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Technical Rules for Hazardous Sub- stances	Risk Assessment for Activities involving Hazardous Substances	TRGS 400
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The Technical Rules for Hazardous Substances (TRGS) reflect the state of technology, occupational safety and health and occupational hygiene as well as other sound work-scientific knowledge relating to activities involving hazardous substances including their classification and labelling. The

Committee on Hazardous Substances (AGS)

compiles or adapts the rules and they are announced by the Federal Ministry of Labour and Social Affairs (BMAS) in the Joint Ministerial Gazette (GMBI).

The TRGS concretizes within its scope the requirements of the Hazardous Substances Ordinance (GefStoffV). Provided the Technical Rules are complied with, the employer may assume that the relevant requirements of the Ordinance have been met. If the employer chooses a different solution, he must at least attain the same degree of safety and health protection for the workers.

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1 Scope

(1) TRGS 400 describes procedures for gathering information and the risk assessment according to Article 6 GefStoffV. It incorporates the specifications of the German Hazardous Substances Ordinance within the framework specified by the German Occupational Safety and Health Act (Articles 5 and 6 ArbSchG).

(2) TRGS 400 is supplemented in particular by

1. TRGS 401 "Risks resulting from skin contact – identification, assessment, measures",
2. TRGS 402 "Identification and assessment of the risks from activities involving hazardous substances: inhalation exposure,
3. TRGS 800 "Fire Protection Measures" and
4. TRGS/TRBA 406 "Sensitising substances for the respiratory system"

(3) TRGS 400 makes it possible to conduct a simplified procedure for the risk assessment when measures are specified as a standardised working procedure for activities involving hazardous substances. Standardised working procedures are present if

1. process- and substance-specific criteria (VSK) according to TRGS 420 "Process- and substance-related criteria (VSK) for the risk assessment" are described,
2. substance- and activity-related TRGS have been drawn up,
3. sector- or activity-specific aids are available,
4. a provided risk assessment of the manufacturer or the legal entity responsible for placing on the market according to Article 6 GefStoffV is available,
5. an exposure scenario based on a Chemical Safety Report pursuant to Article 14 or 37 of Regulation (EC) 1907/2006 (in the following "REACH Regulation") is available in the extended Safety Data Sheet of the manufacturer or legal entity responsible for placing on the market.

For the application of standardised working procedures see Number 5.

(4) Under Article 2 GefStoffV TRGS 400 must also be observed by entrepreneurs without employees who perform activities involving hazardous substances so that measures required under the Hazardous Substances Ordinance to protect third parties can be laid down. In addition it is recommended to entrepreneurs without employees that they also take measures based on this TRGS to ensure their personal safety and protect their health.

(5) This TRGS refers both to the hazard classes and hazard statements (H phrases) according to Regulation (EC) 1272/2008 (Regulation on classification, labelling and packaging of substances and mixtures, in the following "CLP Regulation") and to the symbols and indications of danger and R phrases according to Directive 67/548/EEC (Dangerous Substances Directive) or Regulation 1999/45/EEC ("Dangerous Preparations Directive"). In the review period the terms "preparation" (according to the Dangerous Preparations Directive) and mixture (according to the CLP Regulation) are used synonymously.

2 Definitions

In the present TRGS the terms are used as defined in the "Begriffsglossar zu den Regelwerken der Betriebssicherheitsverordnung (BetrSichV), Biostoffverordnung (BioStoffV) und der Gefahrstoffverordnung (GefStoffV)"¹ ("Glossary of terms for the regulations of the Plant Safety Ordinance (BetrSichV), Biological Agents Ordinance (BioStoffV) and the Hazardous Substances Ordinance (GefStoffV)") of ABAS, ABS and AGS. This applies in particular with respect to the terms: working conditions, agent, sector- and activity specific aids, chemical agents, exposure, knowledgeable person for the performance of the risk assessment, risk, risk assessment, hazardous substances list, skin contact, provided risk assessment, physicochemical action, protective measures, effectiveness of the protective measures.

3 Principles for the conduct of the risk assessment

3.1 Organisation and responsibility

(1) The risk assessment is the systematic identification and evaluation of relevant risks to workers aimed at establishing the measures required to ensure safety and health at work. The basis is an assessment of the inhalative (breathing-related), dermal (skin-contact-related) and physicochemical hazards (fire and explosion risks) and other risks due to hazardous substances.

(2) The employer may only commence an activity involving hazardous substances after a risk assessment has been conducted and the requisite protective measures have been taken. A proposal for a systematic procedure is shown in Annex 1.

(3) The risk assessment must be conducted at regular intervals or for a reason given and must be updated, if necessary. Reasons given for this may be:

1. The introduction of new hazardous substances in working areas,
2. Modifications to activities or conditions at the workplace (quantities, working procedures or protective measures, ventilation circumstances),
3. Results from the regular effectiveness check of protective measures according to Number 7,
4. Knowledge gained from occupational health care,
5. Modification of the occupational exposure limits, biological limit values or assessment criteria according e.g. to TRGS 900 "Occupational exposure limits", TRGS 903 "Biological limit values" or Announcement on Hazardous Substances 910 "Risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances",
6. New knowledge gained on the properties of hazardous substances (e.g. labeling and classification, safety data sheet, TRGS 905 "List of carcinogenic, muta-

¹ www.baua.de/nn_57220/de/Themen-von-A-Z/Gefahrstoffe/Glossar/Begriffsglossar.pdf

genic or toxic-to-reproduction substances", TRGS 906 "List of carcinogenic activities or procedures" and TRGS 907 "List of sensitising substances"),

7. Amendments to statutory requirements (e.g. to Ordinances such as GefStoffV, ArbMedVV and to technical regulations),

(4) The risk assessment must also embrace activities during the operating states such as maintenance, cleaning and repair work, start-up and shut-down operations of processes as well as rectification of operational disturbances. If necessary, a separate risk assessment is required for these activities.

