Risiken erkennen – Gesundheit schützen

The new European chemicals legislation and consumer protection

A position paper of the Federal Institute for Risk Assessment

Abridged version

Preface

The Federal Institute for Risk Assessment (BfR) in Berlin is the scientific institution in the Federal Republic of Germany which draws up expert reports and opinions on questions of food safety and consumer health protection using internationally recognised scientific assessment criteria.

Based on risk analysis, BfR formulates action options for risk reduction. In this respect, the Institute assumes an important task when it comes to improving consumer protection and food safety. The assessments are to be presented in a transparent and understandable manner to the general public, science as well as other involved or interested circles.

On the European level and on the national levels of the 25 EU Member States, extensive discussions are underway about the best possible version of the legislative framework REACH (Registration, Evaluation and Authorisation of Chemicals). This proposal, which is 1,300 pages long, is highly complex. Various interest groups are involved and many professional groups are called on to input their expertise.

The new European chemicals legislation, REACH, will very much shape the consumer safety of chemicals and chemical products over the next 20 years in Germany and Europe. In addition to substances and preparations, the Commission proposal for new substance legislation also covers any products that have been regulated up to now within the framework of existing chemical legislation. The comprehensive regulatory approach of REACH is also reflected in the objective to generally record substances in products. The future work of BfR will be influenced to a major degree by the forthcoming provisions.

BfR welcomes the proposal for the new chemicals legislation (REACH) of the European Union as a contribution towards improving environmental protection and occupational safety because one goal in the REACH regulation is to place existing chemicals and new chemicals on the market on a par and to procure the missing information on potential health and environmental hazards in a foreseeable period of time by means of a new procedure for registration, evaluation and authorisation (REACH). BfR advocates major improvements to the level of consumer protection envisaged under the REACH legislation. This also includes a transparent procedure for consumers for risk assessment and consumer-friendly risk communication.

This goal can only be achieved with an acceptable outlay of money, laboratory capacity and animals if at least the basic information on the inherent toxicity of chemicals can be obtained using methods involving no animal experiments. BfR strongly backs the use of test methods involving no experimental animals. REACH is dependent on a change in paradigms expres-

sed in the willingness to move away from a rigid test system towards flexible evaluation strategies and greater use of alternative test methods to animal experiments.

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Introduction

In the "EU White Paper Chemicals Policy" of the European Commission, it is stated that the previous provisions on chemical safety have not afforded consumers sufficient protection. Hence, the White Paper attributes the utmost importance to consumer health protection in Europe whereby the principles of hazard prevention and precaution are to be given priority when it comes to evaluating, identifying and also managing known risks.

In the view of the Federal Institute for Risk Assessment the political intentions outlined in the White Paper on EU Chemicals Policy are not reflected in the proposed REACH regulation. One fundamental criticism is that the REACH system for a new chemicals policy adheres to risk assessment based on production volumes. However, even small volumes of substances – processed in consumer products (e.g. toys) – can lead to major health risks.

Given that the planned REACH regulation aims to evaluate around 20,000 substances (with a production volume of 1 to 10 t/year) and their different areas of application in many different types of products like paints and coatings, toys, glues, paper, detergents, cosmetics as well as the most diverse applications of these substances and products, there must be calls for a comprehensive evaluation basis for possible exposure and, by extension, the corresponding investigations.

The statement that production volumes do not provide any insight into levels of exposure is wrong in this simplistic form. Depending on the type of exposure, e.g. environmental exposure, exposure at work and consumer exposure, this statement must be discussed from different angles. The production volume does indeed play a role when it comes to consumer exposure. When substances are used in consumer products, higher production volumes lead to higher cumulative consumer exposure. That’s why this risk has to be classified as higher than in the case of substances which are only produced in low volumes. Besides the physico-chemical properties, contents and volumes used, the level of exposure of consumers is determined by the type of products used, application frequency and duration. A distinction must also be made between acute (directly from application) and chronic burdens. Furthermore, it must also be borne in mind that the range of applications of a substance in, for instance, a paint can extend from a few grams to several kilograms. However, it still does not make sense to draw up rough categories. What is really needed is a concept for different categories of exposure and use. The authorities involved in the evaluation procedure - Federal Environmental Agency (UBA), Federal Agency for Occupational Safety and Health (BAuA), Federal Institute for Risk Assessment (BfR) - have submitted a discussion proposal for exposure and use which is going to be strongly raised again by BfR in discussions about REACH.

BfR believes that the success of REACH will largely depend on how the technical implementation of the safety assessment of substances and, more particularly, of exposure assessment succeeds and how the results of risk description are then communicated downstream.

