

The risk-based concept for carcinogenic substances developed by the Committee for Hazardous Substances

From limit-value orientation to an action-oriented approach



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Foreword

After an intensive discussion between the social partners, labour inspectors of the Federal States and occupational accident insurance funds (Berufsgenossenschaften BG) as well as other experts, the Committee for Hazardous Substances (AGS) developed a "Risk Concept for Carcinogenic Substances". The particular aim is concretising the requirement to minimise exposure set out in the German Ordinance on Hazardous Substances.

The risk concept will replace the former technology-based approach. In addition to the existing system based on occupational exposure limit values and procedure and substance-related criteria, it introduces new substance specific assessment values and a graduated system of risk control measures. The aim is to ensure transparency and provide planning and legal certainty to inspection services, employers and workers.

By means of the "Announcement 910 on Hazardous Substances, risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances" and TRGS 400, the risk concept has been incorporated into the regulations related to the Hazardous Substances Ordi-



nance. Now it will be applied and further tested in the framework of practical risk assessment. This leaflet aims at ensuring a greater diffusion of the risk concept and intends to support its test phase.

A feedback on your experience would be welcome and help the Committee for Hazardous Substances (AGS) further develop the risk concept in view of incorporating it into the Hazardous Substances Ordinance by 2015 at the latest. Thank you very much!

Dr. Martin Kayser, BASF SE Chairman of AGS

Dr. Martin Henn, BAuA AGS Bureau

Regulations up to 2005						
	Maximum Allowable Concentration (MAC)		Technical Reference Concentration (TRC)			
→	Concentration of a substance to which employees may be exposed without harming their health, even if exposed repeatedly or over a long period	→	Lowest possible concentration of a carcinogenic substance that can be (reasonably) achieved in accordance with the state-of-the-art.			
→	No residual risk	→	Residual risk			
→	Health-based limit value	→	State-of-the-art based limit value			

Limit values at the workplace: handling hazardous substances

The risk-based concept for carcinogenic substances

1.1 Introduction

In their daily professional activities, employees are exposed to certain risks including contact with dangerous substances, the risk of injuries caused by machinery, noise, biomechanical stress or illness attributable to stress. Often, it is impossible to reduce the existing risk to zero; a certain residual risk will remain. Nevertheless, the primary goal is to make the situation at the workplace as safe as possible.

In the case of non-carcinogenic hazardous substances, the maximum permitted concentration workers may be exposed to at the workplace is defined by occupational exposure limits (OELs). OELs were introduced by an amendment of the Hazardous Substances Ordinance (GefStoffV) in 2005 replacing the former maximum allowable concentrations (MAC).

The occupational exposure limit defines the concentration of a substance (in the form of gas, vapour or airborne particles) to which employees may be exposed at their workplace without harming their health, even if exposure to the substance occurs repeatedly or over a long period. These I support the concept because, for the first time, it provides a scientific basis for a comparative assessment of workplace exposures and includes a concept defining protective measures depending on the level of exposure. The comparison with other types of workplace risk and the risks of everyday life shows that government policy and private sector activity cannot aim at zero risk.

Prof. Dr. Herbert Bender Vice President BASF SE limit values are also referred to as "health-based" values. However, OELs can only be defined for substances for which animal studies have shown a concentration threshold below which no harmful effect occurs.

As a threshold of effect cannot normally be determined for carcinogenic substances (i.e. there is no concentration at which the substance is entirely safe), OELs were not specified for these substances. However, in order to minimise the risk for employees the so-called Technical Reference Concentrations (TRC) were applicable until 2004. In contrast to OELs, Technical Reference Concentrations (TRC) are not health-based but oriented on the best available technology (state of the art) and therefore do not provide full protection against damage to health. The TRC of a carcinogenic substance was defined as the lowest possible concentration of the substance (in the form of gas, vapour or airborne particles) that can be (reasonably) achieved in accordance with the state-of-the-art.

Weaknesses of the old concept

TRC limited the risk for employees but could not totally exclude variable and often unknown residual risks. Another disadvantage was that in practice the health-based OELs and the technology-based TRC were perceived to be "equally safe". The main focus was on compliance with both values. However, in the case of the TRC, the legislator required employers to continue minimising exposure, where this was technically feasible, even if the actual values were below the applicable TRC. Exposure was to be reduced continuously in line with technological progress. In practice, companies were often slow to meet this requirement. Particularly in the case of workplaces where exposure levels remained below the TRC, there was little incentive for employers to reduce exposure still further, even if it were technically practicable.