(5) The change of the classification according to CLP Regulation has no effects on the protective measures of the risk assessment. The safety data sheet indicates under section 2 (hazard identification) until 1st June 2012 the classification according to old and new law. This ensures that during the transitional period the risk assessment can still be performed on the basis of the old law (see Announcement on Hazardous Substances 408 "Application of the GefStoffV and TRGS upon entry into force of CLP Regulation"). It is left up to the employer where he takes account in the risk assessment of the classification and identification according to CLP Regulation before the expiry of the transitional periods.

(6) The overall responsibility for the risk assessment is always borne by the employer.

(7) The conduct of the risk assessment for activities involving hazardous substances demands knowledge

1. concerning the information sources mentioned under Number 4.1 which are required for the assessment,
2. concerning the hazardous substances used and their dangerous properties as given under Number 4.2,
3. concerning the activities conducted with the hazardous substances in the facility,
4. concerning the procedure for the assessment of inhalation, dermal and physicochemical risks under Numbers 5 and 6,
5. concerning substitution, technical, organisational and individual-related protective measures,
6. concerning the check of the effectiveness of protective measures under Number 7 and
7. concerning the documentation of the risk assessment under Number 8.

(8) The employer may delegate the conduct of the risk assessment to one or more knowledgeable persons or obtain knowledgeable advice. He must ensure that the persons working for him have the necessary knowledge. The employer must make available all documents and information required for the risk assessment.

(9) Knowledgeable persons according to Article 6 GefStoffV must be qualified for the performance of the risk assessment on the basis of a corresponding vocational training, professional experience or corresponding professional activity exercised in the recent past as well as on the basis of attendance at specific measures of further training. They must be able to assess the working conditions prior to commencement of the activity and evaluate or check the established protective measures during the

performance of the activities. The scope and depth of the necessary knowledge may differ in relation to the activity being assessed and does not have to be present in one single person. Knowledgeable persons can be in particular the specialist for occupational safety and health or the company doctor.

(10) Special requirements for the necessary knowledge and the requisite equipment may be required according to Article 7 GefStoffV for certain procedures for the assessment of inhalation exposure, and in particular for workplace measurements. These requirements are described in TRGS 402.

(11) If external companies are contracted to perform work in a facility and if there is a possibility of a reciprocal risk from activities involving hazardous substances, all employers (clients and contractors) must collaborate and consult in the conduct of the risk assessment (Article 15 GefStoffV).

3.2 Identical working conditions

(1) Basically the employer must conduct a risk assessment for all activities involving hazardous substances. Where the working conditions are identical it is sufficient to assess one workplace or activity (Article 5 (2) ArbSchG).

(2) Identical working conditions may be selected for activities (e.g. sampling operations) which are located together in one space or are spatially separated and they may cover one or more hazardous substances. The activities must be comparable in terms of the risks, exposure conditions, working sequences, processes and ambient conditions.

(3) Activities where the risk is determined to a major degree by particularly dangerous properties or high exposure should not be assessed in general terms, but always individually. This also applies to activities which are not performed regularly, such as in the case of maintenance or repair work.

(4) The activities selected for the risk assessment as having identical working conditions must be evident from the documentation according to Number 8.

4 Information gathering

4.1 Information sources

(1) The employer shall first identify whether workers perform activities involving hazardous substances or whether hazardous substances arise or are released during such activities. For this purpose information must be obtained

1. on the chemical agents used,
2. on the activities,
3. on the possibilities of a substitution,
4. on possible and existing protective measures and their effectiveness and
5. on conclusions drawn from preventive medical examinations conducted.

(2) The most important information sources for the risk assessment concerning activities involving hazardous substances are the labelling of dangerous substances and preparations/mixtures, the safety data sheet and a possible information provided on standardised working procedures (see Number 5).

(3) The most important information for the risk assessment in the safety data sheet are

1. Identification of the dangerous substance or the preparation/mixture and of the company (supplier),
2. Relevant identified usages of the substance or the preparation/mixture and usages which are considered inadvisable,
3. Classification and labelling of the substance or mixture,
4. Dangerous ingredients of preparations, mixtures,
5. First-aid measures and fire-fighting measures,
6. Accidental release measures,
7. Information on safe handling and storage,
8. Limit values for occupational exposure, e.g. occupational exposure limits according to TRGS 900, biological limit values according to TRGS 903 as well as DNEL,
9. Information concerning limitation and monitoring of the exposure
10. Type and quality of the necessary personal protective equipment,
11. Physical and chemical properties,
12. Stability and reactivity,
13. Toxicological information, including references to dangerous properties not yet tested and
14. Exposure scenarios in the Annex.

Reference is made to the Announcement on Hazardous Substances 220 "Safety data sheet".

(4) The safety data sheet must be checked for obviously incomplete, contradictory or missing information, in particular in the sections: "possible hazards" "handling and storage", "exposure limitation and monitoring/personal protective equipment" and "regulations". If necessary the legal entity responsible for placing on the market must be requested to supply a correct safety data sheet and he must supply it. Safety data sheets are only automatically supplied retrospectively by the supplier during a year following the last delivery of the product and only in the case of a risk-relevant change. For the risk assessment a current version must be used. If the employer does not receive the requisite information, he must acquire this information himself or assume that the risks on which no information is available are present and must lay down the corresponding measures. As an alternative it is recommended that products be used for which the manufacturer supplies complete information.

