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Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

Exposure-based waiving

Concrete specifications of the waiving-conditions in the context of the registration procedure according to REACH

Project Report
Final translation

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Dirk Bunke, Öko-Institut
Klaus Schneider, FoBiG
Ismene Jäger, Ökologische Netze

Öko-Institut e.V.
Geschäftsstelle Freiburg
Postfach 6226
D-79038 Freiburg
Tel. +49 (0) 7 61 – 45 295-0
Fax +49 (0) 7 61 – 47 54 37

Hausadresse
Merzhauserstr 173
D-79100 Freiburg
Tel. +49 (0) 761 – 45 295-0
Fax +49 (0) 761 – 47 54 37

Büro Darmstadt
Rheinstraße 95
D-64295 Darmstadt
Tel. +49 (0) 6151 – 81 91 - 0
Fax +49 (0) 6151 – 81 91 33

Büro Berlin
Novalisstraße 10
D-10115 Berlin
Tel. +49 (0) 30 – 28 04 86-80
Fax +49 (0) 30 – 28 04 86-88

Project Report, English version

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The project report summarizes the results from the perspective of the project moderators. The members of the project working group had the opportunity to comment in a draft version of the text. These commentaries have as far as possible been taken into consideration in the preparation of the final report.

Remarks were however not added to the text when it appeared to the project moderators that they represented isolated individual opinions. Such remarks were then documented at the corresponding places as footnotes.

Contact:

Frau Gärtner, Bundesumweltministerium (BMU), Tel. 0049-1888 – 305 – 2741,

sabine.gaertner@bmu.bund.de,

Herr Romanowski,Verband der Chemischen Industrie e.V. (VCI),Tel. 0049-69-2556-1481, romanowski@vci.de

Herr Bunke, Öko-Institut e.V., 0049-761 – 45 295 46, d.bunke@oeko.de

Project moderators:

Privatdozent Dr. Dirk Bunke,
Öko-Institut e.V., d.bunke@oeko.de

Dr. Klaus Schneider,
Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG), klaus.schneider@fobig.de

Ismene Jäger,
Ökologische Netze, info@OekologischeNetze.de

Participants of the project working group:

Dr. Ann Bambauer, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)

Prof. Dr. Armin Basler, Ministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU)

Dr. Rüdiger Bias, BASF AG

Dr. Elmar Böhlen, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)

PD Dr. Dirk Bunke, Öko-Institut e.V.

Dr. Ralf Burgstahler, Bundesministerium für Wirtschaft und Arbeit (BMWA)

Dr. Jakob-Matthias Drossard, Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU)

Dr. Christian Eppelsheim, Wacker-Chemie GmbH

Dr. Helene Findenegg, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)

Dr. Dieter Fink, Verband der Chemischen Industrie (VCI)

Dr. Ulrich Föst, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)

Ulrike Frank, Umweltbundesamt (UBA)

Dr. Mario Funk, Degussa AG

Dr. Sabine Gärtner, Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU)

PD Dr. Gerhard Heinemeyer, Bundesinstitut für Risikobewertung (BfR)

Dr. Sylvia Jacobi, Degussa AG

Ismene Jäger, Ökologische Netze

Dr. Udo Jensch, Clariant GmbH

Dr. Detlef Keller, Henkel KgaA

Dr. Manfred Liebsch, Bundesinstitut für Risikobewertung (BfR)

Dr. Michael Lulei, Verband der Chemischen Industrie (VCI)

Dr. Wilfried Mayr, Degussa AG

Dr. Birgit Müller, Umweltbundesamt

Dr. Harald Müllerschön, Degussa AG

Dr. Hugo Obermann, LANXESS Deutschland GmbH

Dr. Andrea Paetz, Bayer AG

Dr. Hans-B. Richter-Reichhelm, Bundesinstitut für Risikobewertung (BfR)

Dr. Ulrike Reuter, Beratergremium für Altstoffe, BUA-Büro, TU München

Dr. Michael Ringel, Degussa AG

Dr. Dorothy Rose, Bayer MaterialScience AG

Dr. Eckehard Rosenbaum, Bundesministerium für Wirtschaft und Arbeit (BMWA)

Dr. Rolf Sarafin, BASF AG

Dr. Elisabeth Schmid, Sachverständigenrat für Umweltfragen (SRU)

Dr.-Ing. Karin Schmidt, Bundesministerium für Wirtschaft und Arbeit (BMWA)

Dr. Klaus Schneider, Forschungs- und Beratungsinstitut Gefahrstoffe (FoBiG)

Dr. Agnes Schulte, Bundesinstitut für Risikobewertung (BfR)

Dr. Volker Soballa, Degussa AG

Dr. Klaus Steinhäuser, Umweltbundesamt

Lars Tietjen, Umweltbundesamt

Dr. Frank Wangemann, Cognis Deutschland GmbH & Co KG

Dr. Hans-Jürgen Wiegand, Degussa AG

Dr. Andreas Willing, Cognis Deutschland GmbH & Co KG

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1 Introduction

In October 2003 a proposal for a Regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) was presented, that sets forth which information is to be provided in the framework of the registration procedure for substances.

These information requirements are laid out in Annexes V to VIII; basically these are tiered according to the production or import volumes. In the framework of REACH however several possibilities are anticipated to exempt from conducting individual tests, when this step is adequately documented and justified.

The exemption from conducting individual tests is termed **„waiving“** in REACH. Of importance here are:

1. the theoretically generally anticipatable possibility, not to conduct tests when this is scientifically not necessary or technically not feasible, corresponding to Annex IX;
2. consideration in Annex IX of the REACH-Regulation of general provisions for deviations from the standard testing programmes according to Annexes V to VIII, in particular the customized testing according to Chapter 3. According to Annex IX the tests according to Annexes VII and VIII can be waived, if in the chemical safety report corresponding exposure scenarios were developed;
3. special waiving-conditions for individual tests (example: according to Annex VI.6.6.1: Exemption from the 28-day-test for non-relevant exposure of humans), as specified in Annexes VI to VIII (Column 2).

Due to the time constraints in the project, only selected aspects of the exposure-based waiving could be considered. As „**exposure-based** waiving“ one means here the exemption from the conducting of studies according to Annex VI, when the justification for the waiving is based on the fact that there is no relevant exposure of humans and environment to the substance to be registered. In the human toxicological area high priority was given to dealing with the question, under which conditions the 28-day-toxicity test can be waived according to Annex VI (corresponding to the above given possibility Nr. 3), as an example of a test with repeated application.

Up until now there is no legally certain definition or criteria, as to what is meant concretely for the condition „no relevant exposure“. In the Proposal for a Regulation in Annexes VI, VII and VIII, depending on the specific place in the text, different terms are used for a waiving on the basis of the exposure („no relevant exposure“, „limited exposure“, „no exposure“, „no significant exposure“, „unlikely exposure“). Hereby **exposure** means the contact of humans or the environment with a substance (see here also Section 3). For completeness, also in Annex IX exposure-based waiving is considered. Risk management measures, which

influence the exposure, are mentioned in several places in the REACH-Regulation proposal. (For those text passages in REACH relevant for the project see Section 2.1 and Section 9.1 of this report).

The approach in the REACH-proposal to the information requirements can be understood as a „**top-down-approach**“: A deviation from the general obligation for the conducting of tests corresponding to Annexes V – VIII can be made in justified cases.

Substantially stronger exposure-based information requirements are called for in the alternative approaches to REACH. In the approach of the Verband der Chemischen Industrie (VCI 2005) tests with repeated application are already proposed at substantially lower production or import volumes. The concept of the VCI is not tonnage-dependent. The data of a basic data set should be obligatory here for all substances to be registered („basic data set“, see Table in Section 9.2). Additional data and, as necessary, herewith associated tests are then first called for, when there are relevant repeated exposures. This is described as a „**bottom-up-approach**“.

Independently of the approach chosen, a fundamental question arises in deciding for or against a test on the basis of exposure considerations: What is a (non-)relevant exposure? A concrete specification of this waiving-condition is thus far not available.

In this research project it should be concretely specified, what is meant by non-relevant exposure. Application situations of substances which lead to such an exposure should be described in generalised form. Using substance examples it should be determined, whether such exposure situations („non-relevant exposures“) exist in practice.

The project was carried out together with the Bundesumweltministerium (BMU) and the Verband der Chemischen Industrie (VCI). Experts of the VCI and its member enterprises, the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), the Umweltbundesamtes (UBA) and the Bundesinstitutes für Risikobewertung (BfR), the Bundesministeriums für Wirtschaft und Arbeit (BMWA), the Beratergremiums für Altstoffe (BUA) and the Sachverständigenrates für Umweltfragen (SRU) took part in the project.[1]

The results presented in the following are based on the one hand on the discussion of **criteria**, on the basis of which the decision for or against a waiving can be made, and on the other, on the concrete evaluation of the exemplary substances in the described uses.

Among the criteria here, a distinction is made between qualitative criteria (e.g. introduction of risk management measures) and quantitative criteria. For several criteria (e.g. exposure level at the work place) individual numerical thresholds were also discussed, such that when these

[1] Organisatorially and in substance the project was supported by the Öko-Institut e.V. in cooperation with the Forschungs- und Beratungsinstitut Gefahrstoffe (FoBiG) and the Institute Ökologische Netze.

were not exceeded it could be assumed that there was no relevant exposure.[2] These values are referred to in the report as „**cut-off criteria**“ (see here also Section 3).

On the basis of the exemplary substances and their uses the evaluating agencies examined, whether the proposals for the waiving of certain tests with repeated application can be agreed to or not.

The results of the project should be incorporated both in the Discussion of the REACH-Regulation text and its Annexes as well as in the relevant RIP-Processes.

Follow-up possibilities: In the project not all topics could be thoroughly discussed to the end. Follow-up possibilities are noted especially for the following points: risk management measures for preparations, waiving for substances with multiple uses, establishment of values for individual criteria, definition of the terms and their connotation (incl. „relevant exposure“, „short-term“ / „single exposure in the work place”, clarification of the relationship between risk management measures and exposure scenarios), discussion of the significance of the sample size (number of subjects), comparison of the protection level, harmonisation of the substance presentation and the evaluation, examples of risk management measures and their evaluation, as well as possibilities for using matrices for the structuring of exposure situations.

[2] Comment from the Bundesinstitut für Risikobewertung (BfR): For the BfR, quantitative estimates of the exposure are first of all necessary, in order to justify a waiving.

2 Starting points of the work

2.1 Possibilities of exposure-based waivings according to REACH

The REACH-proposal of October 2003 considers in column 2 of Annexes VI – VIII as well as in Annex IX, 3 and in Annex I, 0.4 the possibility, under certain conditions, based on the exposure, to adapt the standard requirements as regards the test data according to Annexes VI to VIII. The corresponding text passages are given in Section 9.1 of this report.

The following observations were made on the current formulations in REACH:

- For the area of human toxicological tests different words were used to describe the condition for an exposure-based waiving: „no relevant exposure“, „limited exposure“, „no“ or „no significant exposure“.
- Furthermore in Annex I, 0.4 risk management measures were mentioned and in Annex IX, 3 exposure scenarios, on the basis of which, tests could possibly be waived (see Section 9.1 of this report).
- In Annex VII (≥ 100 t/a) (6.6.2; testing of the sub-chronic toxicity (90 days)) a limited exposure represents only one of several conditions, which must be fulfilled in parallel (incl. reaction inertness, insolubility, no inhalability, no signs of adsorption).[3]
- In the area of environmental exposure the condition is mentioned throughout, that the exposure of the respective compartment is unlikely.
- Regarding the environmental exposure here, there is a problem of interpretation through the formulation in Annex VII, 7.1: The proposal and the choice of tests for aquatic long-term toxicity is made dependent on the result of the substance safety assessment, thus on risk considerations. The specific provisions in column 2 for the individual tests under VII.7.1 refer, however, to the exposure, along with other conditions such as the molecular weight. These special provisions in column 2 of Annex VII as regards the tests for ecotoxicity in the Regulation text are in need of clarification.

[3] According to Annex VIII (≥ 1000 t/a) (6.6.3) in contrast, a test of the long-term toxicity is only necessary, when in addition to the frequency and duration of the exposure at least one other criterion is fulfilled.

