

# REACH: The New Chemicals Policy in Europe

2007



Risiken erkennen – Gesundheit schützen

## **Imprint**

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REACH: The New Chemicals Policy in Europe – How will things change for consumers?

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# **REACH: The New Chemicals Policy in Europe**

How will things change for consumers?



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## Prefaces

### Dear Reader,

After many years of difficult negotiations the REACH Regulation was approved in Brussels in December 2006. The new Regulation will lead to the gradual introduction of a Europe-wide system for the **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals. The purpose of this Regulation is to identify and to avoid risks to humans and the environment from the dangerous properties of chemicals more effectively than before.

We all come into contact with chemicals in articles we use daily. We know that some of these chemicals can accumulate in the human body and are often held accountable in public debate for the increase in certain diseases like allergies. However, the gaps in scientific knowledge make it difficult to prove or disprove claims of this nature and, by extension, to come to the right conclusions, be it as a consumer, manufacturer or politician.

REACH will change this situation by systematically collecting information and, in this way, enabling environmental and health protection to take a major step forward. Companies will have more obligations and will assume responsibility for the safe use of their substances from production down to the final product. The ensuing additional burdens for industry and the need to achieve the right balance were some of the reasons for the difficult nature of the negotiations. REACH introduces major incentives to

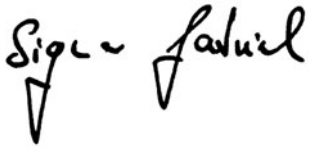


*Sigmar Gabriel*

no longer use particularly problematic substances and to replace them with less dangerous ones. At the same time, the framework conditions for innovations of this kind will be enhanced by means of an improved flow of information within industry.

Consumers will benefit above all from safer products. The information on remaining risks on the product labels and in the instructions for use will be improved. In a free Internet database consumers will be able to actively seek out information on the properties of chemical substances and their areas of use. Furthermore, they will be entitled to ask their retailers whether their products contain specific substances of very high concern even if they don't have to be indicated on the label. Of course, no-one will want to admit this and will prefer to attract customers with safe products. I, therefore, see this right of consumers to

ask for information as an important driver behind the disappearance of substances of this kind from consumer products.

A handwritten signature in black ink that reads 'Sigmar Gabriel'. The signature is written in a cursive style with a large 'S' and a prominent 'G'.

**Sigmar Gabriel**

Federal Minister for the Environment,  
Nature Conservation and  
Nuclear Safety

**Dear Consumers,**

Is the public at large sufficiently protected when handling chemicals? This question has been addressed not only by BfR but also by consumers, manufacturers and politicians. Life in Germany is no longer conceivable without products consisting of technically produced chemicals. However, the information about the risks is still too sparse.

Up to now there has not been sufficient examination of all substances in products or of all substances used in the production process to be able to reliably estimate the health risks. BfR is of the opinion that for most substances, there aren't even any estimates of the most important harmful effects, for instance hazards during pregnancy. Up to now, no studies have been carried out either in test animals or in cell cultures in the laboratory for most chemicals. As experience over the last two decades has shown, the current chemicals legislation of the European Union was not sufficient for manufacturers to close the gaps in knowledge. That is why the EU Council of Ministers for the Environment, with the approval of the European Parliament, adopted the REACH Regulation, the system for the registration, evaluation, authorisation and restriction of chemical substances, in December 2006 following



*Professor Dr. Dr. Andreas Hensel*

years of negotiations. What impact will REACH have on people in Germany? This brochure provides answers to those aspects of this question which are popularly attributed to the term consumer protection and come under the remit of BfR.

We describe the protection afforded already today to consumers from harmful substances in products and what changes are to be expected as a consequence of REACH. We also look at the subject of animal testing. This brochure is intended first and foremost for multipliers involved in consumer advice who need an overview of the highly complicated legal situation. But consumers can also benefit from this brochure if they want to take a closer look at this topic.

That's why this subject is explained in such a way that it can be understood by people who have not studied medicine, chemistry or related areas.



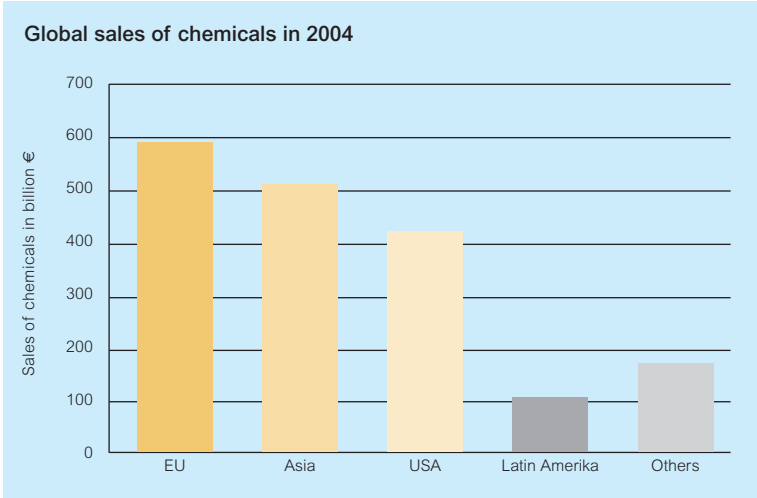
**Professor Dr. Dr. Andreas Hensel**

President of the Federal Institute for  
Risk Assessment

# 1 We live with chemical substances

Chemical substances and compounds are the foundation of our world. Since time immemorial people have been surrounded by chemical compounds which they inhale from the air, ingest from their food or take in through their skin. People change compounds which they find in nature. They produce new “substances”: chemicals. Fire retardant agents in





computers, preservatives in foods and plasticisers in plastics – the number of substances used is estimated to be more than 100,000.

Worldwide chemical production grew from one million tonnes in 1930 to 400 million tonnes today. The European Union is the largest chemicals producer in the world. The products are used in many different ways (see graph, p. 12).

