

A photograph of two sunscreen bottles on a sandy beach. The bottle in the foreground is white with a gold cap, and the one behind it is light blue with an orange cap. The background is a blue wooden fence.

Everything under control?

Regulating nanomaterials and other chemicals

Robust but proportionate regulation



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More than three decades have passed since the publication of *Chemie im Haushalt*, Rainer Grieshammer's guide to chemicals in the home. It became an instant non-fiction bestseller. Compared with the 1980s and the time before that, we now live in a world with far fewer unregulated hazardous chemicals in the home and – more importantly, for it is a much larger field of application – in industry. This is due to more robust regulation, a frequent area of work for us here at the Oeko-Institut in recent decades.

However, this does not mean that we can rest on our laurels. With so many new substances and users, we must be meticulous in monitoring and assessing the potential risks to human health and the natural environment. As with any area of scientific discovery, there are still gaps in our knowledge, which makes it more difficult to predict future scenarios, as we must. Nonetheless, the goal is clear: to keep substances that may cause problems out of the environment and prevent them from polluting our soils, water resources and atmosphere and harming our health. With that aim in mind, we need legislation, which must be proportionate and workable in practice.

This is where our experts and their years of experience come in. Our teams combine technical skills in the assessment of pollutants with an in-depth knowledge of the law. This carefully calibrated blend of interdisciplinary expertise is one of our particular strengths, which we have continuously refined since the Oeko-Institut was first established. In this issue of *eco@work*, we describe the challenges arising in the regulation of chemicals at the European level, with particular reference to nanomaterials and hazardous substances in electrical and electronic equipment. And our interview with an expert from Germany's Federal Environment Agency (UBA) offers you some insights into chemicals management at the international level.

With this issue, *eco@work* is back to its regular format after the special anniversary edition last time. We hope that you find both of them interesting and inspiring.

Yours,

Michael Sailer

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“We want to position sustainable chemistry as a key concept”

In 2002, participants at the World Summit on Sustainable Development (WSSD) in Johannesburg made a commitment that by 2020, chemicals must be produced and used in all phases of their life cycle to minimise significant adverse effects on human health and the environment. Is this an achievable goal? In this interview with *eco@work*, Dr Hans-Christian Stolzenberg, Head of the International Chemicals Management Unit at the German Federal Environment Agency (UBA) and an expert in international chemicals policy and regulation, describes the advantages and disadvantages of international conventions, spells out what he would like to see in future agreements and explains what sustainable chemistry has to offer.

Dr Stolzenberg, wouldn't you say that chemicals need an international framework agreement with clear targets and commitments, as is already in place for climate change?

I think that an international framework convention on chemicals is unrealistic, for several reasons. Many emerging economies would distance themselves from this type of agreement on the grounds that it would limit their freedom to pursue their own approach to national development. There would also be strong opposition from industry, which would argue that many countries are still not complying with even the most basic regulations on chemicals management. For example, a large number of countries have not yet introduced the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). But more to the point, there is already a measure of “convention fatigue” in relation to this highly complex topic. And last but not least, we already have a number of international agreements in place, such as the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention, which deals with hazardous wastes, the Rotterdam Convention on international trade in hazardous chemicals, and the new Minamata Convention on Mercury, which was years in the making.

How effective are these agreements?

These conventions are binding under international law and are therefore an important building block in international chemicals policy. However, in many cases, they are simply the lowest common denominator. A further chal-

lenge is that they do not yet include any compliance mechanisms, which means that there are no sanctions to impose on countries which fail to implement them. For that reason, additional measures are required.

Can you give us some examples?

A good example is the Strategic Approach to International Chemicals Management (SAICM), which was adopted in 2006 and is administered by the United Nations Environment Programme (UNEP). SAICM is a policy framework which aims to achieve the sound management of chemicals throughout their life cycle and includes objectives and implementation arrangements. It is a voluntary approach but in my view, its particular value is that it covers so many different sectors and stakeholders. It is currently looking at the period beyond 2020, and as the SAICM national focal point, my team and I are involved in this process, working closely with the German Environment Ministry.

What would you like to see coming out of this process?

We need to look at what has worked and what could be done better. Globally, we need a higher level of ambition for chemicals management, with more action plans and mandatory targets. It is also important to prioritise and to adopt a science-based approach to determine where the need for action is greatest. At the Federal Environment Agency, we are also trying to position sustainable (green) chemistry as a key concept to guide chemicals management.

What contribution can sustainable chemistry make?

It combines economic innovation with a precautionary approach to the protection of the environment and health, weighs up all the levels of sustainability in order to find the best way forward, and seeks to use chemicals as sustainably as possible. Sustainable chemistry is based on a holistic approach which aims to achieve continuous improvements in processes. Support for the evolution and broad-based application of sustainable chemistry will be provided, incidentally, by the International Sustainable Chemistry Collaborative Centre (ISC3) launched by the German Environment Ministry and the Federal Environment Agency. Among other things, ISC3 will analyse and disseminate commercially viable business models based on sustainable chemistry.