A further disadvantage was a lack of transparency, because a "residual risk" for employees to develop cancer existed even in the case of compliance with the TRC. However, the level of residual risk and the likelihood of illness strongly vary from substance to substance (depending on their carcinogenic potential). These differences were not reflected in the TRC values. Consequently, there was a lack of comparability and the substance-related residual risk was not clearly identified. With the amendment of the Ordinance on Hazardous Substances in 2005, the TRC ceased to be in force. Instead, the

Weaknesses of the TRC concept In practice OELs and TRC were perceived to be "equally safe". Companies were often slow to meet the requirement for further reduction of exposure. Particularly in case of workplaces where exposure levels remained below TRC, little incentive to reduce exposure further existed, even if technically practicable. The level of residual risk strongly varies from substance to substance and is not reflected in the TRC values.

Committee for Hazardous Substances (AGS) developed a new, risk-oriented concept for assessing the risks associated with exposure to carcinogenic substances. The concept, which is currently being tested in practice, focuses in a more transparent manner on the residual risks associated with individual substances.

Strengths of the new risk concept for carcinogenic substances

The novelty of the risk concept – where it differs fundamentally from the former TRC concept – lies in its graduated approach: the higher the level of exposure to a carcinogenic substance and the associated residual risk, the higher the pressure to minimise exposure. Thus, the concept provides a uniform, consistent and clear criterion for comparing and assessing workplace exposure and the urgency of putting in place additional measures for its minimisation.

Strengths of the new concept

- → A uniform, consistent criterion for comparing and assessing workplace exposure
- The higher the level of exposure to a carcinogenic substance and the associated residual risk, the higher the pressure to minimise exposure
- Findings are being disclosed. Different activities may be linked to different risks and entail different measures

Increased pressure to minimise: proportional to the risk

1.2 Basic principles

In accordance with the well-known traffic-light model, the risk concept first defines three risk areas – high, medium and low (red/yellow/green).

The boundary between high risk (red area) and medium risk (yellow area) is referred to as tolerable risk. The tolerable risk defines the additional cancer risk of 4:1,000 that is tolerated, meaning that, statistically, 4 out of 1,000 persons exposed to the substance throughout their working life will develop cancer. This value roughly corresponds to the risk of an agricultural worker to be killed in an accident or the risk of a non-smoker who is not exposed to hazardous substances at work to develop lung cancer. Above the tolerance risk, employees should not be exposed.

The boundary between medium risk (yellow area) and low risk (green area) is referred to as acceptable risk. The acceptable risk defines the additional cancer risk of 4:10,000 that is accepted during an initial phase (until 2013, during the phase of the concept's introduction), meaning that, statistically, 4 out of 10,000 persons exposed to the substance throughout their working life will develop cancer. Beginning in 2013 until 2018 at the latest, this risk will be reduced to 4 out of 100,000 cases.

This corresponds to the risk of cancer outside the workplace ("remaining general environmental risk"). In the case of activities in the range of medium risk (below tolerable risk, but above acceptable risk) exposure must be continuously reduced



I support the concept because it provides the opportunity to make exposure to carcinogenic substances at the workplace transparent and find ways to reduce it systematically.

Dr. Henning Wriedt Staff member of the Counselling and Information Centre Work and Health, Hamburg further. The concept lists a detailed catalogue of suitable measures.

In the area below the acceptable risk, employers are not for the time being obliged to put in place additional protective measures.

Tolerable risk

- \rightarrow Concentration of a substance with a risk of 4:1,000
- → This value corresponds roughly to the lung cancer risk of a nonsmoker who is not exposed to hazardous substances at work.
- → Above the tolerance risk threshold employees should not be exposed at all



Tolerable risk = Threshold of danger

1.3 Application of the concept to individual substances – identification of substancespecific risk

First of all, the actual risk must be identified for every substance in order to determine whether exposure is in the range of high, medium or low risk. For example, an employee who is daily exposed to a concentration of 1 mg/m³ could have a risk of cancer of 1 out of 1,000 (high risk) or only 1 out of 10,000 (low risk), depending on the carcinogenic potency of the substance. The derivation of so-called substance-specific exposure-risk-relationships makes it possible, on the basis of suitable data, to determine for every substance the statistical probability of employees developing cancer after. The risks refer to a presumed exposure of 8 hours per day over a working life of 40 years.