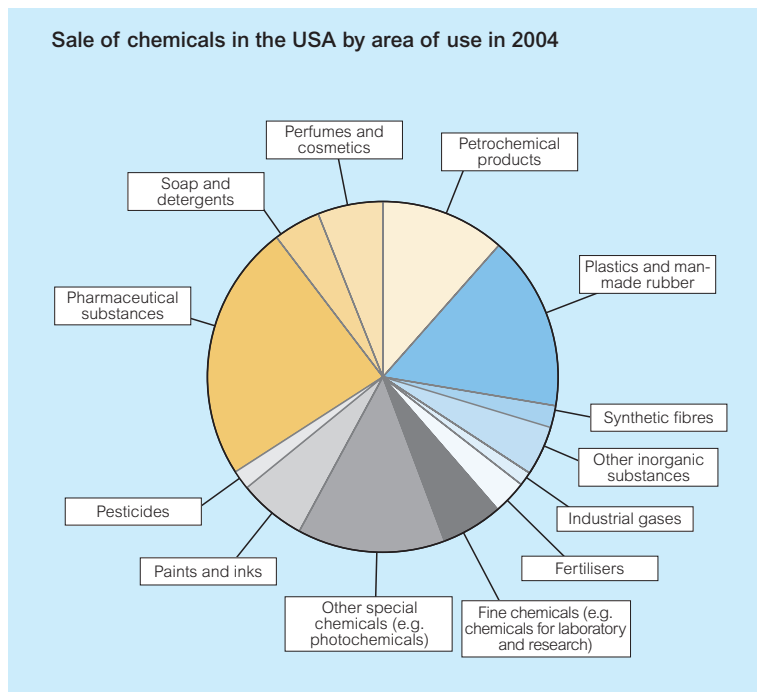
#### Chemicals are useful

Chemicals are part of our daily lives. They are useful in many different ways for instance in health care or in the home. All chemical substances have different, desired or adverse, healing or harmful effects. Knowledge about the effects of chemical substances is growing. But is it growing fast enough?

#### Chemicals are everywhere

Scientific studies confirm that many industrially manufactured chemical substances can be detected in hu-





man beings and animals. For instance, Greenpeace and the World Wide Fund for Nature reported that up to 70 substances, which do not occur naturally in the environment, were detected in the blood of people in Europe. Some chemical substances are passed on during pregnancy from the mother to the foetus. Furthermore, many chemicals are not broken down and can, therefore, accumulate in the environment and in our bodies.

### Chemicals and risks

In western countries, many chronic diseases are on the advance today like allergies, diabetes, dementia disorders or infertility. A bad diet, a lack of physical exercise and higher life expectancy are thought to be contributory factors. Some of these diseases could be caused by the many chemical substances to which we are exposed first of all in the womb and then as babies, children and adults.



## 2 Protection afforded to consumers up to now

### The statutory provisions

At work or at home we are confronted to varying degrees with undesirable and, in some cases, harmful substances: in the air, in food, water and soil and, last but not least, through chemical substances in products.

There are a number of statutory provisions to monitor and reduce this exposure as demonstrated by the following graph. For instance the goal of the Immission Control Act is to offer pro-



tection against harmful substances in outside air. An approval procedure is necessary for the construction of a power station in the course of which the impact of emissions is identified and assessed. When it comes to monitoring the safety of foods, besides pollutant input from outside air, other inputs must be taken into account like fertilisers or additives in feed. The various instruments complement each other.

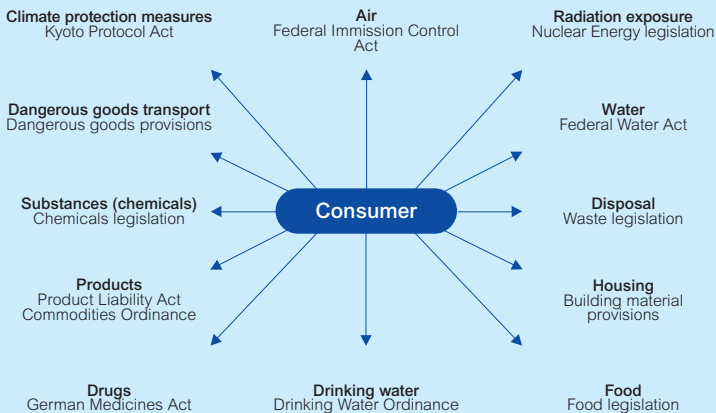
### Chemicals legislation

The statutory provisions for the safe handling of chemicals are an important component. They are very comprehensive as a scarcely calculable number of substances and products are traded globally. They differ in terms of their properties and their possible effects on human health. They include many substances which are further processed industrially. Not



all the uses of these substances are regulated in the chemicals legislation. There are specific laws for the safety of foods, cosmetics and drugs.

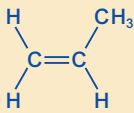
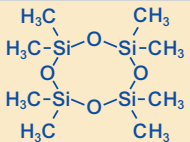
### Statutory provisions on consumer protection



## Examples of chemical substances

A classification system is needed to cope with the large number of chemical substances. Frequently, the same substance goes under different names. In order to ensure clear identification, registration numbers from international systems are frequently used today in the statutory provisions, in

which the structure of the substances is described in detail. The database of the European Commission (EC) contains around 100,000 chemical substances which are on the market. More than 19 million substances are recorded in a scientific database, the Chemical Abstracts Service (CAS).

Name(s)	Use	Chemical formula	Registration number
<b>Propene, propylene</b>	Basic substance of the chemical industry mainly used to produce polypropylene		CAS: 115-07-1 EC: 204-062-1
<b>Tributyl tin oxide, TBTO, bis(tributyl tin) oxide</b>	Antifouling ship paint, for finishing special textiles and banknotes		CAS: 56-35-9 EC: 200-268-0
<b>Octamethyl cyclotetrasiloxane D4</b>	Antifoaming agent in paper production		CAS: 556-67-2 EC: 209-136-7

### How dangerous is a substance?

In order to establish whether a substance is dangerous and what type of hazard it represents, it has to be examined. In this context both the chemical and physical properties as well as the harmful effect on health or the environment are important. The choice of test methods and the evaluation of the

results have been harmonised in the EU. Global harmonisation is under way with the support of the United Nations.

The nature of substances (gaseous, liquid, solid) and the large number of possible effects mean that the right test methods must be selected from the many ones available. The proce-

cedure for selecting and conducting tests and for assessing the results is set out in a directive of the European Union. According to this, the physico-chemical properties, the impact on human health and environmental hazards are to be examined.

The most complex tests are those which look at the long-term impact on human health. Normally, for preventive purposes, animal experiments must be conducted to establish whether a substance leads to cancer or harms the unborn child in the womb.