Thank you for talking to *eco@work*.

The interviewer was Christiane Weihe.



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Under the radar

Regulating nanomaterials

The word “nanomaterials” evokes a wide range of associations: microscopically small; an exciting field of research; innovative functions. Nanomaterials can make products more lightweight and efficient, thus helping to save energy and resources. And yet despite all the research, we still do not know all there is to know about nano. There are critical gaps in our knowledge, especially as regards the possible long-term effects on human health and the environment. So there is every reason not only to continuously research and monitor but also to regulate their manufacture and use. The Oeko-Institut is engaged in numerous projects which explore the opportunities and risks associated with nanomaterials – and show why they need to be regulated.

Nanomaterials can provide products with improved features, including better eco-efficiency. “Using nanomaterials has made it possible to produce more efficient dirtproof solar cells and dimmable glass panels,” says Andreas Köhler, a Senior Researcher at the Oeko-Institut. “Other examples of improved product features are more lightweight beverage packaging and innovative thermal insulation.” A 2014 study conducted by the Oeko-Institut on behalf of the German Federal Environment Agency (UBA) analysed particularly promising nanotechnology applications and their resource and energy requirements. This Study of the Effects of Selected Nanotechnology Products on Resource and Energy Demand showed that significant savings

can be achieved: “Dimmable electric windows have the potential to reduce energy demand and CO₂ emissions by around 30 per cent compared with conventional windows with blinds,” says Andreas Köhler.

But there are also signs that nanomaterials may pose risks to human health and the environment. “Synthetic nanomaterials released from products or industrial processes can be absorbed by human or other organisms – and some of these materials have toxic effects,” says Andreas Köhler, who works in the Oeko-Institut’s Sustainable Products and Material Flows Division. “How toxic are they? That largely depends on the type of nanoparticle – and the dose.”



The application of nanotechnology to windows can cut energy demand by around **30 per cent.**

Nanomaterials disperse differently in the environment and organisms compared with conventional chemicals; theoretical studies indicate that they can penetrate natural defences and affect even well-protected organs, including the brain. "If silver nanoparticles enter the body, for example, they can release toxic silver ions in places that conventional silver can never reach." Far too little is known at present about the long-term effects of nanomaterials: "For example, they may be carcinogenic or influence the body's endocrine functions," says Andreas Köhler.

THE NEED FOR REGULATION

His colleague, legal expert Andreas Hermann, is convinced that standards, legislation and governance are essential in identifying, minimising and monitoring existing risks effectively. "This means registering and labelling nano-products, but above all, it must include a standardisation process for the characterisation and measurement of nanomaterials. We cannot simply treat them like any other chemical, because the level of hazard posed by these materials depends not only on dose but also on their particle size and surface characteristics," he says.

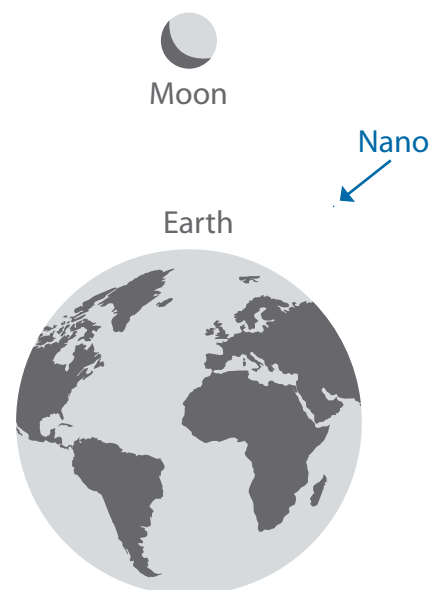
The EU has initiated a process to regulate nanomaterials, but this Senior Researcher is far from satisfied. "The current approach is neither sustainable nor transparent, and there is no evidence of the precautionary principle being applied," he says. "And let's not forget that products containing nanomaterials have been on the market for quite some time and are even used in sensitive applications such as food and cosmetics." The lack of a clear regulatory framework is hampering the safe development and use of nanotechnologies, in his view. "What is needed, among other things, is a revision of REACH, the European regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, so that it takes adequate account of the specific properties of nanomaterials at last. And there needs to be a management strategy that covers the entire life cycle of products containing nanomaterials." Appropriate information for the public, e.g. through product

labelling, and continuous bio-monitoring of human health and the environment are also important for sustainable management of nanotechnologies, he says. "The EU is reluctant to put jobs at risk in this booming sector, so its approach to the industry is far too lenient. As a result, the EU is dragging its feet on introducing binding provisions in REACH that would specify which data must be collected by the manufacturers of nanomaterials and passed to the European Chemicals Agency (ECHA). What's more, there have been considerable delays in implementing existing rules on the registration and licensing of nanomaterials in cosmetics. Some of these nanomaterials are already on the market, and yet in line with the „no data, no market“ principle, they shouldn't be on sale at all."

