



# REACH protects against hazardous substances

Chemicals are a part of everyday life. The EU chemicals regulation REACH has been in effect for a decade. The regulation is an important tool for chemicals safety. Currently, it is being used to restrict the use of asthma-triggering diisocyanates throughout Europe on the initiative of Germany.

At the end of 2017, the European Chemicals Agency (ECHA) came to the conclusion that the use of diisocyanates can pose an unacceptable health risk. This conclusion was based on an assessment report by the BfR and the Federal Institute for Occupational Safety and Health (BAuA). Together, the two institutes had shown that this group of substances can trigger asthma and that no safe limit value can be derived for it. In accordance with the German Chemicals Act (ChemG), the BfR assists in the implementation of the European chemicals legislation as the "assessment body for health and consumer protection". It collaborates with the Federal Institute for Occupational Safety and Health (BAuA), the Federal Environment Agency (UBA) and the coordinating Federal Office for Chemicals (BfC) under professional supervision of the Federal Ministry for the Environment (BMU).

## Restricted or prohibited substances

If an unacceptable, insufficiently controlled risk is determined for a substance, the authorities can suggest restricting chemicals according to the European chemicals regulation REACH (EC) 1907/2006. Their use can then be subject to specific conditions or generally prohibited in all EU states. 68 substances or groups of substances have already been restricted throughout Europe. Examples include benzene, asbestos fibres, lead, mercury, arsenic, cadmium, nickel, azo

dyes and certain plasticisers. Many of these substances can cause cancer, damage genes, impair the development of offspring or adversely affect fertility (so-called CMR substances), but substances can also be restricted because of other health risks. In the case of diisocyanates, the main issue is the sensitising effect of these substances on the respiratory tract.

### Reducing new cases of asthma throughout Europe

Diisocyanates are highly reactive chemicals that are used primarily for manufacturing polyurethane plastics with an estimated market volume of 2.5 million tonnes per year in the EU. Cured polyurethane can be found in foams and coatings, for example for insulation boards, mattresses and cushions. Uncured diisocyanates can be contained in special lacquers, seals and in construction foams which are generated and applied on site (so-called in-situ foams). Some of these products are also on the market for DIY use.

In contrast to cured polyurethane, uncured diisocyanates are highly sensitising. Even minimal contact can lead to asthma and skin allergies. Workers who handle products containing diisocyanates are particularly affected. However, uninvolved third parties also need to be protected during construction work with such products so that they do not come into contact with diisocyanates as bystanders. To better protect workers from occupational illness, Germany took the initiative to restrict the use of these chemicals throughout Europe. Together with the BAuA, the BfR performed the toxicological risk assessment and made contributions regarding the safety of bystanders.

### Evidence of an unacceptable risk posed by diisocyanates

The BfR and BAuA proved that the use of diisocyanates can pose an unacceptable health risk. This proof is an important prerequisite for the success of an application for restriction. Proving an unacceptable health risk from diisocyanates was scientifically difficult because measured or estimated exposure of the affected population could not be compared to a limit value for harmful effects, as is otherwise common for restrictions. The BfR and BAuA jointly evaluated several hundred experimental animal studies and epidemiological human data. Even using this comprehensive data base, the reliable determination of a dose without a harmful effect was not possible. At the same time, an extrapolation based on recorded and recognised occupational illnesses and the assumption of a high number of unreported cases, showed that the use of diisocyanates might cause over 5,000 new cases of work-related asthma throughout the EU each year.

The proposal to restrict diisocyanates was submitted to ECHA in October 2016. In December 2017, ECHA's Risk Assessment Committee (RAC) recommended acceptance; the Socio-Economic Analysis Committee (SEAC) of ECHA also agreed with the proposal in March after the end of the official consultation period. Now, the European Commission will present a proposal for the final restriction text. The approval on this will then be made via a comitology procedure involving the member states and the European Parliament.

If the restriction procedure is successful, diisocyanates will only be able to be used above a concentration level of 0.1% if it has been demonstrated that usage poses only a minimal risk, e.g. through the safe design of the product. Alternatively, people who use such products must be informed about the health risk and have received sufficient training on protective measures. In this way, they will be able to better protect themselves and others from substances triggering asthma in the future. ■

### German proposals to restrict chemical substances

**Carcinogenic PAHs:** Certain polycyclic aromatic hydrocarbons (PAHs) are carcinogenic. They can now only be contained up to a defined limit in consumer products and toys. The BfR's health assessment of PAHs and the data on occurrence in consumer products were the basis for the restriction.

**PFOA, -salts and -precursor substances:** Perfluorooctanoic acid (PFOA) accumulates in the human body and is transferred to the foetus through the placenta during pregnancy and to breastfed babies through breast milk. The intake of PFOA and its precursor substances into the human body takes place primarily through food, indoor air and drinking water. In animal experiments, PFOA demonstrates hepatotoxic, carcinogenic and reprotoxic properties. The BfR supported its Norwegian partner authority in the health assessment of PFOA.

More information (in German):  
[www.reach-clp-biozid-helpdesk.de](http://www.reach-clp-biozid-helpdesk.de) > REACH > Zulassung und Beschränkung > Beschränkungsverfahren > Anhang XVII Beschränkungen

## The REACH Regulation: Registration – Evaluation – Authorisation – Restriction

Chemicals produced, imported or procured in the EU in quantities of one tonne and more per year must be registered in accordance with the REACH regulation. For substances which were on the market before REACH came into effect, the registration deadlines have been spread over nine years, depending on the tonnages involved. The last deadline expires on 1 June 2018. To get a substance registered, manufacturers or importers have to submit a registration dossier. The European Chemicals Agency (ECHA) and national authorities of the 28 member states examine these dossiers for data gaps and request any data which might be missing. In order to be able to better assess data quality, the BfR has conducted several research projects (see box), because the quality of the toxicological data plays a key role in health and environmental protection.