(5) In the case of preparations/mixtures not labelled with hazard symbols and that are referenced with the indication "Safety data sheet available to professional users on request" or "EUH210 – Safety data sheet available on request", it must be ar-

ranged that the information is obtained. In addition, for substances and preparations/mixtures for which it is not mandatory under the statutory provisions to supply a safety data sheet, suppliers are obliged to send to recipients available and appropriate information which is necessary to identify and use suitable risk management measures.

- (6) The information accessible without problem to the employer encompasses:
1. Technical Rules for Hazardous Substances and Announcements on Hazardous Substances (www.baua.de >> Themen-von-A-Z >> Gefahrstoffe >>TRGS),
 2. information on the packing, instructions for use, technical factsheets which describe the knowledge gained from notification, risk evaluation or authorisation procedures,
 3. sector- and activity-specific aids (e.g. rules and information of the public accident insurance institutions, instructions for action regarding good working practice, control guidance sheets),
 4. sector-related hazardous substance and product evaluations of the public accident insurance institutions (e.g. GISBAU hazardous substances information system of the Berufsgenossenschaft in the construction industry, GisChem hazardous substances information system of the Berufsgenossenschaft for the raw materials and the chemical industry),
 5. substance information of the federal states and the public accident insurance institutions (e.g. the hazardous substances database of the federal states (GDL), GESTIS - substances database of the Institute for Occupational Safety and Health (IFA) of the German Social Accident Insurance (DGUV), information system for hazardous substances (IGS) of the state of North Rhine-Westphalia,
 6. easy-to-use workplace control scheme for hazardous substances (EMKG) of the Federal Institute for Occupational Safety and Health,
 7. classification and labelling inventory according to CLP Regulation.

4.2 Hazardous substances

(1) The criteria for deciding whether a chemical agent must be treated as a hazardous substance are described under Article 2 GefStoffV. The following paragraphs explain this definition.

(2) Substances and preparations/mixtures classified and labelled as dangerous by the manufacturer or legal entity responsible for placing on the market are hazardous substances. This also includes hazardous substances and preparations/preparations that are not labelled with hazard symbols or hazard pictogram, but can be assigned to one or more hazardous properties according to Article 3 GefStoffV, e.g. flammable substances and preparations marked with the R phrase 10.

(3) Substances and preparations/mixtures not classified as dangerous as well as articles from which during manufacture and use hazardous substances arise and are released are also hazardous substances. Examples are given in Para 10.

(4) Substances or preparations/mixtures or intermediates manufactured in-house that are not placed on the market must be classified by the employer himself. Until 1

June 2012 this can be done with the help of TRGS 200 "Classification and labelling of substances, preparations and articles". However, he may also already perform the classification according to the CLP Regulation. Substances not placed on the market for which the REACH Regulation provides a registration or notification must be classified according to CLP Regulation.

(5) Cosmetics, foodstuffs and food additives, animal feed and feed additives, medicinal products, medical products, tobacco products, waste products for disposal and used oils as well as effluent are normally not labelled as hazardous substances or mixtures, but are nevertheless hazardous substances if they possess dangerous properties within the meaning of the Hazardous Substances Ordinance. The hazardous substances also include constituents of plants and animals if they exhibit dangerous properties (e.g. sensitising according to TRGS 907).

(6) Hazardous substances are also all substances with occupational exposure limits (TRGS 900) or biological limit values (TRGS 903).

(7) Hazardous substances also include chemical agents not classified as dangerous but which may give rise to a risk for the safety and health of workers at work, e.g. due to

1. skin contact (see TRGS 401 "Risks resulting from skin contact – identification, assessment, measures"),
2. formation of a hazardous explosive atmosphere, e.g. due to combustible dust whirled up,
3. cryogenic or hot liquids, vapours and gases or
4. asphyxiating or anaesthetic gases.

(8) In the context of the risk assessment substances must be treated as hazardous substances if basic tests or evaluations of dangerous properties are not or only partly available:

1. test for acute toxicity,
2. test for skin irritation,
3. test for mutagenic potential,
4. test for skin sensitisation and
5. evaluation of toxicity in the case of repeated application (test or qualified evaluation).

It can be established with reference to the safety data sheet (section 11 "Toxicological data") whether the tests or evaluations have been carried out or this must be identified elsewhere, in particular by enquiring of the supplier.

(9) If it is not possible to gather information according to Para 8, in the risk assessment protective measures must be laid down for these substances on the basis of the property

1. toxic (R23, 24 or 25) or Acute Tox. 3 (H331, H311, H301),
2. irritating (R38) or Skin Irrit. 2 (H135),
3. mutagenic category 3 (R68) or Muta. 2 (H341) and

4. skin sensitisation (R43) or Skin Sens. 1 (H317)

This also applies to preparations/mixtures where the safety data sheet does not make any statements on the dangerous properties.

(10) New substances used in scientific laboratories or for scientific or product- and process-oriented research and development according to REACH Regulation Article 3 No. 22 must be treated in the risk assessment according to the specifications of TRGS 526 "Laboratories" if there is no knowledge available on the dangerous properties.

(11) Hazardous substances can also be dusts (including fumes, ultrafine particles), gases, vapours or mist released during activities. The following are examples of the release or development of hazardous substances:

1. welding fumes arising from a welding electrode,
2. wood dust released during grinding,
3. solvents released from cleaners,
4. silicogenic dust arising when drilling concrete ceilings,
5. clearance work in contaminated areas,
6. pyrolysis products arising during activities,
7. metal-cutting using cooling lubricants.

For the evaluation of these hazardous substances information sources according to Number 4.1 Para 6 may be referred to.