REACH AND NANO

As part of a three-year collaboration with the Center for International Environmental Law (CIEL) and the European Environmental Citizens' Organisation for Standardisation (ECOS), the Oeko-Institut has been working to ensure that the social and environmental benefits but also the risks posed by nanomaterials are duly considered at international and EU level. One of the tasks of this project on the safe production and use of nanomaterials in Europe was to support the standardisation bodies ISO and CEN and the international OECD working group on nanomaterials in the development of clear standards and recommendations. With funding from the Danish Villum Fonden, the researchers also produced accessible factsheets on standardisation, along with information and arguments for improving health and environmental protection in relation to nanomaterials, with a focus on their potential toxicity. "We have also produced a position paper commenting on the changes proposed by the European Commission to improve safety assessment and communication on the risks associated with nanomaterials within the REACH framework," says Andreas Hermann.

REACH requires manufacturers, importers and users of chemicals to gather information about substances and



Nanomaterials are measured in **millionths of millimetres.**

products and submit it to the European Chemicals Agency (ECHA). "At present, however, there are no nano-specific rules, and that needs to change as a matter of urgency," says Andreas Hermann. "For example, back in 2011, the Oeko-Institut produced a feasibility study for the German Environment Ministry which showed that a nano-product register is legally viable and is workable in practice. In their position paper, CIEL, ECOS and the Oeko-Institut are now calling for nano-specific rules to be built into the main text of REACH. Among other things, manufacturers, importers and users should take the surface characteristics of nanomaterials into account in the monitoring of environmental behaviour and risks. "We are calling for the safety data sheet to include information on nanomaterials' composition, manipulation, exposure controls, chemical and physical properties and toxicology," says Andreas Hermann. "This will require very extensive data-gathering, reflecting the highly diverse properties of materials located on the nano scale."



A NANO FACILITY REGISTER

The Oeko-Institut's researchers are looking at registration options not only for nano-products themselves but also for facilities which manufacture, process and store nanomaterials. In a feasibility study on the legal options for a nano facility register, conducted on behalf of North Rhine-Westphalia's State Agency for Nature, Environment and Consumer Protection (LANUV), they reviewed the existing legislation and looked at new legal arrangements that could potentially be adopted for this purpose. "The aim of setting up this type of register and introducing reporting obligations for facility operators is to avoid risks to human health and the environment, in compliance with the precautionary principle," says Andreas Hermann.

The study identifies vast gaps in the relevant authorities' information. "They don't know enough about which specific facilities are working with nanoma-

terials, the quantities of these materials being produced or processed, and their level of toxicity," says Hermann. "There are also knowledge gaps relating to the ways in which nanomaterials can enter the environment from these facilities – and how much has already been released." This information should be gathered and stored in a nano facility register. The study also recommends the adoption of nationwide regulations and a three-step approach establishing reporting obligations, initially for manufacturers and then for processing facilities and, finally, users of nanomaterials. "Regulation is urgently needed at various levels in order to protect human health and the environment from negative impacts," Andreas Hermann emphasises. In other words, the main associations evoked by nanomaterials should include transparency and governance.

Christiane Weihe



Technical environmental law at national, European and international level is a focal point of Andreas Hermann's work. A legal expert, he has been employed in the Oeko-Institut's Environmental Law and Governance Division since 2001, analysing, developing and assessing mechanisms for environmental governance of technical innovations such as nanotechnologies. A Senior Researcher in the Oeko-Institut's Sustainable Products and Material Flows Division since 2014, Andreas Köhler works on issues such as the regulation and standardisation of nanomaterials.
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Efficient substitution

Restricting hazardous substances in electrical and electronic equipment

Electrical and electronic equipment contain substances which pose a risk to human health and the environment but which, from a technical perspective, have long been regarded as essential components in the manufacture of products such as printed circuit boards (PCBs), compact fluorescent lamps and fluorescent tubes. Since 2006, the EU's Restriction of Hazardous Substances (RoHS) Directive has limited the use of six of these substances: lead, mercury, cadmium, hexavalent chromium and flame retardants polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). In July 2019, four phthalates, which are used as softening agents in plastics, will be added to the list of restricted substances. However, the RoHS Directive permits time-limited exemptions for these substances in certain applications. Since 2006, the Oeko-Institut has conducted studies on behalf of the European Commission, reviewing more than 100 exemption requests in order to determine whether they were justified and complied with the relevant criteria. Recommendations were then submitted to the European Commission.