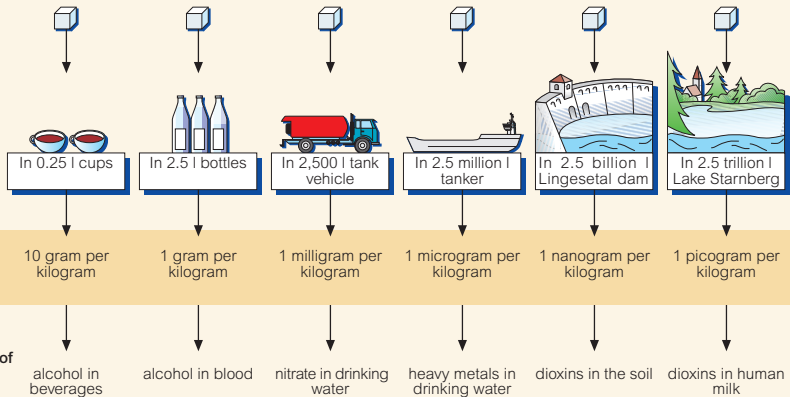
### Chemical substances frequently have an impact already at very low concentrations

Thanks to progress in analytical methods, more and more substances can now be detected. Reports in the press often contain information about the concentrations of these substances in environmental media, food or daily products. Often these are minute amounts. The decisive factor when it comes to assessing the risk to health is not the de-

tectability but rather the total intake of the substance. Besides the concentration of a substance (for instance in children's toys), another important factor is how easily it can be ingested by the human body. This factor is taken into account when setting threshold values (for instance on the admissible concentration in products).



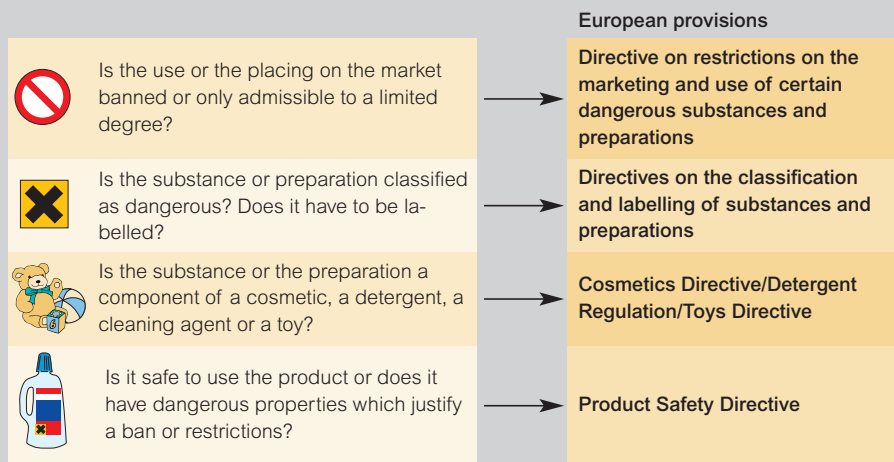
One dissolved sugar cube (2.5 g):



## Statutory provisions concerning chemicals in products

The goal of a number of statutory provisions is to protect consumers from dangerous chemicals in products. The use of many substances is either banned, like for instance asbestos or polychlorinated biphenyls (PCBs), or considerably restricted. For instance cadmium may not be used to dye plastics. When a substance in a product has been classified as dangerous, then this must be clearly indi-

cated on the product label along with instructions on safe use. The level of protection afforded by the current provisions in the European Union is already high. Nevertheless, there are good reasons for making further improvements. Very little is known particularly about the long-term effects of many substances.



### How does classification work?

Substances are judged on the basis of test results. Furthermore, decision making rules are laid down: if a substance has a negative impact from a specific dose or concentration upwards, then it must for instance be

classified as harmful and correspondingly labelled. Even if a substance is classified as dangerous, often it may still be safely used under certain conditions. Depending on its classification, special safety measures must be complied with.






### How dangerous are products manufactured with chemicals?

Chemicals are used in the manufacturing process of almost all products. During this stage the properties of the chemical may change. Safe substances may be formed from dangerous, toxic ones. For instance the harmless polyacrylate is formed from the dangerous acrylic acid. Polyacrylate is a synthetic used in babies' nappies as it can absorb a great deal of fluid.

The mixing and dilution of a substance can reduce its harmfulness. In concentrated form citric acid is an irritant, but small amounts are added as an acidifier to many foods (e.g. iced tea) and they are completely harmless.



However, harmless substances can also lead to the formation of dangerous substances as a consequence of processing. Harmless common salt can form toxic chlorine gas through the use of electricity.

Common Test Methods		
Flammability		
<p><b>Test method:</b></p> <p>The flammable properties are determined in the laboratory. The lowest temperature is determined at which the substance spontaneously ignites.</p>	<p><b>Classification</b></p> <ul style="list-style-type: none"> <li>The liquid already ignites at 0°C, the boiling point is below 35°C.</li> </ul> <p><b>F+ = extremely flammable</b></p> <ul style="list-style-type: none"> <li>The liquid ignites readily and continues to burn / glow on its own.</li> </ul> <p><b>F = highly flammable</b></p>	<p><b>Labelling</b></p> <p>F+ (F)</p> 
Corrosive effect on the skin		
<p><b>Test method:</b></p> <p>The substance is applied to a biotechnologically cultured model of human skin and the inhibition of the vitality of skin cells is measured.</p>	<p><b>Classification</b></p> <ul style="list-style-type: none"> <li>After an exposure time of three minutes 50% of the skin cells are no longer vital.</li> </ul> <p><b>C = Corrosive</b></p>	<p><b>Labelling</b></p> <p>C</p> 
Toxicity in mammals		
<p><b>Test method:</b></p> <p>In the past, the amount of a substance which led to the death of half of the animals after administration was exactly determined. This is the LD50. Methods are now available by means of which it is possible to estimate the LD50 with fewer animals. To do so, the substance is administered to three rats which are observed for at least 14 days.</p>	<p><b>Classification</b></p> <ul style="list-style-type: none"> <li>The estimated LD50 is lower than 25 milligram per kilogram bodyweight</li> </ul> <p><b>T+ = very toxic</b></p> <ul style="list-style-type: none"> <li>The estimated LD50 is between 25 and 200 milligram per kilogram bodyweight.</li> </ul> <p><b>T = toxic</b></p> <ul style="list-style-type: none"> <li>The estimated LD50 is between 200 and 2,000 milligram per kilogram bodyweight.</li> </ul> <p><b>Xn = harmful</b></p>	<p><b>Labelling</b></p> <p>T+ (T)</p>  <p>Xn</p> 
Toxicity in aquatic organisms		
<p><b>Test method:</b></p> <p>At least 20 water fleas are placed in the water mixed with the substance and are observed for 48 hours. The concentration is determined at which 50% of the animals become immotile.</p>	<p><b>Classification</b></p> <ul style="list-style-type: none"> <li>50% of the water fleas become immotile at a concentration of 10 milligram per litre. Furthermore, the substance is not readily degradable.</li> </ul> <p><b>N = hazardous to the environment</b></p>	<p><b>Labelling</b></p> <p>N</p> 

### **Are animal experiments necessary?**

Animal experiments are frequently conducted to determine the harmfulness of chemicals. To what extent are experiments admissible that can lead to suffering, harm and even the death of animals if this can help to prevent the suffering or death of humans or long-term environmental damage? Different social groups give varying answers to this question. Efforts are being made to reduce the number of animal experiments to the absolute minimum. Some possible measures are:

- ▶ More *in vitro* tests (test tube experiments) for instance in cell cultures, organs from the slaughterhouse or biotechnologically cultured materials
- ▶ Waiving of tests, for instance, by recourse to test strategies, analogy conclusions or where there is no human exposure to the chemical

- ▶ Predictions using computer-based analyses of structure-activity relationships
- ▶ Conducting of animal experiments only after approval has been given
- ▶ Renunciation of the conduct of multiple similar tests
- ▶ Reduction in the number of animals used in an experiment

In recent years the Federal Institute for Risk Assessment has secured international recognition for several methods to determine the toxicity of chemicals which require fewer or no animal experiments. Major research efforts are needed in order to further reduce the number of animal experiments which are necessary to ensure the safety of man and his environment.