(12) If no information or only incomplete information is available on the dangerous properties of hazardous substances under Para 11, the employer must identify their dangerous properties at least with the help of the following information sources:

1. CLP Regulation, Annex VI with the substance lists of the legally classified substances in the current version,
2. TRGS 905,
3. TRGS 906,
4. TRGS 907,
5. TRGS 900,
6. TRGS 903,
7. Announcement on Hazardous Substances 910,
8. sources with new scientific knowledge, e.g. the current list of the senate commission of the DFG for the evaluation of agents which are harmful to health ("MAK list").

(13) If it is not possible to gather adequate information for the dusts (including fumes), gases, vapours or mist released during activities, at least the dangerous properties according to Para 9 must be assumed as present for the purpose of the risk assessment.

(14) If other persons are involved in decisions concerning the selection and use of agents, they should also be involved in the gathering of information. This applies among other things to

1. the use of construction products: architects, owners of buildings under construction and planners,
2. specified services in the automotive domain: car manufacturers,
3. clearance of contaminated areas: client,
4. use of disinfectants: client, health authorities.

Such involvement does not release the employer from his responsibility for the risk assessment.

(15) Alongside the classification the following substance-related information may be relevant to the risk assessment:

1. the release capacity of the hazardous substance (dust formation behaviour, vapour pressure, boiling point),
2. the skin-resorptive properties of hazardous substances (TRGS 900, TRGS 401, "MAK list"),
3. new, sound scientific knowledge of the dangerous properties of a hazardous substance which have not yet led to a change in classification in Annex VI of the CLP Regulation,
4. indications that toxicological or occupational health knowledge is lacking concerning major dangerous properties for the hazardous substance ("gaps in data"),
5. properties of non-classified hazardous substances which may nevertheless lead to a risk to the safety and health of workers at work (e.g. action as a catalyst in the emergence of a fire),
6. nuisance properties to be taken into account when establishing measures to be taken, e.g. major odour development,
7. existing contamination, e.g. information from the owner of the building under construction or the client where plots of land or buildings are being cleared,
8. information on physicochemical or safety characteristics, e.g. explosion limits, flashpoint, ignition temperature, maximum explosion pressure, pressure rise rate, burn-off rate, self-accelerating decomposition temperature (SADT), thermal stability (T_{onset}) decomposition temperature, self-ignition temperature, grain size distribution.
9. references to nanomaterials.

4.3 Activities

(1) During the activities all operations and operating states must be taken into account, in particular also start-up and shut-down operations of processes, re-start after extended standstill, cleaning, maintenance, repair, clearance and demolition jobs, storage, transport, disposal as well as the removal of foreseeable operational disturbances. Control and monitoring activities must also be taken into account where they may cause a risk to workers from hazardous substances at the workplace.

(2) The following information must be considered:

1. knowledge gained from an on-site inspection of the workplace and from the questioning of workers or the works or personnel council,
2. the processes, work equipment and working techniques used,
3. the quantity of the hazardous substances stored or used at the workplace,
4. the type, extent, duration and course of the exposure to hazardous substances due to inhalation or skin contact, where relevant also to unconscious oral intake with deficient hygiene,
5. existing protective measures,
 - a) technical protective equipment such as enclosure, source extraction, ventilation devices
 - b) organisational protective measures,
 - c) personal protective equipment such as respiratory protective equipment, chemical protective gloves, goggles and
6. possible disturbances to the operational sequence which may lead to increased exposure to hazardous substances.

(3) In addition further information may be required:

1. working environment and conditions, e.g. room size, ventilation conditions, temperature, relative humidity, noise, heavy physical labour, burdensome personal protective equipment,
2. possible visual impairment or slipping hazard due to aerosols,
3. sources of hazardous substances in the surrounding area with time and duration of a potential release,
4. probability of the formation of a dangerous explosive atmosphere (TRGS 720 "Hazardous explosive atmosphere – General" – TRGS 721 "Dangerous explosive atmosphere – Assessment of the risk of explosion") and
5. probability of the presence or emergence and developing effectiveness of ignition sources including electrostatic discharges.

(4) If during activities a number of hazardous substances arise simultaneously, the risk assessment must take account of interaction and combination effects known from the information sources in Number 4.1 and which influence the health and safety of workers at the workplace. The following are examples of known interaction and combination effects:

1. solvent mixtures which may lead to diseases of the nervous system (polyneuropathies, encephalopathies),
2. asbestos and polycyclic aromatic hydrocarbons (PAH) or smoking (reinforcement of the carcinogenic effect) or
3. substances such as certain solvents which enhance the absorption of other hazardous substances via the skin (carrier effect).

Interaction and combination effects may also involve physicochemical risks (see Number 6.5).

4.4 Information on substitution possibilities

The employer must identify whether substances or processes are available which have a lower health risk than those being used or are being considered for use (see Number 6 and TRGS 600 "Substitution").

4.5 Information on protective measures and their effectiveness

Account must be taken in the risk assessment of information on possible protective measures and knowledge gained from the check of the effectiveness of existing protective measures. This may be obtained from:

1. workplace measurements or other methods for the effectiveness check according to Number 7 (conducted in-house or published examples of comparable workplaces) or
2. records of accidents, disturbances to the operational sequence and "near-accidents" (in-house or known from relevant publications).

Further details can be found in TRGS 401, 402 and 500 "Protective measures".

4.6 Inferences from Occupational Medical Check-Ups

(1) Pursuant to Article 6 GefStoffV, findings from occupational medical check-ups must also be taken into consideration in the risk assessment; these findings can provide valuable evidence for determining the necessary measures and, if necessary, for reviewing the effectiveness of such measures within the framework of the risk assessment. Findings can be derived from:

1. evidence from the work of the occupational health officer implying an elevated exposure to hazardous substances;
2. evidence and results from any biomonitoring that has been carried out.