The methodology for exposure–risk relationships and substance specific concentration values is described in a comprehensive "Guide for the quantification of cancer risk figures after exposure to carcinogenic hazardous substances for establishing limit values at the workplace". Normally, exposure-risk relationships are based on data from animal studies but they may also be derived from human data. The derivation of exposure-riskrelationships takes account not only of the carcinogenic potential of a substance but also includes other hazard potential (as for example in the case

Acceptable risk

- For a transitional period until 2013, the acceptable risk will be
 4:10,000 because in many cases a further reduction does not appear to be possible at the moment.
- From 2013 to 2018 at the latest it will be reduced to 4:100,000.
- Corresponds to the risk of cancer outside the workplace ("remaining general environmental risk").

Acceptable risk = Threshold for concern

of acrylamide). However, the establishment of exposure-risk-relationships for all carcinogenic substances is likely to be quite a lengthy process. Just as a reminder: At the end of 2004, TRC were in force for 70 substances. Currently, there is a list of priorities containing 30 substances for which exposure-risk-relationships have been derived or still need to be derived.

I support the concept because it opens a public debate on risk and because new approaches help us expand our knowledge particularly in the complex area of carcinogenic substances. In the test phase, it is important to gain new insights for practical application and ensure their transparency.

Prof. Dr. Helmut Blome Director of the Institute for Occupational Safety and Health – IFA of the German Statutory Accident Insurance

1.4 Application of the risk concept to activities involving hazardous carcinogenic substances – the concept of graduated risk control measures

A comparison between the exposure level at the workplace and the derived substance-specific "acceptable" and "tolerable" concentrations determines the necessity and urgency of protective measures according to a graduated concept. The concept lists 19 individual measures classified into five categories (administration, technology, organisation, occupational medicine and substitution). The extent to which these measures are obligatory depends on the respective risk area. For example: respiratory protection is obligatory in the case of activities involving respirable carcinogenic substances in the high risk area; in the area of medium risk respiratory protection must be prescribed if exposure limits are exceeded for short periods and must at least be offered (decision left to employees) in all other cases. In the green area of low risk, respiratory protection does not need to be prescribed or offered. The principle is: the higher the risk, the more stringent the requirements as to the measures to be put in place. Thus, the substitution of a hazardous substance is obligatory in the case of high risk (if alternatives are available), whereas in the area of low and medium risk technical feasibility and proportionality may also be taken into consideration.

Employees are to be informed of the outcome of the risk assessment in the course of their safety

and health training at the workplace. It must be clarified that different activities may be associated with different risks and consequently must give rise to different safety measures. The specific measures to minimise exposure must be documented in the company and must be communicated in a transparent manner.

I support the concept because the risks are no longer hidden. With this concept, we can all take targeted action wherever employees are exposed to a particularly high risk of cancer.

Dr. Bettina Schröder Senior expert on Legislation on Chemicals and Hazardous substances Free Hanseatic City of Hamburg

Exposure-Risk-Relationships (ERR)



Application to individual substances: substance-specific risk

Graduated concept of measures (typical measures extracted from BekGS 910)							
Measure	Low risk	Medium risk	High risk				
Administration		Report (if conditions are met) action plan	(Report,) action plan, ban, approval subject to conditions*				
Technical measures	Spatial separation (mini- misation of exposure level)	Technical measures spatial separation Exposure minimisation	Technical measures spatial separation exposure minimisation				
Organisational-	Hygiene measures operating procedures, instruction, training risk communication						
measures	Optimising or	Minimising duration of exposure and number of persons affected					
Occupational health check	Voluntary	Mandatory*	Mandatory*				
Substitution	If proportionate	Mandatory, if proportionate	Mandatory, if feasible				
* This AGS recommendation has no basis in law and does not in itself create a legal obligation.							
Application to workplaces: graduated measures							

1.5 Integrating the risk concept into the hazardous substances legislation

At present, the concept is still in its test phase. Before it can be formally integrated into the Hazardous Substances Ordinance, any possible weaknesses must be identified and corrected. Currently, June 2015 has been envisaged as possible date for the necessary amendment of the Hazardous Substances Ordinance.