Conclusions:

The terminology for exposure in REACH should be more precise. Uniform terms should be used, in order to describe exposure qualitatively. If no agreement can be reached here at the expert level, then it may be sensible to seek agreement, as needed, at the political level.

2.2 Matrices for the structuring of exposure situations

In the project, possibilities for the structuring of exposure situations with the aid of matrices were discussed. Due to time constraints however there was no in-depth consideration of substances and of the advantages and disadvantages.

3 Fundamental terms and their interpretations

A Fundamental terms

A.1 Exposure

Exposure in the sense of workers- and consumer protection in the context of this project means contact of humans with a substance, i.e. the nature and the extent (incl. duration, level, frequency) of the contact on the biological barriers (epithelia of the body surface and the respiratory and gastrointestinal tracts). Exposure considerations also include the nature and the extent of release from preparations (evaporation of volatile substances, release of solid substances e.g. through rubbing off) and from articles with solid matrices (e.g. migrations from plastics, solid objects like ceramic tiles etc.). Environmental exposure is the entry of a substance into one of the environmental compartments and the ensuing exposure of biota.

A.2 Relevant exposure

The boundary between a relevant („significant“) and non-relevant exposure is regarded as lying at the point where even for a toxicologically very potent substance no detrimental effects on the subjects to be protected are to be expected.[4]

A.3 Specifications to exposure conditions

This is understood to include the specifications of the manufacturer with regards to the areas of application, the uses, and risk management measures, which the manufacturer provides to the downstream users (here instructions may be included) and specifications of the manufacturer as regards the maximal concentration not to be exceeded.[5]

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4 The following alternative definitions of „non-relevant exposure“ were suggested:
VCI: The boundary between a relevant and a non-relevant exposure as regards waiving is seen to be at the point, where the results obtained in additional tests
a) have relevance for risk management in practice,
b) are correct in regard of the exposure.
BfR: instead of „detrimental effects on the subjects to be protected“ „any substance-induced effects on the subjects to be protected“.

5 Here the BfR calls for a distinction between information on assessment of the exposure from information for downstream users.

A.4 Uses

The identified use according to REACH is that use of a substance or a preparation, which is intended by a stakeholder in the supply chain or is communicated to him in writing by an immediately downstream user and is mentioned in the safety data sheet.

A.5 Exposure-based cut-off criteria

An exposure-based cut-off criterion is defined in this report as the numerical value for an exposure (dermal, inhalative, oral), which if not exceeded, based on current estimations, for the great majority of substances and for the particular application route involved, is not associated with relevant risks for the target group involved (workers, consumers). For the environmental area, a cut-off criterion means a concentration in aquatic systems, at which a non-acceptable effect most probably will not arise (corresponding to the PNEC-definition of the EU-TGD).[6]

B Interpretations of terms and accompanying discussions

B.1.1 Exposures at the work place and their assessment

In order to ascertain whether at a work place a „relevant exposure“ is present or not, this must be quantified[7] [8]. As regards the quantitative assessment of exposure at the work place, differences of opinion were evident between representatives of industry and the BAuA, in particular concerning the question whether in the quantification of exposure the effect of personal safety measures (PSM) should be considered or not.

The industrial representatives assume that lightly burdensome measures (protective clothing, protective gloves, and where needed a dust mask) can be worn for longer periods or repeatedly and, insofar as they are supplied by the employer, are actually worn. The regulation-compliant use of personal safety measures is in their view obligatorily specified in the TRGS 500, as well as in § 19 Abs. 4d ChemG and in the Hazardous Substance Regulation. Their consideration in making the exposure estimation corresponds, in the view of the industrial representatives, to the real situation. The BAuA elaborates here further, that

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[6] Addition by the BfR: Cut-off criteria cannot be applied for substances, for which the substance-based exception criteria pertain.

[7] The industrial representatives speak here of the necessity of making a „qualitative and as needed a quantitative evaluation“.

[8] If effects such as corrosive/irritating effects or sensibilisation are involved, then it is sufficient, in the view of the industrial representatives, as a rule, to make a qualitative estimation of an exposure. It is crucial above all to establish the temporal duration of the exposure (especially also for the measures).

in distinction to actual hazards identified through testing, in the case of a waiving-justification the conducting of a test cannot be waived through the imposing of burdensome work safety measures (this includes all PSM). In the view of the BAuA, only in individual cases, and only when with sufficient likelihood it can be made plausible that only occasional, short exposures of a few persons are possible, then the exposure reduction through personal safety measures might be brought into consideration, in order to evaluate the possibility of a waiving. Technical and organisatorial risk management measures (RMM), by contrast, should be taken into account in assessing the exposure.

The REACH-Text (Annex I) is not clear in this regard.[9] RMM are mentioned as possibilities in Annex I, 5.1. (Step 1. Development of exposure scenarios), in order to reduce the exposure of humans (see also 6. Risk characterisation). Under 5.2. (Step 2. Exposure estimation), however, RMM are not included in the list of points which should be considered in estimating the exposure.

There is a shared common view that the exposure assessment, if necessary in an approach to be refined step-wise, can also consider the resorption potential of humans (here, see also REACH Annex I, 5.)

B.1.2 Exposure of the consumer and its assessment

In the view of the BfR, for the question, whether a relevant exposure of the consumer exists, a quantitative consideration is called for. The exposure of the consumer cannot be described alone through risk-reducing measures. The BfR particularly emphasizes here that for such a quantitative estimation of consumer exposure the RMM are also to be considered, insofar as these are controllable. An especially important element for the evaluation of the exposure has turned out to be the data on the migration of substances out of products. Without a quantitative value here, an estimation is not possible. If the substances are integrated in a matrix, the migration can often be considered to be minimal, while for substances with a high vapour pressure a migration can practically always be assumed.

B.2 Relevant exposure

[9] The industrial representatives view the REACH-text in this regard to be unequivocal and would add: „RMM are to be considered in assessing the exposure. In the exposure **scenarios** they must be described. In Annex IV of the guidelines on the fulfilment of the requirements of Annexes IV – IX and further in the second step („determination of the information requirement“): For determining the need of information about the substance it is most important to consider the data on the exposure, the use and risk management. There is no restriction of the RMM with respect to PSM included neither in Annex I nor in Annexes IV – IX.“

There was unity in the project that, for the concrete specification of the relevance of the exposure, different criteria need to be developed, in particular the extent of the exposure (see Chap. 4). Criteria for characterising the relevant exposure should be won with consideration of experiences with known substances and with the use of uncertainty factors. Hereby account should be taken in the criteria of the aspects relevant for an exposure such as frequency, duration, level and the group affected.

In regards to the frequency of the exposure, the industrial representatives strictly equated „relevant“ with a repeated exposure, based on the 28-day-test. According to the BUA however a single exposure can also represent a relevant exposure (see here also Section 5).

B.3 Specifications for exposure conditions (concentration maximum limits, RMM) In the view of the industrial representatives it is possible, through exposure-limiting specifications to the user to ensure that the exposure for the user is kept within non-relevant limits. In the discussion it was brought out that unclear, in part divergent views exist over the nature of such specifications: Do these involve abstract restrictions for the user, untested in reality and possibly not maintainable? Or do specifications result from the examination of the state of the art of the technology and represent suitably adapted and detailed descriptions of the conditions for use and RMM (in the sense of a component of an exposure scenario according to REACH)?

B.4 Uses

In the project it was intensively discussed, which uses of a substance must be considered for assessing the exposure for justifying a waiving. After examining the REACH-text, the majority opinion was reached, that only the uses given by the manufacturer (including those reported by downstream users, insofar as these are supported by the manufacturer) must be considered. The BAuA sees however several possible interpretations of the REACH-text. Also in the final report of the SPORT-project the need for clarification here was formulated (http://www.sport-project.info/) (see here also Section 6.4 of this report).

C Conclusions

The factors, which are to be taken into account in the quantification of the exposure of workers, consumers and the environment, should be defined in the REACH-text. This holds generally as well as with respect to the procedure for the justification of a waiving, especially with regards to the question, whether or not, and if yes, in which form personal protective measures at the work place should be taken into account.

The relevance of an exposure must be unequivocally validated through the criteria to be developed and through a description of the surrounding circumstances

Exposure-limiting specifications of the manufacturer or the importer for one's own handling of the substance as well as for the downstream user must be defined in their nature and implementation.

The definition of the given use should be precisely presented in the REACH-text.

D Open questions

Exposure:

In the project it was not extensively discussed to what degree in the estimation of the exposure for the justification of a waiving of the test requirements one should assume „normal handling and use", „extreme use or misuse" or „reasonable foreseeable misuse" (ECB, February 2005).

4 Conditions for an „exposure-based“ waiving

In the following sections criteria are discussed, which are of importance for justifying exposure-based waivings. Here at the beginning of the discussion the VCI brought in a working paper with suggestions (Fink 2005).[10] The starting point here is that the information of a basic data set is available.[11]

4.1 Fundamental substance-related requirements

In the discussion of the individual criteria for an exposure-based waiving (see below) the opinion was expressed by the agencies, that certain substances should as a rule, on grounds of workers and consumer protection, be excluded from exposure-based waivings. Substances/substance groups, for which on the basis of the group involved or the structure a high mammalian toxicity, high accumulation or carcinogenicity might be expected, should be explicitly excluded with respect to the application of cut-off criteria in workers- and consumer protection.

The agencies reject a waiving based on the availability of certain classifications. For example, a skin-sensitizing effect with classification as R43 does not lead to comparable protective measures as would possible classifications on the basis of ‚serious health effects‘ from the 28-day-test. Basically, the intrinsic characteristics of hazardous substances are to be considered separately. This applies to currently valid hazardous-substance law as well as in the future under the GHS System. Exceptions are substances which are regarded as carcinogens or mutagens of category 1 or 2.

In the view of the industrial representatives, for certain intrinsic characteristics of a substance not all waiving criteria are applicable. Thus, substances, for which on the basis of a suspicious structure high long-term mammalian toxicity or high accumulation might be expected, should be excluded from the application of cut-off criteria for the exposure level for workers and consumers.

In the view of the industrial representatives certain intrinsic characteristics, such as, e.g. carcinogenic effects, demand in any case exposure-limiting measures, and make a 28-day-test superfluous, because no more massive protective measures could result from

[10] These suggestions are based on an exposure-based waiving in the case of Annex VI, 6.6.1 (28-day-study) and 6.7 (reproduction toxicity).

[11] According to the VCI-proposal, this basic dataset consists of the information requirements of Annex V of REACH, augmented by the data from Annex VI on the acute toxicity (for one uptake route) and on ready biological degradability. Annex 9.2 of this report compares this basic dataset with the requirements of Annexes V and VI of REACH.

the test result. Thus because of the protective measures an exposure by the corresponding uptake route(s) is no longer to be regarded as relevant.

In the discussion substances or substance groups were mentioned by various parties, for which a waiving should be excluded a priori, but without any consensus being reached for a list of such substances. Named were (not complete): metals, metalorganic compounds (incl. tin-organic compounds), isocyanates, plant protection-agent-ingredients and substances with biocidal action, insofar as relevant according to REACH, hormones and hormone precursors, polychlorinated dibenzodioxins and –furanes and related compounds, potentially additionally also nitro-PAK, nitrosamines.

Conclusion: As regards the letter and the spirit of how, in the context of an exposure-based waiving, substances with special intrinsic characteristics should be dealt with, there are divergent views or there is a need for clarification. The procedure should be discussed in detail for concrete exemplary substances.

Open questions: In the view of the Umweltbundesamt it is categorically not possible, for persistent and accumulating substances in the environmental area, to proceed without long-term investigations. However, the non-applicability of waiving criteria for substances with such intrinsic characteristics was not discussed in the project.

4.2 Individual criteria

4.2.1 Cut-off criterion exposure level at the work place

Starting point: In the VCI-concept from 24.5.2005, as cut-off criterion for the exposure level at the work place for gases and fumes a value of 0.1 mg/m^3 as well as a value for dust particles of 0.05 mg/m^3 was proposed This was based on the consideration of existing work place threshold values and the discussion of the available data on the chronic toxicity of chemicals. For the dermal exposure of humans at the work place a cut-off criterion of 1 mg/day/person was proposed by the VCI.