## 3 REACH improves consumer protection

### Starting point: The list of chemical substances

In Europe industry had to list chemical substances in a register which were on the market in 1981. This led to a list containing approximately 100,000 “existing substances”. Around three-quarters of the substances are manufactured in volumes of less than one tonne per year. All substances manufactured after 1981 for the first time are deemed to be “new substances”. So far, there are approximately 3,000.



Up to now in Europe only new substances were obliged to undergo systematic examination for dangerous properties. As this is a highly complex process, manufacturers tended to continue producing and using existing substances as tests and assessments are not prescribed in a uniform manner for them. The EU did try to change this situation by means of the “Existing Substances Regulation”. However, only approximately 100 of the 100,000 existing substances underwent a full examination. Already in 1999 the EU Ministers of the Environment observed:

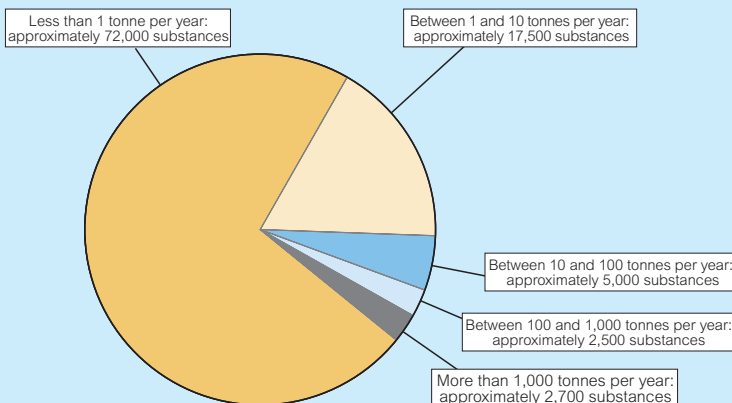
*“Our knowledge so far about the toxicological and ecotoxicological properties even of substances produced in large volumes (more than 1,000 tonnes per year), that constitute a considerable burden for humans and the environment, is not sufficient to be able to undertake an adequate risk assessment.”*

This realisation led to the development of the new European chemicals regulation REACH, which enters into force in June 2007. The European Chemicals Agency will start work in June 2008.

### Hazard and risk

In popular language risk is often equated with hazard. The labelling of a dangerous substance only describes the hazard potential. Whether this hazard actually materialises, whether a risk really exists depends on whether contact is possible and, if so, with what amounts of the substance. Exposure assessment examines how, when and what amounts of the substance are used. If the exposure is far lower than the dose which constitutes a hazard potential, then the risk is low. If the exposure dose increases, this heightens the risk too. Many substances classified as dangerous e.g. petrol, which contains up

**Production of “existing substances” in the EU**



to 1% carcinogenic benzene, have technically desirable properties and, if handled correctly, may be used safely. The risk is then deemed to be small. By contrast, the use of substances, which are not classified as danger-

ous, may mean other disadvantages, for instance they may lead to more waste. Various aspects have, therefore, to be taken into account when assessing whether the use of a substance is acceptable or not.

### What is REACH?

► The REACH Regulation regulates afresh the registration, evaluation, authorisation and restriction of chemical substances. Many of the previously valid directives and regulations regulating the EU-wide handling of chemicals, are integrated into or replaced by REACH.

► There will be major changes for existing substances which were placed on the market before 1981. In a step by step procedure, they will have to be examined for dangerous properties in the same way as new substances.

► Chemicals which are produced by a manufacturer in quantities of one tonne or more per year must in principle be reported and will, therefore, be registered within the REACH system. This applies to around 30,000 substances. The one-tonne limit is a compromise between what is desirable and what is economically viable. The biggest part of the total amount of chemicals processed will be covered by this.

► REACH requires manufacturers and importers to assume responsibility themselves for the safety of their chemicals. To this end they must procure the data needed for

assessment (reversal of the burden of proof). If up to now the motto applied “no data – no worries”, this has now been replaced by “no data – no market”. Previously, it was primarily the task of public agencies to identify problems and to oblige industry to remedy them.

The volume of data to be submitted with the registration is dictated by the volume of the substance produced. From a volume of ten tonnes per year upwards there is an obligation to prepare Chemical Safety Reports (CSR) and, where appropriate, to submit proposals for risk reduction.

► The European Chemicals Agency in Helsinki and the competent authorities in Germany are responsible for monitoring compliance.

► The Regulation enters into force on 1 June 2007.

► One major innovation in REACH is that, in addition to substance properties, the uses must also be taken into account. The manufacturers of a substance must indicate which uses of a substance are envisaged, what exposure could result for humans and what steps could be taken to reduce any eventual risks. A use can be described for

instance by indicating a range of temperatures at which a substance is used in production.

Up to now information only had to be passed on to the users of chemicals. Now users are also obliged to inform manufacturers about previously unknown uses (e.g. use at a higher temperature). If a product is to be placed on the market whose production involves using a chemical substance in a way that deviates from the manufacturer's information

(e.g. use at a higher temperature), then the user of the chemical (producer) must test and register this new use itself.

- ▶ Substances of very high concern may be obliged to undergo an authorisation procedure. This means it will now be possible to prevent substances with unacceptable risks from reaching the market. Products containing authorised substances must be labelled correspondingly.

#### **Deadlines and milestones in the REACH Process for “existing substances”:**

Registration is, of course, also necessary when the production or import volumes are exceeded in later years.