Exemptions permitting the use of substances listed in the RoHS Directive may only be granted if certain criteria are met. "The general criteria which must be met for an exemption to be granted are that substitution is not possible from a scientific and technical point of view, or if there is no permitted alternative, or

if the negative environmental or health impacts caused by substitution are likely to outweigh the human and environmental benefits of the substitution," says Yifaat Baron, Senior Researcher at the Oeko-Institut. "However, the exemptions are time-limited and must be renewed at regular intervals." In contrast

to the four heavy metals, no exemptions were requested by industry for the brominated flame retardants (BFRs) mentioned above. "In these instances, substitution was the easier option, but that's not to say that it is sustainable," says Yifaat Baron. "In some groups – as is the case here – the substances differ





Since 2006, the Oeko-Institut has reviewed more than **100** requests for exemptions under the RoHS Directive.

only slightly, in terms of their structure, from the banned equivalents, so they may be equally hazardous to human health and the environment.”

Over the past decade and more, researchers at the Oeko-Institut have been continuously reviewing and assessing exemption requests, evaluating the available data and analysing information provided by stakeholders or applicants. “With its criteria, the Directive certainly offers scope to assess whether or not substitution is already possible for certain substances from a scientific and technical point of view,” says Yifaat Baron. “However, we do rely heavily on applicants submitting adequate data and stakeholders taking an active role in the process.” One often-heard argument is that possible substitutes do not possess all the technical properties of the original substance, such as reliability. To ensure that this aspect is adequately assessed, generally applicable rules on testing are required in order to measure performance. “The example of cadmium in flatscreens shows how important it is to have these rules in place.”

CADMIUM IN FLATSCREENS

One of the new flatscreen technologies is based on quantum dots, used to achieve high-quality colour performance in televisions and monitors but containing cadmium, a highly toxic and

carcinogenic substance. As part of its assessment of the relevant exemption request, the Oeko-Institut looked at the information provided by the applicants and competitors engaged in the development of similar technologies which do not contain cadmium. “One particular challenge was that different measurement standards exist for the assessment of cadmium quantum dot technology and the alternatives,” says Yifaat Baron. “Energy consumption is determined not only by the technology itself but also by the degree of energy efficiency in the electronics required for the operation of the screens.” So while some models available on the market may in theory offer a technological advantage, this is not always achieved in practice; indeed, the screens may consume more energy than other comparable devices. “The information from the applicants and from competitors did not allow any firm conclusions to be drawn about total energy consumption,” Yifaat Baron explains. The study was therefore based on a comparison of the technologies and current standards for the assessment of image quality. On that basis, the researchers recommended an exemption allowing the use of cadmium quantum dots for a period of three years. “From a toxicological perspective, the alternative substances currently offer no significant benefits or disadvantages,” says Yifaat Baron. “The key factor, however, was the much higher energy consumption of cadmium-free screens – by around 20 per cent – found in the comparison of the technologies.” The short exemption period recommended by the researchers has one clear goal: it is specifically intended to support environmentally-oriented innovations in display technology which avoid the use of hazardous substances while achieving high-quality colour performance.

SUCCESSES ACHIEVED BY THE DIRECTIVE

The Oeko-Institut’s researcher regards the RoHS Directive as a valuable and effective tool. “In the years after the Directive’s entry into force in the EU, mercury content in lamps, for example, was reduced by around 75 per cent to 2.86 tonnes in 2013.” However, the number

of exemptions listed in the relevant Annex to the Directive increased at the same time. “But that is positive, as the current exemptions – unlike the initial phase after the Directive entered into force – are much more specific and the use of the restricted substances is now permitted only in certain very clearly defined applications,” says Yifaat Baron. “A larger number of exemptions means that the problematical substances are being used in diminishing quantities and in fewer applications.” These are mainly applications in which substitution is more complicated or no alternatives are available. As these applications tend not to involve mass-produced items, there is less motivation to find a substitute. “It may be beneficial, in such cases, to provide targeted support for the search for substitutes through research funding,” notes Baron.

In her view, it would also be useful to compare the effectiveness and efficiency of various mechanisms such as the RoHS, the European chemicals regulation REACH and the EU Ecolabel. “We should look at how these various frameworks are being applied in practice,” says Yifaat Baron. “It may not be necessary to harmonise the directives, but I think we can learn how to improve the work on restricting and finding substitutes for hazardous substances and see how certain aspects can be better addressed together.”

Christiane Weihe



Hazardous substances in products, sustainable production and technology assessment are among Yifaat Baron’s areas of expertise. Employed by the Oeko-Institut since 2012, her work includes assessing requests for exemptions from the substance restrictions under the RoHS Directive and evaluating the abatement costs of chemicals.
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