanisms. For example, advances in **'-omics'** that reflect the activity of biological pathways and metabolism in cells and tissues have enabled us to get information on how substances can cause molecular and functional changes in cells," Dr Huuskonen tells. Technical developments now allow *in vitro* microsystems to be used – this is also known as

Hannele Huuskonen.

organ-on-a-chip technology. "This method uses human cells that grow on a microchip. They can simulate human organs and even interactions between different organs. It is a promising approach for predicting toxicity in various organs."

Concepts such as the **integrated approach to testing and assessment** (IATA) and the **adverse outcome pathways** (AOPs) enable data from non-animal approaches to be better used.

"This has already reduced the need for animal testing. These developments can also help regulators to take further steps towards replacing, reducing and refining animal testing," Dr Huuskonen explains.

High-throughput and high-content techniques are used to screen substances for possible further analyses and also potentially for future identification of hazards and safety levels. They help to quickly analyse properties of many chemicals and therefore can provide more information on their toxicity.

"Overall, the new approaches will help to produce and analyse data on the toxicity of chemicals and improve their safety evaluation – hazard classification and risk assessment. This will reduce the need for animal-based data in regulatory work," she states.

COMBINING NEW METHODS

Many of these new approaches are still under development and not yet accepted as a direct replacement for animal testing. They need further research and standardisation in order to find an agreement on how to interpret their results in a harmonised way. Only after this can the methods be validated for use under the EU chemicals legislation. This is especially the case for more complex endpoints, such as repeated dose toxicity or reproductive toxicity, where non-animal approaches are not yet available to be used as standalone methods.

However, many of these methods can be used as supporting evidence for other data – for example, as part of grouping and read-across or a weight-of-evidence approach. These are ways to use existing data to predict toxicity of new substances and they reduce the need to carry out new tests on animals. The non-animal approaches can also be very useful for screening substances for further regulatory action.

"To improve the interpretation of results of non-animal approaches, information from humans, animal studies and non-animal approaches need to be combined, so that we can produce reliable and consistent results that can be used for registration purposes or to classify the hazards of chemicals", Dr Huuskonen says.

Some non-animal approaches, such as *in vitro* tests, using cells or tissue, and *in chemico* tests (using abiotic assays) are already the default method for companies who need to provide data on skin corrosion/irritation, serious eye damage/eye irritation, mutagenicity or skin sensitisation of their substance. These methods were included in the REACH Annexes in 2016.

"We expect registrants to use *in vitro* and *in chemico* methods wherever possible. Animal tests can only be used if the non-animal ones are not adequate for the substance or cannot be used for hazard classification and risk assessment. Companies are encouraged to read our guidance to help them get familiar with using non-animal approaches. We also provide tools and advice through updated guidance, practical guides, IT tools, case studies and webinars," Dr Huuskonen reminds.

Further information:

ECHA's report on regulatory applicability of non-animal approaches under the REACH, CLP and Biocidal Products regulations
https://echa.europa.eu/documents/10162/22931011/non_animal_approcches_en.pdf/87ebb68f-2038-f597-fc33-f4003e9e7d7d

GLOSSARY

Adverse outcome pathway - sequence of events from the chemical structure of a target chemical or group of similar chemicals through the molecular initiating event to an *in vivo* outcome of interest.

High-throughput screening - method involving an automated operation platform, data processing and control software to quickly conduct many biochemical, genetic or pharmacological tests.

***In chemico* -** abiotic assay measuring chemical reactivity or other physicochemical properties of substances.

***In silico* -** information from computer software or simulation.

***In vitro* -** Studies using cells, tissues or organs.

Omics - large-scale analytical techniques that can be used to support and understand biological and (eco)toxicological mechanisms.

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