(2) Evidence and results from biomonitoring must be rendered anonymous and conveyed to the employer and included in the risk assessment with due regard to patient confidentiality.

(3) If a biological limit value according to TRGS 903 is exceeded, this can be an important indication of insufficient safeguards for activities involving hazardous substances. The biological limit value according to TRGS 903 can be exceeded even

though the occupational exposure limit according to TRGS 900 is complied with for activities involving a hazardous substance; this can indicate considerable dermal (or oral) exposures or work of a heavy nature.

4.7 List of hazardous substances

(1) A list must be kept of the hazardous substances identified. It should give an overview of the hazardous substances used in the plant and must refer to the related safety data sheets. If the risk assessment reveals that certain activities involving hazardous substances only give rise to a low risk for workers (see Number 6.2), these hazardous substances do not have to be included in the list of hazardous substances.

(2) The list must be kept up to date. It is advisable to break the list down in accordance with the company-specific organisational structure. The list of hazardous substances may be kept as a hardcopy or electronically.

(3) The list of hazardous substances must contain the following information:

1. Name of the hazardous substance (e.g. product or commercial name from the safety data sheet),
2. Labelling of the hazardous substance or information on the dangerous properties,
3. Information on the quantity band used in the company and
4. Working areas concerned.

The details under numbers 1, 2 and 4 as well as the safety data sheets must be accessible for all workers concerned and their representatives.

(4) It is recommended to include in the list of hazardous substances in addition the classification according to CLP Regulation (hazard class, hazard category and H phrases) during the transitional period (see Announcement on Hazardous Substances 408).

(5) The list of hazardous substances can constitute part of the documentation according to Number 8.

5 Risk assessment with specified measures (standardised working procedures)

5.1 Standardised working procedures

(1) The risk assessment can be simplified if standardised working procedures are available and can be transferred directly to the activity being assessed. Standardised working procedures can be:

1. substance- or activity-related TRGS,
2. process- and substance-specific criteria (VSK) according to TRGS 420,
3. sector- or activity-specific aids,

4. an exposure scenario on the basis of a chemical safety report supplied by the manufacturer or legal entity responsible for placing on the market according to REACH Regulation in the extended safety data sheet or
5. a provided risk assessment of the manufacturer or legal entity responsible for placing on the market according to Article 6 GefStoffV.

Standardised working procedures must be up-to-date, i.e. they must refer to the current version of the Occupational Safety and Health Act and the Hazardous Substances Ordinance.

- (2) In addition to the use of standardised working procedures the employer must do the following where necessary in his risk assessment
 1. take account of and supplement hazards due to particular operating states according to Number 4.3 (1) and
 2. consider further information available to him (e.g. results from occupational medical examinations, product quantity used, effectiveness of the protective measures taken).
- (3) The conduct of the risk assessment with standardised working procedures does not release the company concerned from the obligation
 1. to hold available current safety data sheets,
 2. to keep the list of hazardous substances and documentation of the risk assessment,
 3. to draw up operating instructions, to give courses of instruction and to provide consultations relating to occupational medicine/toxicology,
 4. to take the necessary precautions for accidents, incidents and emergencies,
 5. to take measures of occupational health care and
 6. to lay down and implement an effectiveness check according to Number 7.

Exceptions apply in the case of low-risk activities according to Number 6.2.

5.2 Application of a substance- or activity-related TRGS or a VSK

- (1) The employer can directly apply substance- or activity-related TRGS if the activities to be assessed are described there.
- (2) If substance- or activity-related specifications of a TRGS concerning risk assessment and protective measures are applied, the employer may assume in these points compliance with the specifications of the GefStoffV.
- (3) If process- and substance-specific criteria (VSK) on the basis of TRGS 420 have been published for certain activities involving hazardous substances, the employer may take over directly the measures described there without conducting any further checks. To check the effectiveness of the measures taken the specifications of the VSK must be applied; hazardous substance measurements to conduct the effectiveness check according to Number 7 are not necessary.

(4) If there is any deviation from the specifications of a TRGS, this must be justified and documented in the risk assessment. The measures taken must ensure the protection and safety of workers in a comparable fashion.

(5) For a series of chemical substances or groups of substances with dangerous physicochemical properties (e.g. explosive substances, organic peroxides (TRGS in preparation), combustion-enhancing substances, ammonium nitrate, gases in general, oxygen) and for certain hazard areas (e.g. dangerous explosive atmosphere), there are detailed specifications concerning protective measures in other sets of regulations, especially in the Technical Rules for Plant Safety (TRBS) and in the provisions of explosives law.

5.3 Application of a sector- or activity-specific aid, an exposure scenario according to REACH or a provided risk assessment

(1) Before the employer applies a sector- or activity-specific aid, a provided risk assessment or an exposure scenario according to REACH Regulation he must check whether

1. it contains a description of the use
2. his activities correspond to the specifications and stipulations of the standardised working procedures,
3. in the standardised working procedure, under the assumed application conditions, statements to the numbers 1 and 2, letters a to e of Annex 2 are answered with "yes" and
4. the protective measures stated are concrete.

(2) The employer must complete the risk assessment where necessary with undscribed operating states under Number 4.3 (1).

(3) If individual details according to Annex 2 letters a-j are missing, the employer must gather the missing information independently and must consider them in the establishment of measures to be taken.

(4) An exposure scenario according to REACH Regulation or a provided risk assessment is also suitable if reference is made to measures from a substance- or activity-related TRGS according to Number 5.2 or sector- or activity-specific aids. If authorised biocidal products and plant protection products are made use of, details of the manufacturer (labelling, instructions for use) must also be considered and can where relevant used as provided risk assessment.