In the course of the project various data evaluations were brought into the discussion process:

- Evaluation of MAK-values (U. Reuter, BUA)
- Evaluation of the work place threshold values of the TRGS 900 (U. Föst, BAuA)
- Evaluation of the data from 28-day-studies of new substance registrations (U. Föst, BAuA)
- TTC-concept and the underlying data evaluations from Kroes et al. (2000) and (2004) (Presentation by K. Schneider, FoBiG)
- Evaluation of the NOAEL from the CEFIC-ITEM-database for published 28-day-studies (S. Jacobi, Degussa; K. Schneider, FoBiG)
- An evaluation of air-concentrations in 14 facilities according to TRGS 420 (confidential data) (U. Föst, BAuA).

Results: Altogether, with these evaluations an extensive treasure trove of experience from the areas of existing and new substances is available, which can be used to derive a cut-off criterion for the exposure level, even if all investigated datasets manifest certain limitations.[12]

In the discussion the BAuA concluded that on the basis of the above mentioned evaluations of work place threshold values and 28- and 90-day studies from new substance registrations a cut-off criterion of 50 µg/m^3 (both for gases and for aerosols) can be determined[13]. This

[12] For example, Ms. Schulte (BfR) pointed out, that the 28-day-test only has a limited investigation depth as a screening test.

[13] The data from studies with oral exposure (28-day- and 90-day-studies) were hereby extrapolated to the inhalative route with the assumption of certain accompanying conditions (average respiration volumes of an adult during a working day, average body weight etc.).

value was determined, so that it approximately corresponds to the 5th percentile of the substances in the above evaluated databases, i.e. for ca. 95 % of the substances a work place threshold value of > 50 µg/m^3 would result. A value at this level is, in the view of the BUA, a pragmatic, if not scientifically founded approach (because exceptions in the individual case are always possible).

A further key point was obtained from a second evaluation, which the BAuA undertook. Thereby the air-concentrations in closed plants were measured according to TRGS 420 (the evaluation encompassed 14 plants, in which 12 substances were investigated; evaluation of 395 individual measurements). It was found that air-concentrations of 10 µg/m^3 could be maintained.

The industrial representatives note, that it should be examined whether, by the exclusion of certain substance groups with known chronic toxic effects, an even higher cut-off criterion of 1 mg/m^3 might be justified.

Both the BAuA as well as the industrial representatives view it as a plausible course to derive from the cut-off criterion for the air-concentration at the work place a cut-off criterion for the dermal exposure, under the assumption of a comparable resorption via the skin. Since a worker during light physical work inhales in a working day ca. 10 m^3 air, at air-concentrations of 10 - 100 µg/m^3 the resultant theoretically possible daily dose is 0.1 to 1 mg/person and day.

The BAuA assumes further, that for substances with a vapour pressure of 10^{-4} Pa or lower (under process conditions, i.e. in some cases at elevated temperature), a relevant exposure is not reached, if the formation of an aerosol can be ruled out (dust particles, droplets). The industrial representatives consider this vapour pressure to be unrealistically low. A conclusive discussion on this point is still pending.

Conclusions: The establishment of a cut-off criterion for the exposure level at the work place is generally accepted. On the basis of the discussed data evaluations, a cut-off criterion in a concentration range of 10 - 100 µg/m^3 is obtained, both for gases as well as for particulate powders.[14,15] An extrapolation of the corresponding uptake amounts to the dermal exposure route is regarded as plausible.

[14] Remark of the BAuA: The presentation of a range does not represent a consensus, rather it is the consequence of the fact that agreement on one value was not possible.

[15] Remark of the industrial representatives: 10 µg/m^3 is in the view of the agencies the technically maintainable concentration for closed systems. 50 - 100 µg/m^3 is the toxicologically determined concentration range.

4.2.2 Cut-off criterion exposure level in consumer protection

Starting point: In the VCI-concept from 24 May 2005 the following values were given as cut-off criteria for the exposure level in consumer protection:

- indoor air-concentration: 10 $\mu g/m^3$
- concentration in the neighbourhood: 10 $\mu g/m^3$
- Dermal exposure: 0.1 mg/person and day
- Indirect oral exposure of humans (uptake through water, food etc.): 0.1 mg/person and day or an amount entering the environment of 100 tonnes/per year.

The air-concentration values are justified with the analytical detectability and the principle of proportionality: In the indoors there are also such substances of natural origin and displaced environmental pollutants present in these concentration ranges.

Data sources besides the databases already mentioned above include:

- evaluation of the data from 28-day-studies of new substance registrations (U. Föst, BAuA)
- TTC-concept and the underlying data evaluations of Kroes et al. (2000) and (2004) (Presentation by K. Schneider, FoBiG)
- evaluation of the NOAEL from the CEFIC-ITEM-database on published 28-day-studies (S. Jacobi, Degussa, K. Schneider, FoBiG)

The following additional data:

- Foils from Prof. Gundert-Remy (BfR) on the First BfR-Forum Consumer Protection "EU-chemicals law and consumer protection" on 23 and 24 June 2005 (http://www.bfr.bund.de/cd/6499)
- Opinion and suggestions of the BfR for a cut-off criterion in the context of the written comments on the draft report from July 2005
- Brief paper on the data requirements for „food contact materials“ (K. Schneider, FoBiG).

Results: As maximal tolerable uptake amount, the BfR proposes for oral and dermal uptake 1 µg/kg/day (corresponding to approximately 60 µg/person and day). For inhalative uptake an exposure level of 3 µg/m³ was regarded as unproblematic for the consumer. The maintenance of these values is to be documented in the dossier or must be plausibly presented, insofar as testing is waived with this justification. These values are in the view of the agencies also to be maintained for substances in preparations which have a content of under 0.1%. The values lie numerically close to those proposed by the VCI.

Conclusions: Cut-off criteria for the exposure of the consumer were not extensively discussed in the project so far. Nonetheless, the proposals in the discussion for cut-off criteria already fell within a tight range of values. The consensus range for the tolerable exposure level of the consumer is 60 to 100 µg/person and day for the oral and dermal routes and 3 to 10 µg/m³ for the concentration of substances in the air.

Open questions: The data basis for the individual suggestions in the project was not extensively discussed. It was also not extensively discussed, if and how the aggregate exposure over multiple routes or from multiple input sources should be considered and whether the indirect exposure of humans through inputs in the environment requires special consideration.[16]

[16] Remark from the BfR: The BfR holds a consideration of the aggregate exposure for indispensable.

4.2.3 Cut-off criteria (exposure level) for the exposure of the environment

Starting point: As cut-off criterion, the industrial representatives brought a concentration of 0.1 µg/l[17] in aquatic systems into the discussion.

The following documents are available:

- In the context of the project Mr. Willing (Cognis) presented an evaluation of acute aquatic tests.
- In addition, there are publications from Straub (2002) and de Wolf et al. (2005), which make proposals for „thresholds of no concern“ for the aquatic environment.
- The Länderarbeitsgemeinschaft Wasser (LAWA) has recommended, in the context of a report on the determination of thresholds of non-significance (Geringfügigkeitsschwellen, GFS) for the entry of pollutants in the groundwater for poorly investigated substances, a threshold of no concern of 10 ng/l. (LAWA, 2004, http://www.lawa.de/lawaroot/pub/thema/grundw.html).

Results: In a preliminary discussion of the proposal of the industrial representatives the UBA reported that, based on experiences with old and new substances, a relevant number of substances have PNECs <100 ng/l. In the view of the UBA, a cut-off criterion for the environment would not be sensible. Above an annual production volume of 10 t, acute tests are available on three species, which represent different trophic levels, and with their help it is possible to make a risk evaluation (derivation of a „predicted no effect concentration“ (PNEC) and comparison with the estimated exposure). The necessity of conducting long-term tests should be decided case by case depending on the results of the risk evaluation. Basically the UBA is of the opinion, that an exposure-based waiving requires substance knowledge, particularly with regards to the life-cycle and the production-/formulation-/use conditions of the substance.

In contrast to the position of the UBA, the companies consider a cut-off criterion for substances in the aquatic environment to be helpful as a possibility for a rapid initial assessment of a substance.

Conclusions: There are diverse opinions as to whether the establishment of a cut-off criterion for the aquatic environment is sensible. Generally, however, it can be inferred that this criterion can be used through the availability of data on acute aquatic toxicity and the

[17] Remark of the industrial representatives: The value corresponds to the threshold value of the Drinking water-Regulation of May 2001 for plant protection agents and biocidal products.

possibility to use this together with safety factors to determine a value for a concentration without detrimental effects (PNEC, predicted no effect concentration), but that this has less significance than the corresponding criteria in workers and consumer protection.[18]

Need for follow-up: In the view of industry, but not in the opinion of the UBA, the derivation of a cut-off criterion for the exposure of the aquatic environment should be made on the basis of the above mentioned data.

[18] According to REACH there are already adequate data on the acute ecotoxicity in the low-tonnage area (< 100 t). Herefrom an expected environmental concentration without detrimental effects can be estimated (PNEC). This substance-specific PNEC-value can be used in making the decision for or against the conducting of a long-term study – instead of a general, substance-independent value of an acceptable environmental exposure.

4.2.4 Criterion time: frequency and duration

Starting point: In the proposal of the Verband der Chemischen Industrie (VCI) on waiving-conditions, time criteria are also included (see VCI 2005). The starting point for the discussion was the assumption, that there is no necessity for data from tests with repeated application, if only short-term or occasional exposures are involved (where applicable because of instructions or risk management measures). Both for inhalative as well as for dermal exposures, the VCI has proposed values for both the frequency and duration of „short-term“ exposures (see following overview).

- ***inhalative exposure´***
  industrial, commercial use (workers)
  a) 7 x ½ h per week (1/2 h per day e.g. sample collection) or
  b) 1 x 4 h per week (e.g. for maintenance work) (not valid for substances with log pow greater than 3)
  consumer
  a) 1 x ½ h week or
  b) 1 x 4 h per month or
  c) 2 days per year
- ***dermal exposure***
  industrial, commercial use (workers)
  a) 7 x ½ h per week or
  b) 1 x 4 h per week
  (only exposure of the hands)
  consumer
  a) 1 x ½ h per week or
  b) 1 x 4 h per month or
  c) 2 days per year

4.2.4.1 Discussion of the time criteria in work place protection

The workers protection agency did not agree with the proposed assignments. The values given above, which the industrial representatives have put forth as a „short-term“ or „occasional“ exposure, were regarded as being too high.

In the view of the BAuA this proposal cannot be used, in order to waive the sub-acute test. Thus the above mentioned exposures for workers must be regarded throughout as repeated

exposures. Only a single exposure over a whole lifetime could be regarded as a short-term exposure, in analogy to the exposure scenario in the animal-experiment investigations,[19]

It was pointed out by workers protection that at the present time there is no generally accepted definition of „ short-term“ and „long-term exposure“. According to the BAuA, time entries in several Technical Rules (Technischen Regeln für Gefahrstoffe, TRGS) refer primarily to the danger appraisal, in conjunction with which relevant time periods for the wearing of personal protection equipment (e.g. gloves) are given.[20,21]

Despite these concerns, in the evaluation of the exemplary substances in workers protection rough time criteria were successfully used, even though the exact definitions of „one-time“ – „repeated“, „short-term“ – „long-term“ were still lacking. However, in the view of the agencies, criteria are hardly usable for broad use scenarios, at best for specific individual cases. For the examples for substances and uses dealt with in the project, in a majority of cases special uses were involved (see here also Section 6.4).

In summary, it can be concluded that time criteria could have a role for workers protection as waiving-criteria– especially in conjunction with the question of personal safety measures, see Chap. 4.3. A precise specification of the terminology however is still lacking.

[19] The basis for many work protection measures is air limits. These air limits are as a rule based on the evaluation of studies with repeated use. In the context of work protection these values are also used for the evaluation of one-time exposures. Comment from the industrial representatives: The one-time exposures referred to involve short-term exposures, but repeated several times daily. Thus this is not a one-time exposure.

[20] At this point the agencies pointed out that a one-time exposure can also be a relevant exposure, for the evaluation of which data from tests with repeated use are necessary. This view, not shared by industry, will not be discussed here, rather in Chapter 5.1 (with the significance of the 28-day-test).