- ▶ **Up to 1 December 2010:** expiry of the deadline for the registration of substances with a volume of more than 1,000 tonnes per year (in addition: all carcinogenic, genotoxic substances and substances which cause harm to the unborn child with a volume of more than one tonne per year; all substances which harm aquatic organisms with a volume of more than 100 tonnes per year)
- ▶ **Up to 1 June 2013:** expiry of the deadline for the registration of substances with a volume of more than 100 tonnes per year
- ▶ **Up to 1 June 2018:** expiry of the deadline for the registration of substances with a volume of more than one tonne per year

#### **What will change as a consequence of REACH?**

The objective behind REACH is to build on the sparse knowledge available on most chemicals. The guiding principle of REACH is to record the entire lifecycle of a chemical substance and ensure that this is safe – a

joint responsibility for industry which produces the chemicals and for companies which process the chemicals. All companies which use the same chemical are, therefore, connected like the links in a chain. The Regulation lays down obligations: for manufacturers with a registered office in

the EU, importers who introduce chemicals into the EU and, of course, for companies who use or trade in chemicals.

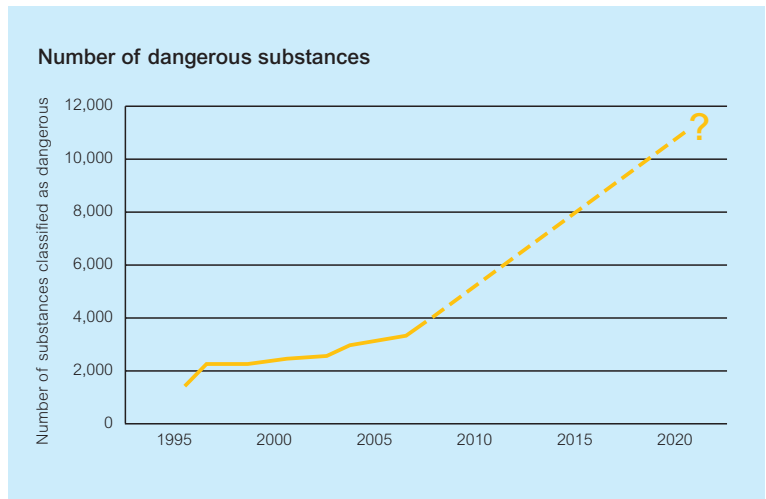
According to the motto **“no data no market”**, only those substances may be placed on the market in future for which sufficient data are available. Data are required for all substances which producers manufacture in the EU or importers introduce into the EU in quantities of 1 tonne or more per year. Completely new provisions now apply to the about 30,000 existing substances. Considerable data are already available to industry on the toxic properties of these substances but up to now they were only publicly accessible in a few cases. New toxicological studies are required under REACH if the existing data are not sufficient.

According to the principle of the **reversal of the burden of proof**, REACH transfers responsibility for

testing chemical safety from national authorities to manufacturers and importers. In future they must ensure that their products can be safely handled and do not have a major adverse effect on human health or the environment. Manufacturers and importers must supply information on their substances to all their customers, including processing plants. Industry now has a statutory duty of care. Control functions are assigned under REACH to public authorities. The precautionary principle is the basis for the provisions.

REACH will bring about major improvements including greater transparency along the entire product chain and put an end to the practice of giving preference to existing substances which is not at all conducive to innovation. In future, all substances must be treated in the same way. The **European Chemicals Agency** in Helsinki will monitor compliance in cooperation with national authorities.

*The number of substances legally classified as dangerous will be larger as a consequence of REACH. This will mean that risks involved in handling these substances will be more controllable.*



## **REACH will ensure that dangerous substances are identified more quickly**

Up to 2005 around 3,300 substances were classified as dangerous by public authorities in Europe. If there is no official classification, manufacturers have to do the classification themselves. Practice shows that this is only done in an inadequate manner as the necessary data are missing. Under REACH manufacturers must disclose their classifications and users must check whether the manufacturer is aware of the way in which they use the substance. This will help to identify any contradictions or gaps.

REACH will help to identify dangerous substances more quickly and either impose restrictions on their use or lead to them being replaced with less problematic substances.

## **Under REACH substances of very high concern now require authorisation**

Already now approximately 900 substances are officially deemed to be of very high concern. They can cause cancer, damage to the genotype or the unborn child in the womb. REACH will lead to an increase in this number because manufacturers are now obliged to undertake more extensive examinations of the substances they use.

Additional substance categories are to be introduced for those substances which are deemed to be of very high concern (see box). Thanks to the statutory obligations set out in REACH, these substances of very high concern can be identified more

quickly and more effectively controlled. Their further use will only then be authorised if there is no suitable alternative, if measures are in place to reduce exposure and if the risk for the environment and human health is acceptable. Products containing more than 0.1% of a substance of this kind must be correspondingly labelled and bear information about safe use. Given the considerable obstacles to authorisation, the general expectation is that most substances of this kind will be replaced by less dangerous ones.

## **This is how REACH improves precautionary care:**

- ▶ A manufacturer must register all substances used in various phases and state their properties if he produces them in quantities of more than one tonne per year. This will

### **Substances of very high concern are . . .**

#### **... already now:**

- ▶ carcinogenic substances
- ▶ genotoxic substances
- ▶ substances which may harm the unborn child

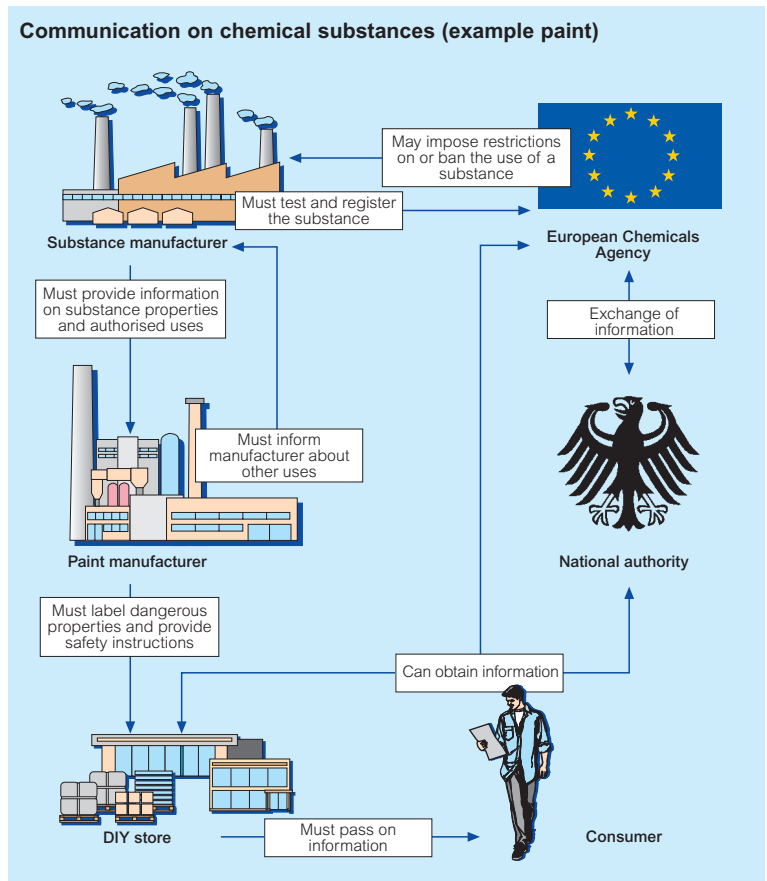
#### **... plus as a consequence of REACH:**