(5) If the employer decides on the application of a standardised working procedure he must check as part of the risk assessment whether the specifications of the standardised working procedure have already been implemented with regard to the activity involving hazardous substances being assessed.

6 Risk assessment without specified measures

6.1 Procedure

(1) If, for activities involving hazardous substances, no measures have been specified by standardised working procedures according to Number 5 or if they are not applicable, they must be derived and established within the framework of the risk assessment. The basis is the assessment of the inhalation, dermal (skin contact) and physicochemical (fire and explosion hazards) risks involved in the activity and other such risks due to the hazardous substance, e.g. due to temperature and pressure.

(2) In the assessment of the risk, risks due to swallowing hazardous substances (oral intake) must be taken into account if it is not possible to discount this possibility with the activity being assessed. This may be the case, for example, when the face is touched with dirty hands or with protective gloves. Account must also be taken of a possible contamination of food eaten in the breaks and of work equipment used due to inadequate hygiene.

(3) The assessment of the risks is conducted on the basis of the information identified under Number 4 taking into account all intake routes stated in Para 1. It is the basis for laying down protective measures which must ensure the health and safety of workers in all activities involving hazardous substances.

(4) The assessment must be conducted and documented in such a way that the decisions taken are comprehensible.

6.2 Low-risk activities

(1) Low-risk activities are those where, owing to the hazardous properties assigned to the hazardous substance, to the working conditions, the use of only a small quantity of substance and a low exposure in terms of level and duration, it is sufficient to take measures according to Article 8 GefStoffV to protect the workers:

1. It is not possible in general to give a clear criterion for "small quantity" because to do this it would also be necessary to take account of the dangerous properties of the substance, the release capacity of the hazardous substance and the concrete activities.
2. For the assessment of level and duration of the exposure, the inhalation and dermal contributions must be considered. For example, in the case of solids, the inhalation exposure is normally low with low-emission use forms, such as pastes, waxes, granulates, pellets or master batches.

(2) Activities involving hazardous substances in confined spaces and containers are not low-risk activities.

(3) TRGS 401 can be referred to in the assessment of whether the conditions for low-risk activities are met with respect to dermal exposure. Under these specifications, in the case of hazardous substances bearing the symbol/pictogram "corrosive" (R34, R35 or H314) activities cannot be regarded as low-risk if it is not possible to exclude skin contact.

- (4) Examples of activities with a low-risk are:
1. Use of hazardous substances which the private end consumer can obtain in the self-service retail trade ("household products"), if they are used under conditions which are usual in domestic households (small quantity and short duration of exposure),
 2. Repair of minor damage to paintwork using touch-up applicators or
 3. Use and storage of quantities of adhesives usual in households,
 4. Titration with potassium chromate solutions.

6.3 Risk due to skin contact with hazardous substances (dermal risk)

- (1) Risk from skin contact is present if during wet work or activities involving skin-endangering or skin-resorptive substances it cannot be excluded that there will be a health risk to workers.
- (2) The procedure for assessing dermal risk in activities involving hazardous substances and for selecting suitable protective measures is described in TRGS 401
- (3) In the case of skin-resorptive hazardous substances for which a biological limit value (BLV) is published in TRGS 903, this one must be referred to as assessment criterion.

6.4 Risk due to the inhalation of hazardous substances (Inhalation exposure)

- (1) Risks due to the inhalation intake of substances can arise if dangerous substances in the form of gases, vapours or dusts in the air at the workplace are present in the respiration zone of the workers. The extent of the risk depends among other things on the toxic properties of the substances and is described by the concentration and duration of its occurrence (exposure). The employer must identify level and duration of the inhalation exposure.
- (2) Methods and procedures for assessing the inhalation risk in activities involving hazardous substances and for checking the effectiveness of protective measures by measurement-based ("workplace measurements") or non-measurement-based identification methods are described in TRGS 402 (e.g. transfer of the results to comparable activities or calculations). The identifications are concluded with a finding which includes a statement as to whether the protective measures taken are sufficient or not. The finding also contains provisions with regard to the methods and deadlines for checking the effectiveness of the protective measures.
- (3) There are various evaluation criteria for the assessment of risks due to inhalation exposure. The occupational exposure limits (OEL) published in TRGS 900 must be used as a matter of priority. They indicate at which concentration of a substance acute or chronic harmful effects to health are generally to be expected. Occupational exposure limits refer to a period of eight hours, although in addition exposure peaks with a fixed duration of short-time value phases must be considered.

- (4) If no OEL is available, the employer must on his own responsibility refer to other suitable assessment criteria. Number 5.3.2 of TRGS 402 contains a list of other suitable assessment criteria. These are:
1. Limit value proposals of the DFG (German Research Foundation) Senate Commission for the Investigation of Agents Harmful to Health,
 2. Indicative Occupational Exposure Limit Values according to Directive 98/24/EC,
 3. Limit value proposals for chemical exposures at the workplace from other scientific expert commissions (e.g. foreign limit values),
 4. "Derived no-effect-levels" (DNEL) according to REACH Regulation,
 5. Provisional target values which the employer himself lays down within the framework of his risk assessment.
- (5) For the assessment of activities involving carcinogenic hazardous substances the employer shall refer to the Announcement 910 drawn up by the AGS. It describes a concept with regard to the assessment of activities involving carcinogenic substances by means of exposure-risk relationships. For relevant carcinogenic substances, risk areas (green, yellow, red) are described via substance-specific acceptance and tolerance concentrations. A comparison of the exposure level to which the workers are exposed with the derived concentration values decides on the necessity and urgency of protective measures according to the graduated Workplace Control Scheme (see Number 6.6 (5)).
- (6) For hazardous substances which may lead to sensitisation when inhaled (e.g. labelling with R42/H334), TRBS/TRGS 406 gives instructions regarding the risk assessment and the stipulation of protective measures.