[21] The agencies also noted here that the use of personal protection measures instead of substitution or technical measures is categorically unacceptable. The use of burdensome personal protection measures is in this context a misdemeanour insofar as it has not been approved. The conditions under which such an approval would be granted can only be decided in the individual case, under consideration of the nature of the hazard and in the light of the basic principle of proportionality. Hereby general criteria as regards the duration and frequency are not predetermined.

Need for definitions, follow-ups and decisions: The terms „one-time“ /“short-term“ and „repeated“ / „long term“ are not yet defined for workers protection.

The formation of a consensus opinion to the question, what a „ short-term exposure“ means concretely, is necessary. The specifications to be developed should have international validity and hence be developed in consultation with the EU-working groups in the RIP.[22,23] For the establishing of values, the existing work protection rules (Hazardous Substances Regulation) could also be taken into account.

4.2.4.2 Discussion of the time criteria in consumer protection

Also the consumer protection agency disagreed with the description for „short-term exposure“ proposed by the industrial representatives. From the viewpoint of the agencies, here a simple distinction between single and multiple exposure appears sensible. Hereby a one-time exposure exists when the exposure of the consumer occurs on one day in the year; all other exposures are multiple. Further gradations were not recommended by the BfR.[24]

There was additional discussion of an evaluation from Mr. Heinemeyer (BfR), as to which usage frequencies are to be expected for consumer-near product groups. The database is the reports for existing substances since 1997 for the existing priority substances according to the four priority lists of the EG-existing-substances Regulation. The evaluation shows that in the consumer area for preparations for everyday needs the majority of exposures (on a yearly basis) occur repeatedly (cleaning agents e.g. daily; dyes, depending on the type, 1 – 6 times). For repeated usage per day (e.g. hand washing) frequencies > 365 are also possible.[25] One-time-only exposures are rare (usage frequency: 1 x/year).[26] The duration of use depends on the product group and also on the specifications of the supplier (e.g. package size, instructions).

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22 Comment from the industrial representatives: The determinations should not be developed in consultation with the EU working groups in the RIP, rather in REACH.

23 Comment from the BAuA: General workers protection rules must be formulated in agreement with national and
EU-legislation; this cannot be clarified through a REACH Implementation Project.

24 Detailed information on the time course of the exposure, in the view of the BfR, comes into question for subsequent steps in the assessment.

25 Comment from the industrial representatives: Such especially exposure-relevant uses have however already been regulated by law outside of REACH (e.g. food, biocide or cosmetics legislation).

26 In the view of the industrial representatives this statement is not correct.

Even for single use of a product (example: carpet glue[27]) a long-lasting exposure of the consumer can occur. Hence single use is not to be equated with one-time exposure. In the tables no information is given on the duration of the exposure as the result of a use. Thereby the question, whether an acute or a chronic exposure is present, is determined not only through the frequency of use, but additionally also through the duration of exposure during and subsequent to the use.

For consumer exposures, based on the available data, it is to be assumed a priori that in almost all cases repeated exposures are involved.[28]

An analysis for a possible exemption from fulfilment of the REACH specification „Relevant exposure can be excluded“ can, in the view of the BfR, only be affirmative upon demonstration of the maintenance of the exposure level (see 4.2.2) and not through reference to a time value.

In summary it can be concluded that time criteria probably have only a very minor role as a waiving-possibility in consumer protection since for almost all product groups repeated exposures can be assumed. For consumer protection an initial distinction between one-time (1x/year) and repeated exposure is sensible, although also here the duration of the exposure must be considered. The result is that time considerations standing alone are not useful for the justification of a waiving for consumer-near uses.[29]

[27] Remark: For these examples, the actually occurring exposure also depends on the volatility of the ingredients and the compliance of the instructions of the manufacturer, incl. room ventilation and non-use of the room for specified times.

[28] In the view of the industrial representatives this statement is not correct.

[29] Comment from the industrial representatives: This paragraph should be replaced by the following text: „ In summary, it can be said that time criteria have only a limited importance as a waiving-possibility in consumer protection for certain product groups, while they do have significance for other product groups. However, there is disagreement as regards the criteria on the duration and frequency of exposure“.

4.2.4.3 Discussion of time criteria in environmental protection

For the area of environmental protection no time criteria were concretely specified in the project.[30]

For the environmental area there has so far been no particular importance discernible for time criteria in exposure-based waiving. Time criteria have played no role in the evaluation of the exemplary substances with regards to the subjects to be protected. The UBA assumes that an emission to the environment, insofar as it exists, usually is continuous.[31]

[30] Comment from the industrial representatives: In the existing TGDs a distinction is made between a single input per month and a continuous input into the waters.

[31] Comment from the Umweltbundesamt: Also a single input of a persistent substance is to be assessed as problematical, since such a substance usually cannot be reclaimed.

4.2.5 Cut-off criteria for preparations

Starting point: The VCI formulated a cut-off criterion for substances in preparations. If substances are used solely in preparations in concentrations of < 0.1%, it should be assumed that the exposure is not relevant.[32,33]

This criterion is orientated on the classification and labelling limits according to existing law (Preparations-guideline 1999/45/EC) as well as the requirements formulated in the REACH-proposal on the preparation of safety assessments for substances in preparations. Article 13 of REACH prescribes a substance safety assessment for PBT- and vPvB-substances only for a content ≥ 0.1 %. For other substances it refers to the so-called general limit concentrations given in the preparations guideline or, insofar as they are available, to substance-specific established limit concentrations, e.g. for carcinogenic and sensitizing substances in Annex I of the Guideline 67/548/EEC.

According to the table in Article 3 (3) of the preparations guideline, a concentration of 0.1% represents the limit, below which, despite the designation hazardous for a substance, no classification and labelling of the preparation is implied.[34] For preparations which contain a substance labelled with R48 („Hazard of serious detriment to health for longer exposure“) a classification is to be made, when the concentration of the substance is ≥ 1 % or exceeds the substance-specific limit concentration if available.

Results: The REACH-proposal prescribes no substance safety assessment for concentrations of a substance in preparations below the given limit concentration. This can be interpreted to mean that REACH assumes that no significant health risk exists, when these limits are met. The proposal of the industrial representatives for a cut-off criterion of 0.1 % (substance concentration in preparations) uses these implicit statements of REACH for the setting up of cut-off criteria for an exposure-based waiving.[35]

The BAuA holds this cut-off criterion to be generally applicable for the area of workers protection. However, even such a low concentration can lead to relevant air-concentrations,

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[32] The industrial representatives propose the use of this criterion for articles as well.

[33] The industrial representatives point out that under REACH for substance concentrations in preparations <0.1% generally no authorisation and no chemical safety report are necessary. REACH assumes that for exposures to substances in preparations below this concentration no relevant regulation-requiring risk exists. The industrial representatives are of the opinion, that this cut-off criterion must also be used for articles.

[34] Endpoint-specific rules: According to the “Guidelines for specific concentration limits for carcinogens in Annex I of Directive 67/548/EEC. Inclusion of potency considerations” from 2002 (http://ecb.jrc.it/) for carcinogens of categories 1 and 2 with higher potency a gradation is called for above 0.01%. Analogous proposals have also been made for skin-sensitizing substances graded for wind strength (Akkan et al., 2004).

[35] Remark of the BfR: REACH does not refer to the preparations guideline. After the implementation of the GHS System into law, the preparations guideline must be adapted to conform to GHS.

when the vapour pressure of the components under consideration is significantly higher than that of the matrix, and consequently, in addition, the partial vapour pressure of the components of the substance under consideration in the preparation must be under 10^{-4} Pa.[36]

The BfR states and documents with exemplary calculations with ConsExpo, that along with the concentration in the product (a preparation such as e.g. a dye) the amount used also crucially contributes to the exposure and that for corresponding amounts applied critical exposures can also occur even with low content in the product. Hence for the chosen example, according to the views of the BfR, for the assessment of the exposure not only the concentration of the substance in preparation used, but also the total amount of the substance applied in the interior room is crucial. The use of a concentration limit as a stand-alone criterion in the consumer area is not agreed to.

The UBA rejects this cut-off criterion for the area of environmental protection. Percentage limits for the estimation of the exposure make no sense in the view of the UBA, since the level of exposure depends on the amount of the substance used, not on its concentration in the preparation.

Conclusion: The proposal of the VCI for a concentration-based cut-off criterion of 0.1 % for substances in preparations is orientated to the requirements for a chemical safety assessment of Article 13 of REACH for substances in preparations.

For the area of workers protection the proposed cut-off criterion finds basic acceptance (under consideration of certain surrounding circumstances such as the physical-chemical characteristics of the substance)[37], while the criterion is viewed critically by the agencies in the area of consumer and environmental protection because it reflects no direct correlation to the exposure level.

The divergent fundamental positions to this point should be presented further in the ongoing RIP-3.3-process and the consequences of the respective positions (e.g. for the information dissemination along the value-creation chain) analysed.[38]

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[36] Remark of industry: This value is regarded by industry as unrealistically low.

[37] In the view of the BAuA, in reality very few examples exist where the substance already in its manufacture falls below a concentration of 0.1%. Unless an imported substance is involved, for the area of manufacture other criteria are to be applied (e.g. closed plant according to TRGS 420), in order to justify a waiving.

[38] The VCI calls for a clarification in the text of the REACH-Regulation in this regard.

4.2.6 Criterion risk management measures (RMM)

Starting point: Risk management measures are an essential element in the presented REACH-Regulation proposal for limiting exposure. In the proposal of the Verband der Chemischen Industrie (VCI) on waiving-criteria two aspects are dealt with:

- When it is prescribed for substances to be used only upon maintenance of stringent measures, it should be assumed that no relevant exposure arises.
- When a substance is manufactured, imported or used exclusively in a preparation, which already contains more dangerous substances, and for these substances strict risk management measures are prescribed, it should be assumed, that no relevant exposure arises („Relative Risk Consideration“, here relative means: the substance is considered in comparison with another substance (VCI 2005).

4.2.6.1 Discussion RMM in workers protection and in environmental protection

Discussion of the topic „Stringent measures“: Initially it was confirmed that risk management measures have a high significance especially for workers and environmental protection in the industrial and professional area. At the same time experiences from workers protection show that the acceptance of risk reduction measures is often low, at least in the commercial area.

Here industry indicated that according to REACH the acceptance of risk reduction measures is of no relevance for the registration and the chemical safety data sheet. According to Annex I of the REACH-Regulation proposal, it is to be assumed that the prescribed risk management measures will be maintained. REACH explicitly stipulates in Article 31, that customers must inform their suppliers when the risk management measures, communicated to them in the safety data sheet, are inappropriate based on the given uses. In case a downstream user regards measures as inappropriate, he may also make the decision to resort to other measures.

Further, the delivering supplier is free, from the viewpoint of the manufacturer, to present the risk management measures (also including instructions, as to if, how and under which conditions a substance may be used), so that certain exposures of humans and environment may not occur or only occur to a certain extent. In the event that he has his own doubts about the realisation of a certain measure, he can instruct his customer to control this measure regularly, or even to document the result of the control (where appropriate occupational medical investigations are to be prescribed as controls).(See here the work of the VCI, Document 35).

A controversy persisted in the discussion as regards the consideration of personal protective measures and the possibility of giving exposure conditions or exposure levels to be

respected. In the view of industry, personal protective measures are a possible waiving-argument, insofar as they are reasonable and based on reality, equally so the giving of instructions. The industrial representatives note here, that in several legal specifications the regulation-conforming use of personal protective measures is obligatorily prescribed.[39] In the view of the agencies the exposure reduction must be substance-, product- or process-immanent.

The BAuA additionally noted hereto, that the use of a burdensome personal protective measure cannot be prescribed without adequate justification. Here the inclusion of knowledge about the characteristics of the substance is necessary.[40]

It also remained controversial, to what extent in the justification of a waiving, knowledge about the actually existing exposures can be replaced by indications of the manufacturer about the exposure conditions or measures to limit the exposure. In the view of the workers protection agency, here a waiving can only be approved, when the given exposure conditions are not variable based on individual behaviour, but rather a consequence of substance-, product- or process-immanent characteristics. A waiving is not acceptable, when the manufacturer merely prescribes to his customers certain measures or the maintenance of a given air-concentration.[41] Otherwise, the consequence would be that knowledge is not generated and the substance thereby does not undergo a possibly necessary classification and labelling. For use in practice in workers and consumer protection, the substance would then be falsely regarded as non-hazardous since it bears no hazard notation.[42] The giving of a very low exposure level for a substance without hazard notation is however inconsistent with the workers protection system in the view of the BAuA. Such inconsistencies are to be strictly avoided, in the view of the agency.[43]

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39 (e.g. §6a PflSchG, §19 Abs. 3 Nr.4d Chem.G).