The actual test phase started when the concept was linked with the existing Technical Rules through an amendment of TRGS 400 (Risk assessment for activities involving hazardous substances) which was decided by the Hazardous Substances Committee in November 2010. TRGS 400 informs companies that the described concept of measures should be applied when protective measures for activities involving hazardous substances are put in place, noting that some of the measures listed are not yet effective (for administrative measures such as "approval subject to conditions" and "communication with the supervisory authority" the legal basis does not yet exist). To create a legal basis for arranging preventive medical check-ups, it will also be necessary to modify the Ordinance on Preventive Medical Check-Ups.

I support the concept because the AGS' socio-political decision to adopt a risk concept will inject greater objectivity into the discussion on cancer risks, and because the concept will open up new ways of risk reduction as required by the Hazardous Substances Ordinance.

Dr. Astrid Smola

Senior Expert on Hazardous Substances, Biotechnology and Genetic engineering, Federal Ministry of Labour and Social Affairs

Integration into the hazardous substances legislation

- A possible date is June 2015 due to the necessary amendment of the Hazardous Substances Ordinance
- Start of the test phase by linking the concept with the existing Technical Rules through an amendment of TRGS 400 (Risk assessment for activities involving hazardous substances)
- → For some of the measures (such as "approval subject to conditions") a legal basis has to be established at first

Next step: testing by means of TRGS 400

List of substance-specific acceptance and tolerance values set out in Announcement 910 Status as of July 2012

Substance	Acceptable concentration (Risk 4 x 10 ⁻⁴)	Tolerable concentration (Risk 4 x 10 ⁻³)	Notes a
Acrylamide	0.07 mg/m³ c	d	
Acrylonitrile	0.26 mg/m³ (0.12 ppm)	2.64 mg/m³ (1.2 ppm)	
Asbestos	10,000 fibres/m³	100,000 fibres/m³	Ь
1.3-Butadiene	0.5 mg/m³ (0.2 ppm)	5 mg/m³ (2 ppm)	
Trichloroethene	33 mg/m³ (6 ppm)	60 mg/m³ (11 ppm)	
Aluminium silicate fibres	10,000 F/m³	100,000 F/m ³	е
4,4'-Methylendianiline	0.07 mg/m³	0.7 mg/m³	С
Ethylene oxide	0.2 mg/m³ (0.1 ppm)	2 mg/m³ (1 ppm)	
Benzo(a)pyrene in certain mixtures of PAH	70 ng/m³	700 ng/m³	f
Benzene	0.2 mg/m³ (60 ppb)	1.9 mg/m³ (0.6 ppm)	
Epichlorohydrin	2.3 mg/m³ (0.6 ppm)	g	

2 List of substance-specific acceptance and tolerance values

The Committee on Hazardous Substances (AGS) in the Announcement 910 (BekGS 910), No. 3, has published substance-specific acceptable and tolerable concentrations for carcinogenic substances based on exposure-risk relationships. The list set out in Announcement 910 is continuously updated.

The most recent version can be found on the website of BAuA (Federal Institute for Occupational Safety and Health) (see also "Further Information").

Substances for which exposure-risk-relationships or – where possible – occupational exposure limits are to be derived, have been included in the work list to be dealt with by the Committee for Hazardous Substances (AGS – UA III) in the context of TRGS 900 and Announcement 910.

www.baua.de/dok/665090

Footnotes to the list set out in Announcement 910 (Status as of July 2012)

- *a* The reasons for the definition of substancespecific concentration values and exposure-riskrelationships are published on www.baua.de/dok/3437502
- b The Technical Rules TRGS 519 "Asbestos: Demolition, Reconstruction or Maintenance Work" and TRGS 517 "Activities involving mineral raw materials potentially containing asbestos and preparations and products manufactured thereof" specify the necessary measures to protect employees and other persons engaged in activities involving asbestos and asbestos-containing hazardous substances in accordance with the concept of risk control measures set out in Annex 1 No. 5.2 of Announcement 910
- c According to the state of the art, a level below the acceptable value is possible. See also Annex
 1 No. 5.2 below, in particular the prohibition of deterioration in the case where measures are already in place.