Why this special emphasis on consumer health protection and when can chemical substances or products be deemed to be sufficiently safe in line with the consumer protection discussed today?

It's all about protecting consumers from damage to their health which may result from the use of chemical products. For ethical reasons the principle of individual protection – at least as far as possible – should be the goal. However, it must be borne in mind that the general population is a highly heterogeneous group which encompasses the sick, the old, pregnant women and children in addition to the healthy. That's why, from the angle of consumer health protection, the concept of comprehensive consumer protection should not be linked to the acceptance of specific risk quotas or special risk-benefit considerations. This would not be a scientific but a political task which would have to be solved against the backdrop of the overall socio-economic environment. In the opinion of BfR the precautionary principle is still not sufficiently anchored in the REACH process and should be included in future to ensure comprehensive consumer protection.

REACH must be seen not only as an opportunity but also as an obligation for the comprehensive use of alternatives to animal experiments. Corresponding modern test strategies, as estimate procedures (QSAR - Quantitative Structure Activity Relationship Procedures) and as *in vitro* methods, are available in order to guarantee a scientifically convincing introduction to comprehensive consumer protection. The consistent use of alternative methods in the chemicals area could become an excellent example and test field for animal protection in practice and help alternative methods to achieve a breakthrough. *In vitro* methods involving no experimental animals will be cheaper and faster in future than animal experiments. And yet when it comes to the validated application area, they offer the same degree of safety. The remaining gaps in possible strategies have been identified and research must, therefore, be targeted towards filling these gaps.

BfR has proposed (see below) an "introductory battery of tests" for existing substances based on suitable alternatives to animal experiments/QSARs. A set of tests of this kind should at least be binding for a chemical with a sales volume of more than one tonne and make possible a decision about which risks are to be expected from the substances, preparations and products. The test results should be made public and lend themselves to prioritisation. Corresponding provisions should also apply to new substances. However, attention must be drawn to one important point: if increased use is made of results from alternative test methods when evaluating the risks from chemicals, then this will have to be done using a database other than the one which existed up to now. The assessable risk situation will be different even if this cannot be quantified. This must be brought home to the consumer when he calls for more alternative methods with a view to improving animal protection.

Risk assessments and safety decisions must take consumers' existing knowledge and skills into account. Public safety decisions must not lead to an unnecessarily paternalistic treatment of consumers. In the field of mass demand the idea of consumer autonomy is common, for instance in conjunction with semi-luxury goods. Of course, if consumers are to be autonomous, they must have access to comprehensive and sound information about the risks and benefits of a product. Holding back important information from them would lead to them being treated in a reverse paternalistic manner.

BfR positions

In this paper BfR lays out its main points of criticism of the proposed REACH regulation. Based on the three following foci

REACH I: New concepts for safe chemical products. Evaluations of substances: properties and exposure

REACH II: Alternative test methods and intelligent test strategies

REACH III: Does REACH create "the informed consumer"?

important topics of consumer health protection are to be taken up and the respective positions of BfR presented as well as solutions put forward for discussion.

New concepts for safe chemical products. Evaluation of substances: properties and exposure (REACH I)

In daily life consumers are exposed to a wide range of chemicals. According to the planned REACH regulation, the risks of around 300,000 substances are to be assessed. Attention has already been drawn to their different areas of use. Both the scale of testing for the individual chemicals or chemical products and knowledge of possible exposure to them are of prime importance when assessing health risks. However, risks from chemicals can only be identified and prevented if there is an adequate database.

Against this backdrop BfR adopts the following positions:

- For chemicals in consumer products a minimum data set is necessary independent of the annual production volume of the substance whereby information on carcinogenic, mutagenic and reprotoxic properties (CMR) is to be given priority in its elaboration.

- When it comes to assessing a substance, the decisive factor is exposure in addition to inherent toxicity. Therefore, solutions must be coordinated when it comes to an exposure-based approach to risk assessment.

- Application and exposure categories summarise the exposure situations which are characterised through comparable types of application/activities and a specific set of elements. With application and exposure categories all the conditions can be described which determine a substance’s exposure.

- When assessing the risk of a consumer product, the various cases of exposure from different consumer products, containing the same chemicals, must be borne in mind. Only consideration of the cumulated and aggregate exposures can guarantee consumer safety.

- For the risk assessment of an individual product in the consumer area, a dose is used that has no effect in man and which takes into account the possible diversity of ex-

posures and indirect exposure. This dose is calculated from the DNEL using a further factor oriented towards production volume.

- When it comes to prioritising the processing of substances, BfR is of the opinion that the criterion of consumer exposure and the criterion of harmfulness owing to lack of knowledge about the CMR properties should be used. The risk-related approach defined in this way must be strengthened in REACH.