40 Comment by the industrial representatives: These substance characteristics are however known, e.g. for preparations based on certain ingredients, without it being necessary to examine all constituents.

41 Thus, for example, a waiving (with consideration of inhalation) could be approved, if dust production of a non-volatile substance was prevented by means of it being manufactured under conditions analogous to TRGS 420 and brought on the market only as an abrasion-free granulate. A waiving would **not** be acceptable, when a manufacturer informs his customers that powdering is to be avoided or that a given air concentration may not be exceeded; this would lead to arbitrary, undefined exposure conditions. Commentary by the industrial representatives: The conclusion of the last sentence is not acceptable for the industrial representatives.

42 In the view of the industrial representatives this statement is not correct.

43 Comment of the industrial representatives: It should however be noted that many substances do not fall under the classification and labelling obligation, because they are not brought into commerce or they have been exempted from the obligation. The measures can be given as a precaution by the manufacturer or importer internally also without classification and labelling. The same is also valid for measures which they recommend to their customers. The classification and labelling are not a precondition or requirement for risk management measures. Hence the argumentation is not applicable.

In the view of the workers protection agency a waiving cannot be justified on the basis of undefined exposure information. The Explanatory Memorandum (Point 2.5, p.27) is so interpreted by the BAuA, that the actual exposure data of the user must be used by the manufacturer in the exposure assessment if they are known to him (hereto see Document 42 (Mr. Böhlen) and Chap. 6.4).

Results: The introduction of risk-reduction measures is an important element for the reduction of the exposure and hence is to be considered in the assessment and evaluation of the exposure level.

However, there still exists some dissent over the question, which measure with which consequence should be brought into the considerations.

Under workers protection aspects, a waiving is in principle to be assumed, when substances are used within closed plants (in the sense of corresponding to the specifications of TRGS 420). Without further exposure considerations or measurement data it is assumed in this case that the exposures are negligibly low under workers protection aspects.

Industry pointed out that the requirements are not realistic for the **professional** area. In the **industrial** area it is assumed that in the individual case a wide-reaching restriction is involved. Also for plants which are closed, but not in the sense of the very detailed TRGS 420, an exposure could by all means be effectively prevented, e.g. with respect to dissolved non-volatile substances. Here it must then be demonstrated that the exposure is in fact low.

In the view of the Umweltbundesamt a reference to the maintaining of the conditions of TRGS 420 is not sufficient, in order to be able to then decide on the granting of a waiving. Here additional information is required on the emission, i.e. on exhaust air, sewage, cleaning processes etc., which are not regulated by TRGS 420. Hence the conditions of production/formulation and the cleaning of the system are to be described. This pertains particularly to the occurrence and fate of sewage and wastes, and process-, rinsing- and cleaning liquids, as well as a possible exposure of soil and waters over the air route.

Follow-up possibility: In the project the discussion could not be pursued beyond the above presented point. The contrary positions are clearly represented.

It is reasonable in a follow-up step to specify on the basis of examples, what specifications are intended by industry. For this, it could also be worked out, which risk management measures are acceptable in the context of a waiving-justification and which are not.

4.2.6.2 Discussion RMM in consumer protection

It was noted that risk management measures in consumer protection are set up differently than in workers protection and that as a rule it cannot be assumed that the measures will be

respected in consumer protection. This is particularly true for personal protective measures. Information about the surrounding circumstances of use is contained in package inserts, on packaging or – in rare cases – in accompanying product information. The compliance of the suggested measures is not obligatory.

In the view of the agencies, for substances with consumer exposure no RMM exist in the sense of protection at the work place. The criterion RMM is thus to be considered differently and in a more differentiated way. It is recommended to distinguish between controllable and non-controllable measures.[44] The former can be initiated and controlled by the producer of consumer-products himself. Examples are: the substitution of hazardous by non-hazardous substances, the limitation of the contents and container sizes, child-safe lids and alterations of the product design (e.g. tabs instead of powder, pump sprays instead of aerosols, dosing attachments).[45]

These measures could find appropriate consideration in exposure models with corresponding factors.

Non-controllable measures are general measures for the reduction of the exposure such as ventilation, following the usage specifications etc. Their maintenance in exposure models is difficult and has so far scarcely occurred. It can be expected that these measures will scarcely find consideration in the assessment of consumer exposure, nor in the making of decisions on an exposure-based waiving.[46,47]

Follow-up possibilities: Examples of controllable and non-controllable measures could be evaluated on the basis of products and their uses in the context of a waiving-justification.

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[44] Comment of the industrial representatives: „It is recommended to make a distinction between measures prescribed by the manufacturer which are difficult or impossible for the consumer to avoid and measures to be actively realised on the part of the consumer (not controllable on the part of the manufacturer.)“

[45] Comment of the BfR: Controllable measures are always application-immanent.

[46] Comment by the BfR: In the risk assessment under REACH „waiving“ would take place in a tiered procedure at an early stage. All non-controllable measures can be neglected in the estimation of the consumer exposure and thus are not considered in the making of an exposure-based waiving.

[47] Comment by the industrial representatives: No agreement on the last sentence and the second half of the previous sentence, Delete these text passages. Addition: „In the opinion of the VCI, a consumer must also abide by the users instructions and other instructions just as is the case for other products such as, e.g. electrical appliances. The instructions to the consumer must however take into account his capabilities for the application of the measures. Measures may not be prescribed, which cannot be fulfilled in practice.

4.2.6.3 Discussion of the topic „Relative risk consideration“

In the view of the agencies, a relative risk consideration for substances used in a preparation or in a shared usage situation with other, more dangerous substances, is only possible in the individual case, if at all. An individual case consideration is necessary because different characteristics of the substances could make different risk management measures necessary, but these are not necessarily transferable from one substance to another. It was also pointed out that there could be alterations in the product formulations (and for hazardous preparations this should occur)[48], which lie in the context of the given application categories. An RRM valid for a preparation till then could no longer be valid with the newly contained untested substance. The previous protective measures could be eliminated and the untested substance could realise its unknown effects unhindered. Thus these alterations are not always followed in every case by new registrations. Such alterations of the product formulations can however have effects on the risk evaluation. However in the individual case the unknown extent of reduction or elimination of an ingredient can have a direct influence on the „relative risk“ derived for another ingredient. Hence in the view of the BAuA the principle of the relative risk is in any case to be subordinated to a temporal revision. The principle is at the moment being discussed in various working groups with regards to workers protection. Most likely it is only applicable when hazardous components in a preparation cannot be substituted.

The BAuA further noted, that with the argument of relative risk consideration the presence of a hazardous substance is in a way tolerated through the presence of a more hazardous substance. A potentially possible substitution would thereby be hindered.[49]

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[48] Example: The benzene content in petrol has been substantially reduced in recent years, and even benzene-free petrol is conceivable (remark of the BAuA).

[49] Comment by the industrial representatives: The presentation of the BAuA is not consistent. When a supplier specifies stringent measures for a particular substance in a preparation, the entire preparation must be handled according to these measures, unless the manufacturer of a different substance component of the preparation calls for stricter measures. For numerous hazardous characteristics, such as e.g. a corrosive/irritating effect, sensibilisation, or carcinogenicity, it is already necessary to take stringent protective measures, and these would not be made stricter through the results of a 28-day-test.

The argumentation, that through product reformulations for a preparation, the valid RMM would no longer apply to the newly contained untested substance, leads automatically to a requirement according to Article 31 that the user notify the supplier. Further, according to Article 34, he must conduct his own risk assessment and according to Article 35 make a report to the EU-Agency.

The concept of a relative risk assessment is of practical value, but needs some clarification. It presupposes among other things a corresponding communication of the waiving-conditions (e.g. risk management measures) and back-notification along the value-creation chain for deviations (through alterations – new uses / new formulations/ other risk management measures).

4.3 The relationship of the criteria to each another

Starting point: The decision, whether an exposure-based waiving of tests is possible, can be made with the help of the criteria presented above. For the exemplary substances the criteria came into use with different emphasis. The investigation of the exemplary substances showed that some criteria by themselves make a decision possible, while others must be combined with others in the argumentation.

The cut-off criteria for the exposure level for work place, consumer and environmental protection[50] and criteria regarding whether plants are closed according to TRGS 420 can stand alone.

- An exposure-based waiving is possible, when it can be shown for all expected exposure situations that the exposure level does not exceed the established cut-off criteria.[51] Precondition: No substances with a structure suspected of possessing particularly critical characteristics / no membership in critical substance groups (see Chap. 4.1).[52]
- Migration capabilities / gasification capabilities: Under consumer and environmental protection aspects an exposure-based waiving is possible, when it is shown that a relevant substance-emission is prevented through firm binding to a matrix or through the gas escape behaviour[53]. This is to be documented through migration studies taking into account the individual usage conditions or comparable information[54]. In these cases the exposure assessment can remain limited to the preceding stages (manufacture, formulation, usage).
- When closed plants corresponding to the specifications of TRGS 420 can be assumed for all relevant stages in the life-cycle of a substance, the possibility of an exposure-based waiving can be directly derived therefrom. Precondition: Limitation to industrial

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50 Comment from the Umweltbundesamt: In the view of the Umweltbundesamt cut-off criteria for the environment are not needed. Such cut-off criteria do not have a consensus of support in the environmental area (as described in 4.2.3).

51 Comment of the industrial representatives: Replace the sentence with the following formulation: „An exposure-based waiving is possible, when for all given exposure situations the exposure level does not exceed the established cut-off criteria“.

52 With respect to the critical substance groups, a substance annex acceptable at the European level would be desirable.

53 In the view of the industrial representatives, the word „documented“ should be stricken.

54 Comment from the industrial representatives: The formulation „is to be documented“ should be replaced by the formulation „can be justified“.

and professional uses, documentation that there is no demonstrable consumer exposure (e.g. complete reaction, no residual content in products).[55,56]

Indications of possibilities of an exposure-based waiving, but which must be additionally supported with further information[57], arise from the criteria frequency and duration of the use and the exposure, number of subjects exposed, risk-management measures (exception: closed plants corresponding to TRGS 420) as well as the content of a substance in the preparation.

- **Frequency and duration of the exposure:** For short-term uses a negligible exposure in workers protection is more likely, because here personal protective measures are more likely to be justified.[58] In the consumer area by contrast, depending on the product type, single uses can also lead to repeated or longer-term exposures. This pertains particularly for indirect exposure over the surroundings.[59]
- **Number of exposed subjects**: There was no consensus that the relevance or non-relevance of an exposure can be established from the number of exposed subjects. The criterion „ number of exposed subjects“ could however be helpful insofar as for a lower number of exposed subjects under consideration of the frequency and duration of the exposure, in the workers protection area, the use of personal protective measures can more likely be assumed to pertain, with better control possibilities. The workers protection agency points out here that the decision can categorically only be discussed for individual cases and is always focused on measures for the protection of the person(s) involved. For the decision about a waiving this aspect can only find limited applicability. For consumer-related uses the criterion „number of exposed subjects “ cannot be brought into the justification of a waiving.[60,61]

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55 From industry it was noted that these requirements are not realistic for the professional area. In the industrial area it is assumed that in the individual case an over-excessive restriction is involved. Also for plants that are closed but not in the sense of the very detailed TRGS 420, an exposure could be quite effectively prevented, e.g. with respect to dissolved non-volatile substances.

56 In the view of the industrial representatives the word „demonstrable“ and the brackets should be deleted.

57 In the view of the industrial representatives the clause „which must be additionally supported with further information “ is not correct.

58 Comment from the industrial representatives: Replace the sentence through the following formulation: „For short-term uses there is as a rule a non-relevant exposure in workers protection. Here personal protective measures are more likely to be justified.“

59 The industrial representatives do not agree with the last sentence.

60 The question of socially acceptable residual risks could not be covered in detail in the given framework of the project.