- d Based on the exposure-risk-relationship for acrylamide, a concentration value of 0.7 mg/m³ corresponds to the tolerable risk. However, this concentration has not been defined as tolerable value in accordance with the Announcement 910 as chronic non-carcinogenic health hazards cannot be excluded. In cases where a workplace concentration of 0.15 mg/m³ is exceeded, the measures to be taken in accordance with the Hazardous Substances Ordinance are the same as in the case where an occupational exposure limit is exceeded. In the case of workplace concentrations between 0.07 mg/m³ and 0.15 mg/m^3 , the measures to be taken are those described for the area of medium risk in the graduated concept of risk control measures (range of measures) set out in the Announcement 917.
- e When applying this risk-exposure-relationship, the existing uncertainty in scientific derivation must be taken into consideration. TRGS 558 "Activities involving high-temperature wool" describes the necessary measures to protect employees and other persons in accordance with the concept of risk control measures set out in Annex 1, No. 5.2 of Announcement 910.
- *f* Benzo(a)pyrene serves an indicative component for assessment

The derivation of the acceptable and tolerable concentrations was based on data for activities i.a. in the following industrial sectors: coking plants, coal gasification, coal liquefaction, aluminium production, iron and steel foundries, production of graphite and carbon electrodes, tar distilling and processing, wood impregnation, chimney sweeping.

g Based on the exposure-risk-relationship for acrylamide, a concentration value of 23 mg/m³ (6 ppm) corresponds to the tolerable risk. However, this concentration has not been defined as tolerable value in accordance with the Announcement 910 as chronic non-carcinogenic health hazards cannot be excluded. In cases where a workplace concentration of 8 mg/m³ (2 ppm) is exceeded (exceedance factor: 2), the measures to be taken in accordance with the Hazardous Substances Ordinance are the same as in the case where an occupational exposure limit is exceeded. In the case of workplace concentrations of between 2.3 mg/m3 and 8 mg/m^3 , the measures to be taken are those described for the area of medium risk in the graduated concept of risk control measures (range of measures) set out in the Announcement 917.

3 Further information

For further information on the status of AGS rules concerning the risk concept, substance-related data or on the development and implementation of the concept, please find below a list of easily accessible sources. Many of these sources are available for download from the websites of BAuA or DGUV.

On the website of BAuA, you will find a number of documents including AGS rules in their latest version, project reports and technical papers on this subject. DGUV makes available, among other things, a fact sheet for every substance referred to in the Announcement 910 (BekGS 910) and a number of links to articles published in the expert journal "Gefahrstoffe – Reinhaltung der Luft".

Rules and documents established by the Committee on Hazardous Substances (AGS)

Announcement 910 on Hazardous Substances – Risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances

The Announcement contains the resolution adopted by AGS on the establishment of general risk limits for activities involving carcinogenic hazardous substances, as well as substance-specific acceptable and tolerable values for a number of substances.

Annex 1 sets out the justification of general risk limits and the graduated concept of risk control measures based on the amount of risk present.

Annex 2 contains the Guide for the Quantification of Cancer Risk Figures to be used for the establishment of exposure-risk-relationships by means of a standard methodology.

www.baua.de/dok/665090

The following information is available in German language only.

Announcement 911 on Hazardous Substances: Questions and answers about the risk concept in accordance with Announcement 910 Announcement 911 is a catalogue of questions and answers explaining the principle and concepts for users in a practice-oriented manner. www.baua.de/dok/2766574

Exposure-risk-relationships adopted by the Committee on Hazardous Substances

This graph (BAuA) gives a comparative illustration of exposure-risk-relationships for the substances covered by Announcement 910 (BekGS 910). In addition to the substance-specific concentrations, the graph also indicates the position of the so-called "threshold values analogous to OEL". www.baua.de/dok/1941662

Renn, O. with the participation of the AGS project group on risk acceptance

Akzeptabilität von Gesundheitsrisiken am Arbeitsplatz – Ein neues Konzept zur Bewertung von Risiken durch krebserzeugende Stoffe (2010) www.baua.de/dok/1134144

Substance-related information

Fact sheets for substances containing acceptable and tolerable concentrations

www.dguv.de/ifa/de/fac/erb/stoffliste/index.jsp

Technical papers and project reports

Länderausschuss für Arbeitsschutz und Sicherheitstechnik (LASI) Handlungsanleitung für die Umsetzung der Bekanntmachung 910 (BekGS 910) http://lasi.osha.de/docs/lv55.pdf

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Wann wird ein Krebsrisiko als Gefahr bewertet? Vortrag anläßlich der 28. Umweltrechtlichen Fachtagung der Gesellschaft für Umweltrecht im November 2004 in Leipzig www.baua.de/dok/676788

Imprint

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