- ▶ substances which are of equivalent concern (e.g. substances with a hormone-like effect)
- ▶ toxic substances which are not readily degradable and may also accumulate in plants or animals
- ▶ substances which are scarcely degradable at all and may accumulate at high levels in plants or animals

help to identify problematic substances more quickly and to replace them with more suitable substances.

use of substances will reduce the risks for production employees, consumers and for our environment.

- ▶ All persons involved in production must work together far more than in the past. It is not just the manufacturers of the substances who must inform their customers. The users of substances must also inform manufacturers about the uses to which the substances are put.
- ▶ The additional knowledge about the substance properties and the exact use of substances will reduce the risks for production employees, consumers and for our environment.
- ▶ Substances of very high concern are to be replaced by less problematic alternatives.
- ▶ If there are good reasons for still using them, the product must carry corresponding information. Substances of very high concern must also be labelled on consumer products. This is to apply to imports into Europe, too.



### **What does REACH cost?**

Critics of REACH claim that the impact of the Regulation will place far too high a burden especially on the chemical industry. The high costs of the data requirements would have a detrimental effect on competitiveness. It is hard to obtain concrete figures as health and environmental effects can only be roughly estimated. The EU assumes that the additional costs incurred by the implementation of REACH will only lead to minor increases in the prices of chemicals. Other cost effects like, for instance, fluctuations in the price of oil are likely to have a far greater impact.

The costs must be set against the expected advantages for national economies. The EU expects to see high savings through positive health effects and a lower level of environmental pollution.

Besides the economic costs the numerous animal experiments must be borne in mind which are necessary for assessment even if efforts are under way to reduce the number.

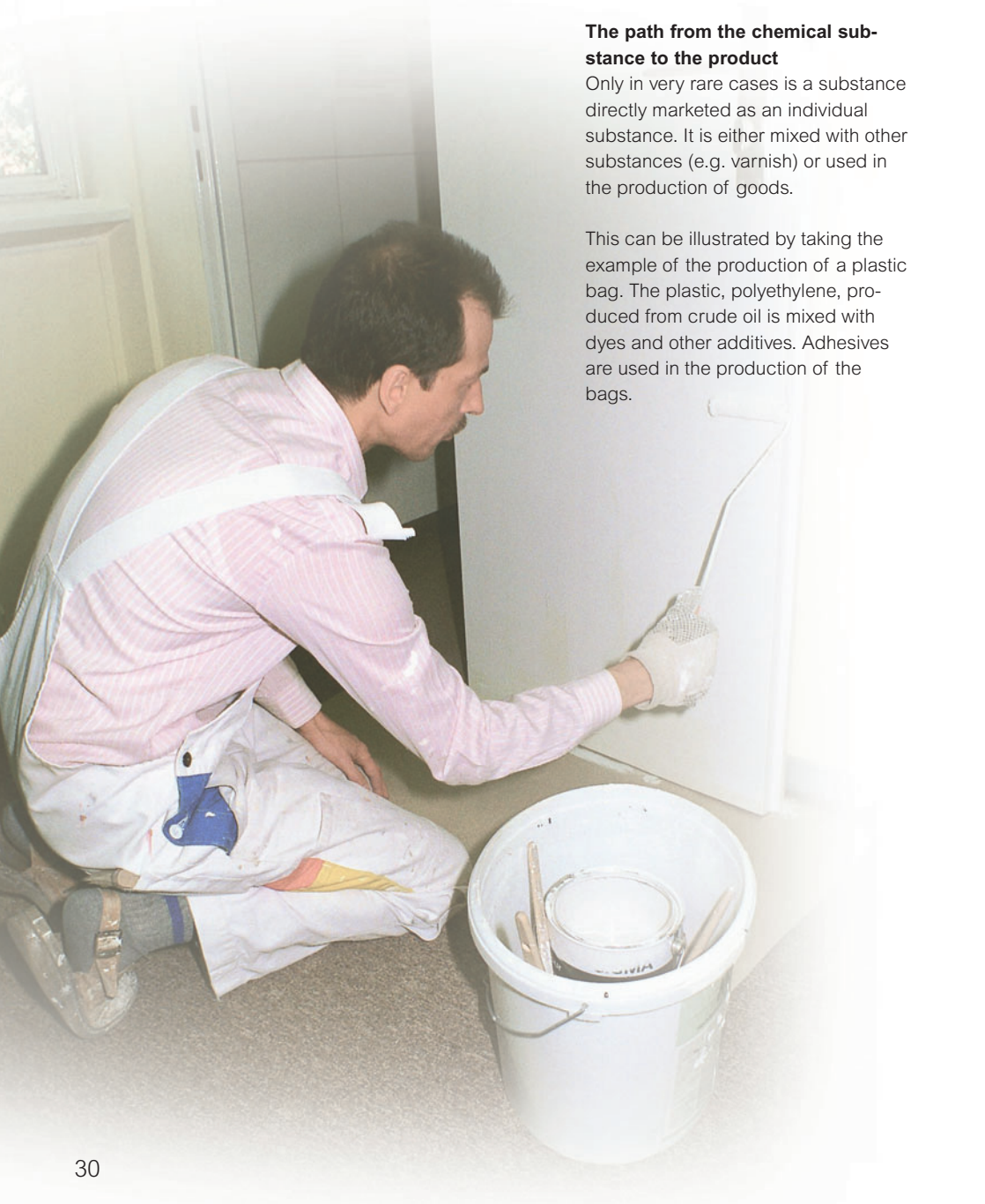
### **The limits of REACH**

Despite the undeniable improvements, an ambitious project like REACH is still a compromise. All substances with a production volume of less than one tonne per year are not affected by REACH. For new substances this even means a worsening of the situation because up to now they had to be registered from a production volume of more than ten kilos per year. Manufacturers, importers and users must also meet the expectations placed in them: they must collect a sufficient amount of high quality substance data, communicate with one another and replace high risk substances with less dangerous ones. Many experts believe that it will be very difficult to push through these requirements.