- **Risk management measures (RMM)**: RMM lead to a reduction of the exposure particularly in the industrial and professional area. For the use of these criteria it should be considered whether system-specific, organisational and product-related measures or personal protective measures are involved. Risk-management measures are to be evaluated in conjunction with the frequency and duration of the exposures occurring (see here also Chap. 4.2.6). RMM in the consumer area are difficult to describe quantitatively in models.[62] It is known, that consumers generally do not respect the instructions of the manufacturer for the use of products or only give them very limited attention.[63]
- **Content in the preparation**: When the classification and labelling limits of the preparations guideline for a substance are not exceeded, it is very likely with respect to workers protection that no critical exposures occur. In consumer protection area however the agencies consider it necessary in every case to calculate the expected room air-concentration or the dermal/oral dose under consideration of the usage and emission conditions (amount used, frequency of use, emission behaviour) (see here also Chap. 4.2.5).[64]

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61 Comment of the industrial representatives: The paragraph „number of exposed subjects“ should be dropped. Proposed additional text: „In the discussion the criterion the number of exposed subjects or the exposed group was also brought up. However, there was no consensus on this. But there was agreement that complete safety for all affected groups without residual risks is not realistically attainable. The REACH-Regulation proposal contains with the limit of 10 tons/year an indirect criterion, that certain residual risks should not be regulated. It is difficult to say whether and how extensively this criterion is transferable to the exposure of groups. The question of socially acceptable residual risks could not be covered in detail in the given framework of the project “.

62 Comment by the industrial representatives: The sentence should be replaced by the following formulation:“ RMM in the consumer area can be quantitatively determined in models by a conservative approach with realistic boundary conditions“.

63 Comment by the industrial representatives: The sentence should be dropped.

64 Comment from the Umweltbundesamt: With regard to environment it is also necessary for the exposure evaluation to consider the absolute substance amount for each affected compartment.

5 Significance of the 28-day-toxicity test

Starting point:

The fundamental priority of the 28-day-test was discussed on the basis of several documents:

- ***significance of the 28-day-toxicity test (OECD 407) (U. Reuter, BUA)***
- aim and priority of the 28 day-study in the context of the chemical assessment (A. Schulte and H.-B. Richter-Reichhelm, BfR)
- evaluation of new substance registrations with R48 (A. Schulte, BfR)
- evaluation of substances of Annex I of Guideline 67/548/EEC with R48 (U. Jensch, Clariant GmbH)

Results: The industrial representatives interpret the waiving-possibility given in the Commission's proposal to be that a relevant exposure is not present, when no relevant *repeated* exposure is present. However, it was noted by the BUA that according to the Regulation proposal it is not a "relevant repeated exposure", but rather a "relevant exposure" of humans which must be excluded, and that a short-term exposure can also represent a relevant exposure.

The fundamental significance of this test lies, in the opinion of the BUA and the BfR, in the identification of organ-specific effects in the non-lethal dose range and the derivation of a dose-effect relationship, because these cannot be obtained from the testing of the acute toxicity.[65,66] The 28-day-test is used as the starting point for further investigations (e.g. of specific toxic effects such as neurotoxicity and immunotoxicity), provides indications of reproductive toxic characteristics and is indispensable for the risk evaluation (derivation of the DNEL) and derivation of limit values for substances. In the context of a test-strategy for high-volume substances, the test provides information for the justification of the waiving of additional longer-term investigations. It was further emphasized, that tests with repeated exposure can also be helpful towards being able to adequately assess effects after a single

[65] Tests for acute toxicity, as they are to be conducted under valid EU / OECD test-methods, serve for the detection of doses which lead to lethality in the test animal and in the usual case do not identify the target-organs and –effects of acute-toxic actions. The revisions of the last decade were focused on the saving of animals, not on gaining scientific knowledge. These investigations are not suitable for the identification and characterisation of the acute toxicity in the opinion of the BfR.

[66] The BfR calls attention to the tabular comparison (in the above mentioned document from Schulte and Richter-Reichhelm) of the investigative parameters of a 28-day-study with those of a test for acute oral toxicity according to currently accepted guidelines.

exposure, and that also single exposures with long exposure-free interim periods can lead to an effect-accumulation as well (example: increased inhibition of cholinesterase by Dichlorvos upon repeated application), which can be detected better by a 28-day-test.

The industrial representatives on the other hand propound the view that tests with repeated exposure cannot give correct or adequate results about effects, which arise after a single exposure.

The industrial representatives emphasise, that the intention of the REACH-Regulation text lies not in the basic results gained (on intrinsic characteristics of substances), but is rather purely based on risk, since it seeks to promote the safety of humans and environment. Correspondingly, it is unnecessary to conduct investigations, when no relevant exposure is present and thereby the ensuing risk is non-existent.

In the project it was also discussed, what possible consequences the forgoing of the 28-day-test has for a classification of a substance as R48. If the study is not conducted and no other data are available on the toxicity upon repeated exposure, then correspondingly no classification with R48 can take place. Two evaluations (from Mrs. Schulte on new substances with R48 and from Mr. Jensch on substances classified as R48 in Annex I of the Guideline 67/548/EEC) were presented, to analyse in which cases the R48 was assigned without the existence of classifications on the basis of health effects observed in acute tests.

In the investigation of Mrs. Schulte on R48 substances an analysis was made for their relation to classifications due to acute-toxic and sensitizing properties. The BfR states that the classification as R48 was decisive for a large number of the investigated substances: 77 of 215 substances with R48 has not been assessed with respect to acute toxicity, and for 18 more substances the R48 led to a more critical classification than the results on acute toxicity.[67] Ca. 60% of the substances classified as R48 labelling had no classifications because of sensibilising characteristics.[68]

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[67] Remark of the industrial representatives hereto: This involves only a very small proportion of the over 3.000 new substances and is thus in the view of the VCI of limited importance. Moreover, the additional labelling of R48 – danger of serious damage to health upon longer exposure – provides no relevant indications for short-term uses / exposures.

[68] Remark of the BfR: The BfR does not regard the discussion about the presence of R-Phrases or the consequences of the lack of an R-Phrase to be a suitable instrument for the development of exposure-derived criteria for the forgoing of the 28 day-test. For one thing, the measures according to R48 are not covered by other endpoints; for another, with newer data previous classifications could be dispensed with. If there was an interdependence between the toxicological endpoints, then all endpoints would have to be reconsidered every time there was any change. This is not desired by the legislators. Under hazardous substance laws up until now, as well as in the new GHS-System, the intrinsic-toxic properties are considered separately for classification and labelling.

The evaluation of Mr. Jensch had the aim of examining whether the R48-substances of Annex I are labelled with an R-Phrase for acute toxicity, corrosive/irritative action or skin-sensibilising effects.

The two evaluations were also distinguished from each other with regards to the accompanying conditions used (consideration only of the classification because of acute toxicity or combined with additional endpoints such as irritative action, sensibilisation, mutagenicity, exclusion of certain substance groups such as metal-compounds, pharma or plant protection agents). According to the evaluation of Mr. Jensch with combined use of the above mentioned accompanying conditions, for only 9 out of 236 substances classified in Annex I as R48, was the R48 decisive.[69] This evaluation was not further discussed in the framework of the project (see hereto also the supplementary comment in Section 10.1 of this report).

The evaluations of Mrs. Schulte and of the BAuA with reference to „simple measuring concept hazardous substances“ show that the labelling as R48 led, in

[69] Comment of the BfR and the BAuA on Mr. Jensch's evaluation: The substance list according to Annex I of the Guideline 67/548/EWG included many substances with incomplete data, for which, among other things, no tests with repeated application are available. A differentiated consideration of the list with separation into substances, for which at least the basic dataset, and thus also a 28-day-test is available, and substances with data gaps is not possible. The list is a cumulative presentation of the already known hazardous characteristics of substances, whose classification has been harmonised in the EU-member states. The „identification of a substance with any R-Phrase“ in the evaluation is not sufficient for the legally prescribed inclusion in the health protection for workers and consumers and is not useful within the scope of the project.

a relevant number of cases, to stricter protective measures than the classifications on the basis of acute effects.[70,71] (http://www.BAuA.de/prax/gefahrstoffe/measuresconcept.htm)

Conclusions: The agencies stressed the particularly high priority of the 28-day-test and reasons were presented, why an exemption from this test can only occur under very stringent conditions. However, as was worked out for exemplary substances, none of the agencies categorically excludes an exposure-based waiving. The, in their view, great importance of the test must however be reflected by appropriate criteria for a waiving.

In the view of the industrial representatives, the REACH-proposal pursues a risk-orientated decision-making system. This means that a plausible and as detailed as possible justification of the non-relevance of an exposure represents the condition for a waiving. This was not contested by the agencies although they stressed the fundamental importance of the test. Consequently the elaboration of generally acceptable waiving-criteria gains crucial importance.

[70] Remark of the industrial representatives: These measures – insofar as they were actually necessary – pertain however only to repeated or longer-term exposures.

[71] Remark of the BAuA: With better knowledge of the hazard characteristics, protective measures can be carried out with more purpose, so as to minimise burdens. The more concrete the classification of the substances to be used, and thus the information, the greater the acceptance of protective measures by those affected.

6 Examination of the examples

6.1 Selection and evaluation of the example set

In the project 17 substances in particular uses were investigated, for which the manufacturer and importers (who will have to register their substances under REACH) and in some cases also downstream users, proceeded under the assumption that in the manufacture and use of the substance no significant exposure would arise and therefore that a waiving of tests with repeated use was justified. The substance selection was made by enterprises participating in the project.

The chosen substance-set was found in an initial evaluation to be meaningful and conducive for achieving the goals of the project. On the basis of intensively dealing with the examples in the context of the commentaries, there was a second discussion of the representativeness, in which it was established, that for the substances in the project, as a rule, only one specific application was investigated. It was noted by the agencies, that this would be somewhat of an exceptional case in registration practice and that usually for registration several uses would be considered. This regular situation is not covered by the examples in the project. The consequences thereof were extensively discussed – see the overview of additional uses in Section 6.4 and the accompanying discussion.

The 17 selected substances are not a representative cross-section of the chemicals currently found on the market. But the substances come from different industrial, professional and consumer-near uses; moreover, the justifications for an exposure-based waiving are satisfactorily diverse.

6.2 Commentary and discussion of the exemplary substances

The national evaluation agencies examine and evaluate the justifications for waiving submitted by the enterprises in the project. These assessments of the agencies were discussed; for some substances the manufacturers/users provided additional information and the agencies were thereby able to re-examine and confirm their conclusions.

From the intensive work on the substances a series of substance-independent, robust conclusions could be drawn concerning the possibilities and limits of an exposure-based waiving. From these conclusions concrete specifications of the conditions to be fulfilled can also be inferred, by means of which an exposure-based waiving can be substantiated.

6.3 Conclusions from the discussion of the exemplary substances

The following text, in the view of the project moderators, presents a fair representation of the consensus regarding conclusions to be drawn from the exemplary substances, as was reached at the project session on 27 July 2005.

At this session the individual points of these subsections were considered and common formulations were discussed, which were then set down in text by the project moderators. The Workshop-participants had the possibility at the conclusion of the session to comment on a preliminary draft version of these sections, with the request that they examine whether they were in agreement with the formulations hereby arrived at.

The remarks of the participants have as far as possible been taken into account in preparing the following text. Remarks of individual participants, which in the view of the moderators do not correspond to the consensus found at the session, are given as footnotes at the corresponding places in the following text.

The treatment of the examples showed that for some substances and the individual uses considered, an exposure-based waiving of studies with repeated application is possible, without workers, environmental and consumer protection being compromised.

6.3.1 Which uses are suitable in principle for an exposure-based waiving?

1. From the viewpoint of workers and environmental protection: Substances which are used within closed plants (in a sense corresponding to the specifications of TRGS 420). However, with regards to the protection of the environment for such plants additional information on emissions (on exhaust air, wastewater, cleaning processes, etc.) is necessary, in order to decide finally about a waiving.
2. From the viewpoint of workers protection: For the area of industrial and commercial uses a waiving is justified for substances which are exclusively used in preparations[72] containing concentrations below 0.1%.[73,74] In this case the exposure during the manufacturing process is not to be considered, when an import of the substance or the preparation can be assumed.