Alternative tests and intelligent test strategies (REACH II)

It is the task of BfR to protect consumers. The strategy for chemicals testing must take this into account. This means that in the case of possible exposure of the consumer the scale of testing must be extended (see below). If there is no consumer exposure, then in the opinion of BfR it may be possible to do without tests in justified cases.

The objective of BfR is to obtain basic information without animal experiments, i.e. through the complete substitution of animal experiments. All other data are to be obtained using as few experimental animals as possible. Here, consideration must be given not only to the complete substitution of animal experiments but also to the aspect of reducing animal numbers in experiments. Against this backdrop BfR calls for the following:

- *In vitro* methods will in future be cheaper and faster than animal experiments. This makes validated *in vitro* methods attractive for the preparation of basic toxicological information.

- In the case of substances with an annual production volume of less than one tonne, basic toxicological data must be recorded using *in vitro* methods.

- In the case of substances with an annual production volume of 1 to 10 tonnes, additional toxicological *in vitro* tests must be conducted.

- If possible, the ATC method developed by BfR is to be specified as mandatory for all application paths in OECD and EU test directives. The use of the ATC method will bring about a major reduction in animal numbers.

- Data from the *in vitro* cytotoxicity test can be used to predict acute oral toxicity.

- Available *in vitro* methods for testing damage to skin and eyes are to be used. Together with statements from the expert systems DSS and SICRET developed within BfR, corresponding animal experiments can be replaced.

- Progress in conjunction with the challenges resulting from the 7th Amendment to the EU Cosmetics Regulation (RL 76/768/EEC) for *in vitro* methods for the prediction of skin irritation potential developed for the toxicological safety testing of cosmetic ingredients is to be monitored and if successful immediately rendered usable by REACH.

- Test methods involving no animal experiments for the endpoints of reprotoxicity have been developed, amongst others, by BfR. Research and validation are to be continued in a large-scale EU project. It is to be expected that in the near future animal experiments requiring large numbers of animals will be restricted or replaced.

- Industry should submit data, which was obtained for internal purposes using alternative test methods (e.g. about non-marketed intermediates), to an independent review in order to support the validation of *in vitro* methods. This will increase acceptance of the new test methods involving no animal experiments and speed up their use.

- The QSAR systems available to predict the effects on human health must be validated. The REACH regulation should ensure that the data recorded during registration is of a sufficient standard for the further development and validation of QSAR systems.

Does REACH create "the informed consumer"? (REACH III)

The key tasks of BfR are to improve information obligations vis a vis consumers and, by extension, its decision-making basis. In this context BfR is following a proposal of the European Commission for a decision of the European Parliament and Council on a Community action programme in the areas health and consumer protection in which the European Commission notes that EU citizens must be able to rely on the safety of products and services which they use. Furthermore, the European Commission is calling for citizens to have a say in decisions which affect their health and – in addition to other stakeholders – for the authorities on the international and national levels to also play an important role in achieving this goal.

Only informed consumers can decide in an autonomous manner about the risks involved in handling chemical products and, by extension, contribute to chemical safety. Information about the properties of dangerous substances and preparations and products that contain them should be provided in the new EU chemicals legislation which is of an appropriate scientific standard for the interested consumer in terms of understandability, clarity and truth. Suitable tools must guarantee that this type of information is made available to consumers by industry and, where appropriate, by public authorities too. Hence, with an eye to modern methods of comprehensive risk communication, BfR makes the following demands of REACH:

- Since REACH is primarily oriented towards environmental protection and the health protection of workers, not enough attention is paid to general consumer health protection. This deficit in terms of the safety of all consumers must be remedied.

- Risk communication is part of risk analysis and the regulation of chemical risks and must, therefore, be intensified.

- Since precautionary care and early detection are not possible for consumers or public authorities if there is insufficient information and inadequate communication structures, the effectiveness and transparency of the evaluation process must be improved by introducing open risk communication.

- Since there is no uniform assessment of potentially dangerous substances, the certainty – but also the uncertainty – of risk assessment must be conveyed to consumers.

- There is also an obvious lack of health consumer protection because information available elsewhere for the agency/public authority is not accessible. As the envisaged database is not sufficient in order to evaluate substances, preparations and products along the lines of freedom of choice, hazard prevention and risk prevention, the information obligations of industry must be extended.

- Since there are no provisions governing the quality of information available to consumers in conjunction with REACH, it must be guaranteed that the information is presented in an easily understandable manner for consumers. This also means that unnecessary confidentiality provisions have to be removed.

- Since, as a rule, consumers do not come into contact with substances but with products, appropriate product labelling is needed.