Compliance with the provisions of REACH on imported products can at best be monitored by means of random samples given the large number of imports and substances. In the case of products which are fully manufactured within the EU, protection against harmful chemicals can be guaranteed more effectively than in the case of imports.

REACH will not solve all the environmental problems of the use of chemicals today. On the global level, however, REACH, together with other regulations, should make a major contribution to the safe handling of chemicals.

## 4 REACH in practice



### **The path from the chemical substance to the product**

Only in very rare cases is a substance directly marketed as an individual substance. It is either mixed with other substances (e.g. varnish) or used in the production of goods.

This can be illustrated by taking the example of the production of a plastic bag. The plastic, polyethylene, produced from crude oil is mixed with dyes and other additives. Adhesives are used in the production of the bags.

A pure chemical is described as a **substance** which may be present as a chemical element or as a stable compound.

A **preparation** is a mixture of several substances.

A **product** contains substances or preparations with a form that determines their function.

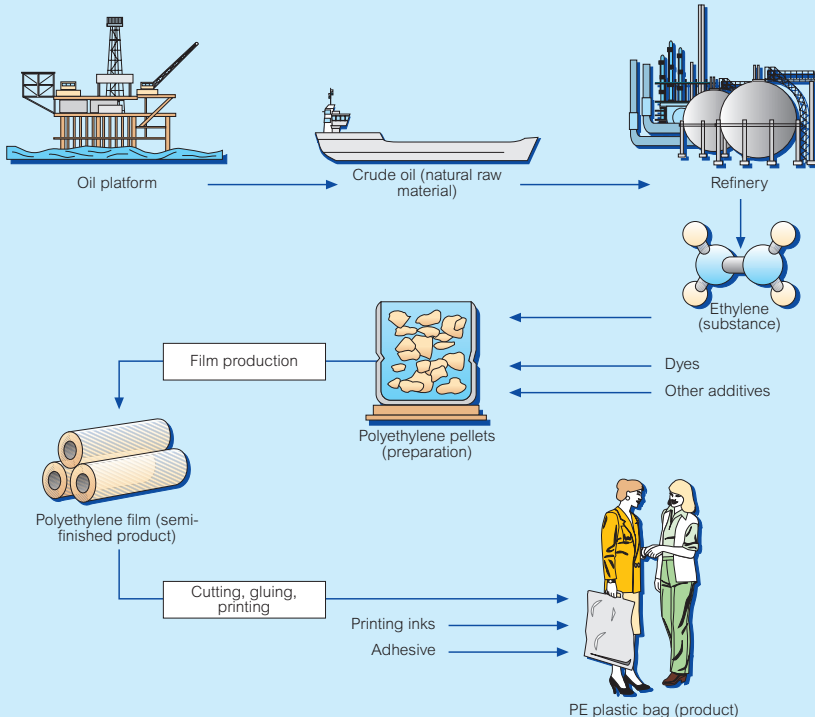
### Examples from the home

Chemicals may be found in the home for instance as components of detergents and cleaning agents and as additives in products.

In recent years in Germany just under 100 cases of moderate to severe health impairments caused by household chemicals were reported to BfR annually. Around 50% were caused by paint, fuel or cleaning agents. Compared to other risks in daily life (for example traffic accidents) this figure seems to be low. Numbers on the level of chronic health damage and environmental damage are disputed because the data are not complete.

A systematic overview of the number of chemicals to be found in household products is only available for some areas. The Federal Institute for Risk

### From the raw material oil to the plastic bag



Assessment documents formulations for more than 220,000 products including ones which must be labelled as dangerous. The table below only contains a small selection of examples of chemicals in household products.

**Chemicals used in the manufacture of products: The example of babies' nappies**

An infant needs around 2,500 nappies until it is toilet trained. In Europe roughly 20 billion disposable babies' nappies were sold in 2004. As a consequence of close contact with the skin, substances may be released



**Examples for chemical substances and substance groups which may be contained in household products**

Product group	Product	Possible chemical components
Cleaning products	Drain cleaners, dishwashing agents, toilet fresheners	Chlorine, alkyl benzene sulphonate, sodium hydroxide, synthetic fragrances
Paints and insecticides	Paints and varnishes	Azo dyes, polyvinyl acetate, propiconazole, dichlofluanide
Fuels	Liquid fuels, matches	Petrol, ethanol, paraffins, potassium chlorate, phosphorus
Electrical appliances	PCs	Flame retardant agents, nickel, lithium
Office materials	Felt tips	Xylene, triaryl methane dyes
Decorative articles	Sparklers	Barium nitrate
Toys	Modelling plasticine, plastics	Alum, acrylates, polyvinyl acetate
Others	Air fresheners, measurement devices for heating costs	Polyglycols, synthetic fragrances, methyl benzoate

<b>Composition of disposable nappies</b>		
<b>Component</b>	<b>Weight percent (Wt %)</b>	<b>Chemicals used</b>
<b>Cellulose</b>	43	Defoaming agents in paper production
<b>Superabsorbent</b>	27	Pouring agents
<b>Polypropylene</b>	15	Spin finish, dye (e.g. titanium oxide)
<b>Polyethylene</b>	7	Dyes (e.g. titanium oxide), antistatic agents
<b>Adhesives</b>	3	Synthetic resin and rubber, additives
<b>Elastic substances</b>	1	Stabilisers
<b>Other substances</b>	4	Fragrances, lotions

from the nappies and penetrate the skin. The nappy is a complex product whose production involves the use of many chemicals. The manufacturers of babies' nappies are aware of their responsibility for placing safer products on the market. They are already undertaking comprehensive tests on possible health risks (e.g. skin tolerance) and environmental compatibility of the substances used.

Comprehensive information is already available today about the effects of the chemicals listed in the above table on human health and the environment. For instance traces of defoaming agents from cellulose production are harmless as is titanium dioxide which is used for the whitening of plastics. Special chemical mixtures are used to treat the polypropylene fibres on the

inside of nappies (spin finish). Synthetic residues and rubber are used for the adhesive strips. So far there have been no indications in the tests of the manufacturers that they cause a hazard. The exposure to these substances can also be assessed relatively well which means that possible risks can be identified and avoided.

Although a high degree of safety is already guaranteed, REACH will also improve precautionary care when it comes to babies' nappies:

- ▶ The exchange of new information on substance properties or restrictions on use between users and manufacturers will lead to improved co-ordination (e.g. regarding temperatures for the processing of adhe-

sives). Lower risk substances may be used.

- ▶ Special attention will be given to those substances which are to be released. For instance, fragrances and lotions also need to be tested

for environmental compatibility even if they already meet the requirements of the Cosmetics Regulation.