6.5 Physicochemical and other risks due to hazardous substances

- (1) In the assessment of physicochemical risks, fire and explosion hazards and other risks due to physicochemical properties of hazardous substances must be taken into account.
- (2) Fire and explosion hazards may arise, for example, as a result of
1. explosion-dangerous or explosive substances, preparations/mixtures and articles,
 2. combustible or inflammable gases, aerosols, solids and liquids (including water-mixable ones which are flammable). These include in particular extremely flammable, highly flammable or flammable substances or substances and mixtures labelled with the hazard pictogram GHS 02 "Flame"
 3. spontaneously flammable substances (pyrophoric and self-heatable substances),
 4. substances which develop extremely flammable gases in a dangerous quantity when in contact with water or moist air,
 5. whirled up combustible dust,
 6. substances with combustion-enhancing or oxidising properties,

7. chemically or thermally unstable substances (e.g. spontaneously decomposing substances and organic peroxides) or
8. dangerous exothermic reactions.

(3) Instructions regarding the assessment of fire hazard and the risk of dangerous explosive atmospheres and the appropriate protective measures are given in TRGS 800 "Fire Protection Measures" or TRBS 2151/TRGS 720, TRBS 2151 Part 1/TRGS 721 and TRBS 2152 Part 2/TRGS 722.

(4) Other risks due to hazardous substances may arise, for example during activities involving

1. asphyxiating or anaesthetising gases, especially when entering confined containers, fermentation cellars ("carbon dioxide lake"),
2. cryogenic or hot liquids, vapours and gases, e.g. molten metal, liquid nitrogen or
3. adhesives (e.g. adhesion of fingers due to superglue).

Account must also be taken of the possible increased intake of hazardous substances as a result of puncture wounds or cuts from contaminated pieces of equipment (e.g. needles or canullas in automatic laboratory devices). If necessary the risks must be assessed by a knowledgeable person on an individual basis with the help of the information given in Number 4.

6.6 Stipulation of protective measures

(1) The risk of safety and health to the workers must be excluded or reduced to a minimum. For this purpose the necessary protective measures must be laid down according to the result of the risk assessment. The basic obligations according to Article 7 GefStoffV do always apply; the general protective measures according to Article 8 GefStoffV must always be applied. Additional protective measures of Annex 1 of the GefStoffV must be observed if the hazardous substances described there are manufactured or used and the activities mentioned there are carried out. The basic obligations and general protective measures are described in greater detail in TRGS 500 "Protective measures" and TRGS 510 "Storage of hazardous substances".

(2) When laying down protective measures priority must be given to the substitution over technical and organisational measures and over the use of personal protective equipment (see TRGS 600).

(3) If the risk assessment indicates under Numbers 6.3 and 6.4 that the general protective measures are not sufficient, additional protective measures according to Article 9 GefStoffV must be laid down.

(4) For activities involving carcinogenic, mutagenic or toxic-to-reproduction hazardous substances of categories 1 or 2 or the categories 1A and 1B according to CLP Regulation the special protective measures according to Article 10 GefStoffV must be laid down if the occupational exposure limit (OEL) is not adhered to or work is not conducted according to process- and substance-specific criteria (VSK). For a series of carcinogenic hazardous substances there are concrete specifications in Technical Rules concerning the risk assessment and the establishment of measures to be taken.

(5) If for a carcinogenic substance an exposure-risk relationship has been established and published in Announcement on Hazardous Substances 910, preference should be given to measures selected with the help of the graduated Workplace Control Scheme of Announcement 910.

1. If the exposure is above the tolerance concentration, it must be assumed that there is a high risk. Risk reduction measures must be implemented without delay which lower the exposure at least to below the tolerance concentration; a plan of measures to be taken to reduce the exposure must be drawn up.
2. If the exposure for the activities being assessed is between the acceptance and tolerance concentrations it must be assumed that there is a moderate risk. Further measures must be taken to reduce the exposure. These also include in particular the drawing up of a plan of measures to be taken.
3. If the exposure for the activity being assessed is below the acceptance concentration it must be assumed that there is a low risk. No further additional protective measures are required under Articles 9 und 10 GefStoffV.

(6) In the case of activities involving hazardous substances which are not labelled or cannot be assigned to a hazardous property, but which still may present a risk for the health and safety of workers according to Number 6.5, those measures according Articles 7 to 9 and 11 GefStoffV must be taken which are needed to protect the workers.

(7) In the case of physicochemical risks, including those arising in activities involving hazardous substances where fire and explosion hazards may arise (see Number 6.5 (2)), supplementary protective measures according to Article 11 and Annex I No. 1 GefStoffV must be laid down to prevent fire and explosion hazards.

(8) The personal protective equipment must be checked for its suitability for the relevant hazardous substance and the activities. If no specific indications are given for the necessary personal protective equipment in the safety data sheet or other information sources, these must be identified by oneself, e.g. by enquiring of the manufacturer. More detailed instructions concerning protective gloves can be found in TRGS 401.

7 Check of the effectiveness of protective measures

(1) As a result of the risk assessment methods and deadlines for the check of the effectiveness of existing and future protective measures must be laid down. Principles for this are described comprehensively in Number 4.6 of TRGS 500.