[72] The industrial representatives recommend here an extension of the concept to articles.

[73] The preparations guideline contains additional details on concentration. These are considered in chapter 4.2.5 of the report.

[74] In the view of the BAuA, in addition to limiting the amount to 0.1%, the partial pressure should be less than 10^{-4} Pascal.

3. From the viewpoint of consumer protection: Uses of substances in consumer products, which are nearly completely reacted away during manufacture (example: crosslinkers, vulcanisation accelerators, monomers), or are permanently integrated in a matrix (example: certain anti-ageing agents, which are bound in a rubber-matrix).
4. From the viewpoint of consumer protection: Uses for substances in preparations and products, which are characterised by very low migration (e.g. upon dermal contact) or vaporisation. Substances which are present in preparations and products only in low concentrations, when these are used only in small amounts.[75]
5. Substances[76], which are characterised by a narrow spectrum of uses, whereby the occurring exposures can be described well and can be successfully dealt with by risk management measures (RMM). For the question of RMM see Point 13.

For the types of use mentioned under 1 through 5 the likelihood is great, that exposures arising remain within acceptable burden limits, i.e. it can be assumed that the exposure is not associated with any hazard potential for human health and the environment. Also when a substance or a use falls in principle in one of these groups, an examination of the various criteria for all relevant stages in the life-cycle of the substance is necessary. A waiving can only be approved, if it is acceptable for all affected areas.

6. The workers protection and consumer protection side agree that cut-off criteria in regards to the exposure level can be brought in for the justification of an exposure-based waiving. With the exception of an inhalative exposure at the work place, the absolute levels for these cut-off criteria could not be specified in the project due to time constraints. No agreement was reached on specific values. The range of values brought into discussion by agencies on the one hand and industry on the other were documented in the report (see Section 4.2.1 and 4.2.2 of the report). For the exposure level at the work place the concentration range was 10 - 100 µg/m^3 both for gases as well as for powders.[77,78]

6.3.2 Which substance-related conditions tend to speak against an exposure-based waiving?

7. Substances which migrate or vaporise in large amounts.

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[75] Comment of the BfR: Addition to Point 4: The quantifying statements (such as e.g. „very limited migration“ or „in low concentrations“) however require a clear definition

[76] In the view of the BfR, here a restriction to workers protection should be made.

[77] A transfer of the corresponding amounts applied to the dermal exposure route is held to be plausible.

[78] In the view of the industrial representatives, concentration limits of 50 microgram/m^3 for powders and 100 microgram /m^3 for gases are regarded as having a consensus.

8. Substances for which the occurring burdens cannot be dealt with by RMM.
9. Substances which due to their structure or based on available data can be expected to be particularly hazardous.

6.3.3 Which requirements must be fulfilled for an exposure-based waiving?

10. An exposure-based waiving requires adequate knowledge or the reality-near description of the exposure conditions along the lifeline of a substance from its manufacture to its use and disposal. The decision for or against a waiving should in general be based upon plausible statements (measurements, modelling results etc.) on the exposure level, including tolerable risk reduction measures. For this a (at least crude) quantitative assessment is expedient, using a tiered approach, if necessary with stepwise refinement.
11. It is necessary to provide suitable data or specifications on exposure-determining substance characteristics (e.g. vapour pressure, log Pow, migration behaviour, evaporation behaviour, and for powders also particle-size distribution, dust number, etc.) and accompanying conditions of the exposure (duration, frequency and level of exposure, affected groups, safety standard of the enterprise, nature of uses (industrial, professional, consumer-near), RMM utilised, nature and level of emissions to the environment)[79]. These data should allow one to make a quantitative estimate of the expected exposure levels for the uses given by the manufacturer.

6.3.4 Follow-up possibilities for the exposure-based waiving

12. For some exemplary substances the exposure assessment was, in the view of the agencies, inadequate to justify a waiving. There was, however, one example, where despite the presence of a relevant dermal exposure, a waiving was justifiable, in that in a follow-up step additional data on the uptake of the substance through the skin e.g. from in-vitro skin penetration studies) was included. In the justification of the decision on a waiving, besides exposure considerations, consideration can also be made in corresponding cases, of statements on toxicokinetic properties, structure-action-relationships and structural relatedness (Read across). Risk-based waiving-conditions were not a subject of this research investigation and thus can only be mentioned for illustration.

[79] In the view of the BfR, here „data“ should be deleted.

6.3.5 What consequences arise from a successful exposure-based waiving?

13. Substances for which an exposure-based waiving is possible are adequately defined as regards the exposures arising from the uses specified by the manufacturer. The exposure even for a high intrinsic toxicity of the substance presumably represents a non-relevant risk.
14. In case RMM are introduced as justification for an exposure-based waiving, the respecting of these RMM acquires high importance due to this justification.
15. The basis for the decision, whether an exposure-based waiving is justified, is the substance usage given and supported by the manufacturer, including the given risk management measures and the exposures estimated therefrom. Uses deviating from these are not covered by the exposure considerations and fall under the responsibility of the associated active parties.
16. From Points 13 - 15 there arises in case of a waiving a special need for communication between manufacturers and users, which must be ensured in a suitable fashion. So far it has not been discussed, how this need for communication can be achieved and if, where appropriate, a supplementary special labelling is necessary. According to Article 30 of the REACH-proposal, the information on exposure assessment and its accompanying conditions (e.g. RMM) must be passed on to the downstream user, even when the substance involved is not hazardous.

6.3.6 Exposure-based waiving: divergent viewpoints[80]

17. Risk management measures and associated instructions as an exposure-limiting factor are not uniformly valued as regards their importance for the justification of a waiving. The relevant passages of the Commission's proposal must be interpreted, in the view of industry, to mean that the prescribed risk management measures are a basis for the derivation of an exposure scenario and for the risk evaluation. The agencies have reservations as to how far the prescription of the personal protective measures and their implementation can be taken into consideration as arguments for a waiving (see Section 4.2.6).
18. Waiving-possibility for substances with many different uses: There exists unity in principle, that the whole supply chain is a subject of the exposure considerations. The REACH-text is interpreted to mean, that the manufacturer only must consider the exposures which can arise for the uses specified by him. However, the Regulation-text here leaves room for another interpretation. In contrast to industry, the agencies

see only a limited possibility for an exposure-based waiving for a substance, when in the context of a registration several different uses are given (see Section 6.3 of the report).

19. In 6.3.1, Point 2 it is stated, that the demands of workers protection are not compromised, when for substances, which are only used in preparations in concentrations under 0.1%[81], the conducting of the 28-day-study is forgone. In the view of the corresponding agencies, however consumers and the environment can also be exposed to a relevant extent to substances in preparations of concentrations below 0.1%; then a waiving would not be justified. Here a case by case consideration is necessary, above all with respect to the total amount of the substance used[82] (see Section 4.2.5 of the report).
20. In the view of industry, it is sensible on pragmatic grounds, in the environmental area to establish numerical values for the exposure level, which must not be exceeded to have a non-relevant exposure („cut-off criterion exposure level“). This view is not shared by the UBA, since it should always be possible to make a risk assessment on the basis of the data on acute aquatic toxicity called for under REACH. The comparison of the expected environmental concentrations with the toxicity data then makes it possible to make a preliminary decision whether a risk exists for the protectable resource environment or not (see Section 4.2.3 of the report).
21. Time criterion: There exists diversity in the understanding of the terms single / repeated, short-term / long-term. Agreement as to which duration and frequency should be regarded as relevant could not be reached (see Section 4.2.4 of the report).
22. The necessity of a sub-acute study for the evaluation of acute exposure situations was evaluated differently (see Section 5.1 of the report).

There was a controversial discussion of the possibility of a relative risk assessment. Hereby for the evaluation of a waiving-possibility for a substance, risk management-measures are considered, which result from the presence of a more hazardous substance in a preparation or in the surroundings. According to this proposal, tests should not be called for, when risk management measures are already present, which take into account a particular hazardous-substance property. This procedure is

[81] In the view of the BAuA, in addition to the amount-limit of 0.1%, the partial pressure should be less than 10^{-4} Pascal.

[82] As an example, the painting of an interior room is given: Here the burden on someone who is in this room is not the concentration of the substance in the paint alone, but also the amount of the product used for the paint job. The concentration of the substance in the room air can only be determined from the total amount of the product used.

recommended by industry, but is not endorsed by the agencies (see Section 4.2.6 of the report).

7 Analysis of the use areas of the exemplary substances

Starting point: In the project it was agreed, that by asking the manufacturers and by analysing publicly accessible data it would be investigated for the exemplary substances whether and to what extent additional uses are possible, which were not investigated in the project with regards to a waiving-possibility. As starting point of the analysis, the 18 exemplary substances presented at the beginning of the project were examined[83] along with the uses of these substances specified by the manufacturers. These are presented in the following table.

Table 7.1 Name and uses of the exemplary substances, which were investigated in the project „exposure-based waiving“.

Nr.	Substance name	Uses
1	Phenol-dialkylphosphite	Glues
2	Thiophendiylbisbenzoxazole	Glues, frame-calking putties
3	Hexanoic acid, 2-ethyl-, 2,2-dimethyl-1,3-propanediyl ester	Lubricant for refrigeration compressors
4	Fatty acids, C18-unsatd. dimers, compds. with coco alkylamines	Disperser- and anti-settling agent for automobile lacquers
5	Tetrahydronaphthaline	Levelling agent (flow-aid for lacquer)
6	Pentaerythrite-bis-tetrahydro-benzaldehyde-acetal	Anti-aging agent in polymers
7	Reaction-products from Phenol, Isobutylene, Styrene and 2,2,4-Trimethylpentene	Anti-aging agent in polymers
8	1,6-bis(N,N-dibenzylthiocarbamoyldithio)hexane	Vulcanisation accelerator
9	Hexamethyldisiloxane (HMDS)	Endstopper in the manufacture of silicone oils
10	Acetic acid	Educt for Vinylacetate, Ketene and other organ. starting material; Pharma-starting material

[83] In the analysis exemplary substance Nr. 5 was also included, but it was later withdrawn.

11	Aliphatic alcohols	Industrial solvent, Intermediate products
12	Red pigment	Inorganic pigment, use in ceramics (e.g. glaze on tiles)
13	Cyclic ether	Industrial solvent
14	Anthrachinon-dye	Dye for mineral-oil products
15	cis-Cyclooctene	Monomer, intermediate product
16	1,7-Octadiene	Cross-linker for PE
17	Hydroxyethylethylene-urea-methacrylate (N-[2-(Methacryloyloxy)-ethyl]-N,N'-ethyleneurea)	Monomer / intermediate product, in emulsion polymers as adhesion facilitator
18	Polyol (no longer polymer)	Industrial/professional/ manufacture of Polyurethane

Results: The results of this analysis are presented for each substance in detail in the composition „Exemplary substances, use areas“ (Document 30). They can be summarized as follows:

- For 10 of the investigated examples there is no indication of additional uses (exemplary substances 4, 6, 7, 8, 12, 14, 15, 16, 17, 18). In 7 cases substances were involved which are used industrially in the area of plastics production, either as monomer or as precursor (15, 17, 18), as anti-aging agent (6, 7) or as cross-linker (16) or Vulcanisation accelerator (8). For these substances, enclosure in a matrix or a (nearly) complete chemical conversion can be assumed. As for the remaining examples, there are two cases involving pigments with special fields of use (12, 14) and an additive for lacquers (4).
- For 8 exemplary substances there are indications that additional uses pertain, beyond those submitted by the manufacturers to the project (exemplary substances 1, 2, 3, 5, 9, 10, 11, 13). These involve organic solvents in 3 cases (5, 11, 13), as well as acids and esters (3, 10), a carrier (9), an optic brightener (2) and a process stabiliser (1).
- In the project, for exemplary substances 1 and 2, certain consumer-uses (glue or frame-calking putties) were included from the beginning in the information on uses from the manufacturers involved in the consideration of a waiving-possibility.[84] For the solvents (5, 11, 13), for the ester (3), for HMDS (9) and for acetic acid (10) it is possible, that in

[84] For exemplary substances 1 and 2, the manufacture and formulation were not considered in the project.

addition to uses in the professional area and in the consumer area there are uses beyond those investigated in the project.[85]

- Thus the conclusions of the project on the waiving-possibility exclusively refer, for these exemplary substances (1, 2 3, 5, 9, 10, 11, 13), to those uses which the manufacturers brought into the project and specified.