ECHA and the national authorities, however, do not only critically examine the risk assessments produced by industry, they also prepare their own risk assessments. Thus, for example, they can identify substances with particularly dangerous properties for humans and the environment as “Substances of Very High Concern” (SVHCs). If necessary, the EU can impose an authorisation obligation on these substances in order to guarantee their safe use and substitute them in the long term with less hazardous substances. All currently known and relevant SVHCs are to be identified and included in a candidate list by the year 2020 (SVHC Roadmap 2020). Subsequently, they can be gradually included in the list of substances requiring authorisation (Annex XIV of the REACH regulation).

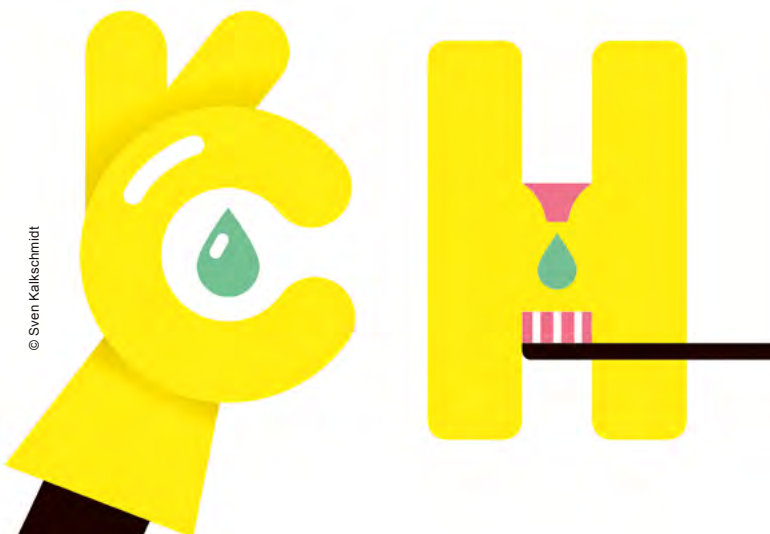
If, as in the case of diisocyanates, an unacceptable, inadequately controlled risk is established for a substance, chemicals can also be restricted. Restrictions are listed in Annex XVII of the REACH regulation. Unlike the authorisation requirement, they also apply explicitly to imported substances and/or substances contained in mixtures and articles. “The guiding principle of REACH is that chemicals are only used in such a way that no unacceptable health risk results for humans or the environment,” says Dr. Agnes Schulte, head of the Chemicals Safety unit at the BfR. The Institute uses the various REACH instruments – Registration, Evaluation, Authorisation, Restriction – above all else to better protect consumers against CMR and allergenic substances. ■

### BfR research project REACH-Compliance I–III: How good is the data provided by industry?

Using a standardised method, 1,814 registration dossiers of chemicals each with an annual market volume of 1,000 tonnes and more were examined to establish whether the necessary data on human toxicity, ecotoxicity, and exposure to the environment is contained in appropriate quality. The result showed that the data basis of many dossiers provided by industry was not in compliance with the requirements. Often data regarding the assessment of the effects of the substance on health and the environment are lacking. As an example: In roughly half of the registration dossiers examined, this was the case regarding the data on developmental toxicity. From the findings made during the project, the BfR has derived recommendations for registrants. The BfR is currently assessing the registration dossiers for substances in quantities of 100 to 1,000 tonnes.

More information:  
[www.bfr.bund.de/en](http://www.bfr.bund.de/en) > Research > Third party projects of the BfR > Detection of contaminants and for the assessment of chemical risks

[www.umweltbundesamt.de/en](http://www.umweltbundesamt.de/en) > Publications



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## “We need high-quality exposure data”

**Dr. Agnes Schulte, Head of the Chemical Safety unit in the Chemical and Product Safety department at the BfR, about chemical assessment under REACH.**

### **More than ten years of REACH – do you consider this a success story?**

Yes! We work well together with all authorities on the European level. For example, we conducted a substance assessment for bisphenol A, and France took this into consideration in its proposal to restrict the substance for consumer products. There is a great deal of cooperation. Together, we agree on the best options of action in order to improve the safety of chemicals for people and the environment. REACH offers a suitable network for this. Now, non-EU countries also want to introduce a programme like REACH and are using the European chemicals legislation as a good example.

### **How has REACH changed the working procedures of authorities in Germany?**

Assessment of substances in terms of health, environment and occupational safety is legally divided between three authorities. These authorities can jointly prepare substance dossiers which are then forwarded to the European Chemicals Agency. Many steps in this assess-

ment work rely on the results of other units or require mutual cooperation. This close-knit, interlinked way of working is something special.

### **Where is action still required, from the perspective of the BfR?**

The registration data often lacks information on the actual exposure of the population, i.e. consumer exposure. When there is a lack of exposure data, risk assessment is difficult. After all, risk assessment means not only assessing the hazard potential of a substance, but also placing this in relation to the dose to which consumers are actually exposed. If we don't know enough about this, our risk assessments are subject to significant uncertainties.

### **How can this be changed?**

It is important to the BfR that high-quality exposure data is routinely incorporated in the risk assessment under REACH. To improve the basis of data here, the BfR has started several projects on the behaviour of consumers when handling chemicals. ■