- ▶ Importers of nappies must ensure that they do not contain any substances of very high concern.

### Comparison of current and future chemicals policy (REACH)

Current chemicals policy	REACH
There are major gaps in our knowledge about many chemicals which are sold in Europe.	REACH aims to close the gaps in knowledge by providing information on the hazards and risks from chemicals for which a volume exceeding one tonne per year is placed on the market by manufacturers or importers.
From an annual production volume of 10 kg upwards new chemical substances must be registered. One animal experiment is already required. From one tonne per year upwards several animal experiments are stipulated.	New and “existing substances” must be registered from a production volume of one tonne per year upwards. If possible, animal experiments are to be avoided.
The burden of proof is incumbent on the public authorities: They must prove that the risk from the use of a chemical substance is too high before bans or restrictions can be imposed.	Industry must show that the risk associated with the use of the chemical substance can be adequately controlled and must recommend risk reduction measures. All participants in the production chain are responsible for the safe use of the chemical substances which they handle.
It is relatively expensive to place a new chemical substance on the market. That's why, in most cases, existing substances that have not been adequately tested are used and important innovation opportunities are not exploited.	REACH supports innovation: there are exemptions for research and development; the costs for the registration of new chemical substances are lower and there is an obligation to examine substitutes if substances of very high concern are to be authorised.
The public authorities are obliged to carry out time-consuming and complicated risk assessments.	Industry will be responsible for proving the safety of use of chemical substances before they are produced or marketed. The public agencies will be able to focus on evaluation, control and authorisation.

### **What will change as a consequence of REACH?**

For many chemicals only incomplete data are available, particularly about the long-term effects on human health and the environment. These “white spots” will gradually disappear as a consequence of REACH. It’s more difficult to predict how products will change. However, some trends can already be identified today.

#### **Composition**

- ▶ The components of some products will change: because risk-related substances will disappear from the market or because manufacturers will use already tested substances for reasons of cost.
- ▶ Already today consumers can identify the components of specific products (e.g. cleaning products). In future more detailed information will be available about the properties of substances as a consequence of REACH.

#### **Costs**

- ▶ The additional work will lead to only slightly higher costs for chemicals in production.
- ▶ The consumer prices of a product will scarcely be influenced by REACH since other factors will have more of an impact.

#### **Instructions for use**

- ▶ As a consequence of the improved information available through REACH, more targeted use can be made of substances. This may lead to changes in the instruc-

tions for use in order to reduce risks.

#### **Hazard symbol**

- ▶ The system of classification and labelling will be retained. During the introduction of REACH labelling is to be harmonised on the international level.
- ▶ It is likely that more substances will be classified as dangerous than before and will have to be correspondingly labelled.
- ▶ REACH defines a new class of substances of very high concern. As a rule, however, they are rarely contained in consumer products.

#### **Safety instructions**

- ▶ Improved knowledge about the substances will make possible targeted instructions for the safe handling of dangerous substances, thereby reducing the risk.

#### **What we can’t see**

- ▶ As a consequence of REACH protection at work will be improved in all production stages. This also applies to substances which are not contained in the final product.
- ▶ Risks for the environment will be recognised and countered more quickly.
- ▶ There will be more communication between the companies involved in the manufacturing process.
- ▶ Precautionary measures will be improved through the rapid detection of hazards.

## 5 What consumers can do

### **Find out more about substances in products**

Already now the relevant data on cleaning agents can be accessed on the manufacturers' websites. Furthermore, they provide explanations about the effects of the declared ingredients in cosmetics as the names on the packaging alone do not generally supply much information. Consumers can make use of the already existing opportunities to find out about chemical substances.



REACH will generate additional information on substance properties and thus enable consumers to be better informed. When a product contains a concentration of more than 0.1% of a substance of very high concern, the consumer is entitled to obtain information from the seller about the substance and its safe use. The sellers of these products must provide the corresponding information free of charge at the latest 45 days after receiving a request from consumers.

The introduction of REACH will lead to the setting up of databases on the Internet. Together with other sources, they will help provide an overview of which substances with which properties are contained in certain products. When it comes to assessing a potential risk, information about the concentration and dose taken by humans are important, too.

Not all consumers wish or are able to make use of these options. REACH aims to contribute to making products safer for all consumers. Harmful existing substances are to be identified more quickly and either completely banned from production or only used in conjunction with strict safety requirements.

The following tips may be useful when it comes to purchasing and handling products.

#### ■ **More targeted shopping**

When buying a product check for hazard symbols, warnings and safety instructions. Look for alternatives, for instance products which do not contain any dangerous substances. Check

labels for environmentally compatible and low contaminant products (e.g. "Blue Angel").

#### ■ **Comply with warnings and safety instructions**

If you have purchased a product that contains a dangerous substance, then it will be correspondingly labelled and carry warnings.

#### ■ **More informed use**

Read and comply with the warnings. When handled carelessly chemicals can damage health. Keep chemicals out of the reach of children in particular. Chemicals should not be mixed or refilled into other containers (e.g. empty beverage bottles).

#### ■ **Be proactive**

The ways in which consumers can influence concrete production are limited but your purchase decisions send important signals to manufacturers. Exercise your new rights under REACH. Ask for information from sellers.

#### **What more comprehensive information is available?**

- ▶ The Federal Institute for Risk Assessment provides more extensive information for consumers and updated links on its website **[www.bfr.bund.de](http://www.bfr.bund.de)**.
- ▶ Anyone interested in product safety, would be well advised to contact the Consumer Organisations of the federal states. You can find the right contact person via the central website of the Federation of German Consumer Organisations, **[www.vzbv.de](http://www.vzbv.de)**.



- ▶ The Federal Environment Agency (UBA) gives a comprehensive overview of the REACH provisions and their environmental impact on its website [www.reach-info.de](http://www.reach-info.de).
- ▶ The EU information system on chemicals, ESIS, contains the

names and registration numbers of approximately 100,000 chemical substances and data e.g. on classification and labelling to the extent that this is available. Safety data sheets can be retrieved on substances with large production volumes. The online information system can be accessed at <http://ecb.jrc.it/esis>.

- ▶ Numerous environmental associations have published their positions on REACH. Information from the BUND (Friends of the Earth) can be accessed on [www.bund.net](http://www.bund.net), from Greenpeace at [www.greenpeace.de](http://www.greenpeace.de).
- ▶ The German Chemical Industry Association (VCI) provides information on the REACH Regulation on its website [www.vci.de](http://www.vci.de) in the section “Chemicals policy”.



**Blue Angel**  
for environmental-ly compatible products



**Emicode**  
for emission free flooring installation materials



**Ökotex**  
for safe textiles



**Natureplus**  
for safe building materials



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