For the exemplary substances with indications of additional uses there are no data as to what proportion of the total amount of the substance produced goes to those uses considered in the project.

When certain uses of the exemplary substances were not discussed in the project, then also no conclusions about a waiving-possibility for these could be made. Before making a generalization of the substance-driven results, all areas should be brought into the waiving-assessment (the use of a rubber-additive in the manufacture of lacquer can lead to different exposures than for its use in rubber-manufacture). This is also valid for substances for which not all consumer-near uses have been examined.

Discussion of the topic „substances with known broad uses“: The manufacturers emphasised, the uses of the exemplary substances in other areas are not to be taken into account for a decision on a waiving by a manufacturer or importer or a downstream user. The registering party can, on his own initiative, without consideration of other possible or known uses, specify the uses which he intends or supports. He must only pay attention to the specified uses which he enters or communicates on his safety data sheet. Consideration of all known uses is not foreseen under REACH, in contrast to the currently valid new and existing substance regulations. In many cases the compilation of all available uses would be very difficult for the manufacturer, since this information is not accessible. For additional uses of a substance the registration in regards to the waiving-agreements would need to be newly examined.

In the view of the BAuA, however the Regulation text here also leaves room for other interpretations, particularly with consideration of the Explanatory Memorandum of the Commission.[86] The BAuA assumes, that it was originally intended initially that all known uses were to be covered by the manufacturer. It was also inferred, that the actual exposure data of the user must be used in the exposure assessment if they are known (see here the work of the BAuA, Document 47, Annex).

For substances for which many different uses are specified in the registration, the agencies see a more limited possibility for a waiving. With an increase in the number of uses, it

[85] For exemplary substance 13 the manufacturer participating in the project assumes, that consumer-relevant uses no longer exist.

[86] Explanatory Memorandum, Point 2.5, p. 27, see work from Mr. Böhlen, Document 42

becomes increasingly difficult to examine whether relevant exposures occur. The agencies therefore propose not to waive, when the notifying registrant knows of additional uses on the basis of generally accessible data sources. Thereby it is also taken into account in the question of the waiving, that for a broad usage (in the sense of many different uses) one cannot be sufficiently certain in assessing the exposures occurring.

Follow-up possibilities: For the exemplary substances investigated it was usually assumed in the discussion that there was only a single special use. On the basis of additional exemplary substances it could be investigated, what possibility for a waiving exists, when for a considered substance several uses are registered. For correspondingly chosen examples it can also be discussed, what waiving-possibility exists for a downstream user, who in fact can operate with narrowly defined uses.

For the question of the interpretation of the REACH-Regulation proposal in the project the various possibilities have been worked out and documented. A continuation of the discussion at this point would not, based on experience, lead to any alterations. A decision about the various interpretation possibilities and the corresponding setting down of precise specifications of the formulations should take place in the framework of the further development of the Commission's proposal.

8 Working papers and further literature

8.1 Working papers

The working papers used in the project will be compiled in a separate Annex volume.

8.2 References

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Straub, J. O., 2002; Environmental risk assessment for new human pharmaceuticals in the European Union according to the draft guideline/discussion paper of January 2001Toxicology Letters, Vol. **131**, 2002, S. 137-143.

9 Annexes

9.1 Text passages of the REACH-Proposal of October 2003 on the possibility of an exposure-based waiving[87]

1. General possibility according to Annex IX, 3. (CSR – exposure scenarios)

"3. SUBSTANCE-TAILORED EXPOSURE-BASED TESTING

Testing in accordance with Annexes VII and VIII may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.

In all cases, adequate justification and documentation shall be provided."

2. Annex I, 0.4, third Paragraph: Reference to risk comparisons and risk-management-measures

"In accordance with Annex IX, Section 3, in some cases, it may not be necessary to generate missing information, because risk management measures which are necessary to control a well-characterised risk may also be sufficient to control other potential risks, which will not therefore need to be characterised precisely."

3. Possibility for an exposure-based waiving and for the exposure-related conducting of additional tests in Annexes VI to VIII, Column 2, human toxicologically relevant tests

Annex VI, 6.6.1	Short-term repeated dose toxicity study (28 days)	does not need to be conducted if: … relevant human exposure can be excluded.
Annex VI, 6.7	Reproductive toxicity: Screening for reproductive/ developmental toxicity	does not need to be conducted if: … relevant human exposure can be excluded.

[87] Independent of the question of the exposure, in Annex IV the general possibility of a waiving of the test is noted, in the event that it is technically not feasible or scientifically not necessary: **Annex IV, Note 1:** "If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions."

Annex VII, 6.6.2	Sub-chronic toxicity study (90-day)	does not need to be conducted if: …the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", test particularly if such a pattern is coupled with limited human exposure
Annex VIII, 6.7.4	Two-generation reproductive toxicity study	The study need not be conducted if: … the substance is of low toxicological activity, it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure and there is no or no significant human exposure
Addition: In the following text passage it is noted, that if an exposure exists, it is necessary to conduct an additional test. This is not a waiving, but is cited at this point as an example of the „Bottom-up-principle".		
Annex VIII, 6.6.3	Long-term repeated toxicity study (>= 12 months)	May be proposed by the registrant or required by the competent authority…if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is

4. Possibility in Annexes VI to VIII, Column 2, of waiving ecotoxicologically relevant tests or (addition at the end of the Table) conducting additional tests

Annex VII, 7.1.5.	Long-term toxicity testing on *Daphnia*	does not need to be conducted if: … direct or indirect exposure of the aquatic compartment is unlikely.
Annex VII, 7.2.1.3	Soil simulation testing	needs not be conducted if: … direct or indirect exposure of soil is unlikely.
As well as analogously to additional tests in Annex VII for aquatic and terrestrial toxicity		
Annex VIII, 7.4.	Effects on terrestrial organisms (long-term)	these studies do not need to be conducted if direct or indirect exposure of the soil compartment is unlikely.

Annex VIII, 7.6	Long-term or reproductive toxicity to birds	The study need not be conducted if direct or indirect exposure of birds is unlikely.
Addition: In the following text passage it is noted, that if an exposure exists, it is necessary to conduct an additional test. This is not a waiving, but is cited at this point as an example of the „Bottom-up-principle“.		
Annex VII, 7.1.	Aquatic Toxicity	Long-term toxicity testing shall be proposed by the registrant if the chemicals safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the safety assessment

9.2 The basic data set corresponding to the proposal of the VCI

Physico-chemical data according to REACH Annex V
Corrosion and irritation of the skin (in vitro)
Irritation of the eyes (in vitro)
Sensibilisation through skin contact
In vitro gene-mutation experiment on bacteria
Short-term toxicity for Daphnia
Acute toxicity (1st application route)
Ready biodegradability

10 Additional comments by the participants

These commentaries were submitted after completion of the working meeting of the project and were not further discussed together. They are listed here by the project moderators without further editing or comment.

10.1 Commentary from Mr. Jensch, Clariant GmbH, on Kap. 5, Significance of the 28-day-toxicity-test

The document „Evaluation of substances of Annex I of the Guideline 67/548/EEC with R48“ was prepared without knowledge of the contribution of Dr. Schulte ("Evaluation of new substance notifications with R48") and thus was not written for the purpose of establishing a contrary position to the evaluation of Dr. Schulte.

Commentary on the evaluation of substances of Annex I of the Guideline 67/548/EEC with R48 in the context of the project goals:

On the part of the VCI, along with other possibilities for waiving the 28-day-test, a waiving criterion of only a single or a short-term human exposure was proposed. As requirement for the application of this criterion, the VCI stated, that the substances coming into question must not be acutely toxic, not irritating, not sensitizing, not AMES-positive and not bioaccumulative. Substances with acute toxicity, irritating, sensitizing, mutagenic or bioaccumulative characteristics would be excluded from the waiving procedure. What is to be understood under single or short-term could not be discussed as a follow-up in the context of the project.

This was also the case for the question, whether data on sub-acute toxicity are relevant for an acute exposure situation. A conclusive development of opinions on the proposed waiving criterion is thus lacking. As a contribution towards the forming of opinions here the question is considered to what extent if at all it can be expected that upon the use of the VCI-proposal, substances with "R48-characteristics" occur, of which one has no knowledge, because a 28-day-test was waived. The relevance of these "R48-characteristics" in the case of a single or short-term exposure remains unconsidered in this assessment. To answer this question, a set of substances was taken, for which R48-characteristics are documented (all R48-substances of Annex I without applying any other selection criteria). This substance group was "sifted" using the VCI-requirements, i.e. the substances with acute toxicity, irritating, sensitizing, mutagenic or bioaccumulative characteristics, using the pertinent legal classification, were eliminated. Upon using this empirical procedure, of the original 236 substances only 9 substances remain, for which the above-mentioned waiving criterion of a

single or short-term exposure would have been applied. Since exclusively R48-substances were considered, this kind of evaluation represents a worst-case approach.

The VCI-approach, that defined acute exposure situations are appropriate as a waiving criterion for the 28-day-test in the absence of certain acute substance-characteristics because data from acute investigations are considered to be suitable for the evaluation of an acute exposure situation, is supported by the results of the above evaluation, which demonstrates, that so to speak as a side-effect the exclusion of substances with the above-mentioned acute characteristics evidently leads to an extensive exclusion (227 of 236 considered substances) of R48-substances. A risk, that is suspected for acute exposure situations, which have only been evaluated on the basis of acute data, is significantly reduced further by this statistical effect.

10.2 Commentaries from Mr. Obermann and Mr. Lanxess, zu Kap. 4.2.6.1, Discussion RMM in workers protection and environmental protection p. 26)

The experiences from workers protection cited in this Section evidently refer to the publication from the year 1993 of Paul Swuste et al., Ann. Occup. Hyg. Vol. 37, No. 2, pp. 117-134, 1993 (see E-Mail-Annex). In this publication the status of workplace hygiene from 1985 to 1991 in the rubber industry is described.

Compared with the findings of this publication the state of the art of technology in the rubber industry has progressed through

- low-dust settings of the substances used in powdered form (e.g. through oiling, granulating etc.),
- use of dosing bags for emission-free use of pulverising products,
- emission reduction through technical equipment such as local vacuuming and improved ventilation systems,
- altered awareness and behaviour of the employees in the use of personal protective equipment/measures (skin-covering work-clothes, protective glasses, protective gloves, dust-masks) and
- improved workplace hygiene (separation of private- and work-clothes, skin- and body care, no consumption of drinks and food at the work place).

The progress achieved in the rubber industry is described in an article in the periodical of the Berufsgenossenschaft der chemischen Industrie, Sichere Chemiearbeit, Nr. 11/04, 56. Jahrgang (see E-Mail-Annex).

Commentary on the maintenance of the prescribed air-concentration values (p. 27)

One RMM, which is supposed to lead to an air-concentration at the work place lower than that specified by the manufacturer, can be realised as follows:

For the use of substance X in the working process XYZ, a local vacuuming hose should be installed at the emission points. The performance of the local vacuuming must be such, that the air-concentration at a distance of 50 cm from the emission points does not exceed 0.05 mg/m^3.

With these specifications a process-engineer will be able to control the exposure reliably.

10.3 Commentaries from Mrs. Bambauer and Mr. Föst, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) zu Chap. 3, section B 1.1

§ 19 Abs. 4d ChemG empowers the federal government to regulate through legislative Regulations, among other aspects, the use of personal protective measures. Detailed provisions on the use of protective measures are spelled out in the Hazardous Substances Regulation

According to the opinion of the industrial representatives, the regulation-conforming use of personal protective equipment is mandatorially prescribed in TRGS 500. In the view of the agencies this is not correct. The TRGS 500 demands expressly and with utmost priority the use of a number of other protective measures, before personal protective measures (but only protective gloves and dust-masks, not breathing protection against gases and fumes) are used, secondarily to more appropriate work techniques.