(2) Technical protective measures, such as ventilation and extraction equipment, must be regularly checked with respect to their adequate functioning and effectiveness. For technical equipment intended to protect against inhalable dust a maximum deadline of one year applies under Annex I No. 2.3 Para 7 GefStoffV. Within these specifications (in the case of work equipment taking into account the Plant Safety Ordinance), the employer must lay down on his own responsibility the nature, scope and inspection intervals. The result of the inspection must be documented.

(3) The effectiveness of the personal protective equipment must also be checked.

(4) If the process- and substance-specific criteria (VSK) according to TRGS 420 are applied, the employer must apply the measures stipulated therein to check the effectiveness of the protective measures.

(5) If there is a finding according to TRGS 402 for an inhalation substance exposure, the methods described in TRGS 402 Number 5.2 for substances with a binding limit value or in Number 5.3 for substances without a binding limit value must be applied to check the effectiveness of the protective measures taken. The results must be recorded, kept and made available to the workers and their representatives.

(6) If the effectiveness check yields the result that the protective measures taken are not sufficiently effective, the risk assessment must be conducted again and additional measures must be taken. This also applies to the application of standardised working procedures according to Number 5.

8 Documentation

(1) For activities involving hazardous substances the employer must document the risk assessment according to Article 6 GefStoffV regardless of the number of workers employed. This documentation is part of the documentation according to Article 6 ArbSchG and must contain at least details of

1. the time at which the risk assessment was conducted and the persons conducting it or participating in it,
2. the working area and activities involving hazardous substances,
3. the inhalation, dermal or physicochemical risks arising at the workplace,
4. the frequency of the activities, the duration of exposure and additional exposure factors relevant to an increased intake of hazardous substances into the body (heavy physical work, high temperature, ...),
5. the technical, organisational and individual-related measures required to eliminate or reduce the risk and the effectiveness check of the technical measures,
6. additional measures taken if an occupational exposure limit is exceeded as well as further planned measures that are intended to comply with the occupational exposure limit in the future,
7. any deviations from the regulations and knowledge published in Article 20 GefStoffV,
8. identification results that prove that the occupational exposure limit is adhered to or – in the case without occupational limit value – the technical protective measures taken are effective,
9. the result of the substitution check according to TRGS 600,
10. justification for the waiver of technically possible substitution for activities involving substances for which supplementary protective measures according to Articles 9 and 10 GefStoffV must be taken.

(2) Furthermore information on the substance quantities used in the activities may be appropriate. It is also recommended that the implementation and review intervals and the persons responsible for the implementation of the measures be documented.

- (3) If for activities involving carcinogenic hazardous substances the risk assessment is conducted on the basis of Announcement on Hazardous Substances 910 and the acceptance concentration is exceeded, a plan of measures according to the Announcement on Hazardous Substances 910 should be attached to the documentation. In the plan of measures to be taken it must be indicated in what periods and on the basis of what additional measures what extent of exposure reduction should be achieved.
- (4) The employer has a free hand with respect to the form of the documentation. Existing documents can also be used which give the aforementioned information. The documentation can also be conducted in electronic form. Existing operational documents can also be used as a constituent part, e.g. the list of hazardous substances, measuring records for workplace measurements, operational and manufacturing regulations, operating instructions, confirmation of the course of instruction given.
- (5) A detailed documentation with all information according to Para 2 is not required if low-risk activities according to Number 6.2 are being conducted. In such cases the information under Para. 1 Nos. 3 to 10 can be dispensed with. It must be documented that a low risk was ascertained.
- (6) In the case of a risk assessment with specific measures (standardised working procedures) according to Number 5 the list of hazardous substances and existing documents are sufficient for the documentation provided these show the necessary information required under Para. 2.
- (7) It is recommended that the documentation of the risk assessment be kept for an extended period. In the case of activities involving carcinogenic, mutagenic or toxic-to-reproduction hazardous substances of categories 1 or 2 or 1A and 1B according to CLP Regulation, records of the duration and level of exposure which workers experienced during activities involving these substances, must be kept 40 years (Article 14 (3) No. 4 GefStoffV).
- (8) It should be pointed out that safety data sheets according to REACH Regulation Art. 36 (1) in combination with Art. 35 must also be held available at the users (downstream users) for at least ten years after the last use of the substances or preparations/mixtures.

Literature

EU Regulations and Directives, German Acts and Ordinances

- [1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) and amendments
- [2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) and ATP regulations
- [3] Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and

labelling of dangerous substances of 27 June 1967 (Dangerous Substances Directive (EC Official Journal No. L 196 S. 1) and amending or ATP Directives

- [4] Directive 1999/45/EC of the European Parliament and the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Dangerous Preparations Directive) (OJ L 200 of 30.7.1999, P. 1) and amending or ATP Directives
- [5] Act on the performance of occupational safety and health measures to improve the safety and health protection of workers at work (Occupational Safety and Health Act – ArbSchG) of 7 August 1996 (BGBl. I P. 1246)
- [6] Ordinance on safety and health protection in the provision of work equipment and its use at work, on safety in the operation of plants subject to mandatory inspection and on the organisation of corporate occupational safety and health (Plant Safety Ordinance – BetrSichV) of 27 September 2002 (BGBl. I P. 3777)
- [7] Ordinance on safety and health protection at work involving biological agents (Biological Agents Ordinance – BioStoffV) of 27 January 1999 (BGBl. I P. 50)
- [8] Ordinance on the protection against hazardous substances (Hazardous Substances Ordinance – GefStoffV) of 26 November 2010 (BGBL. 1 p. 1643)
- [9] Ordinance on Occupational Health Care (ArbMedVV) of 18 December 2008 (BGBl. I p. 2768)

Technical Rules, Announcements on Hazardous Substances (BekGS)

where not yet mentioned (see http://www.baua.de/cln_137/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS.html)

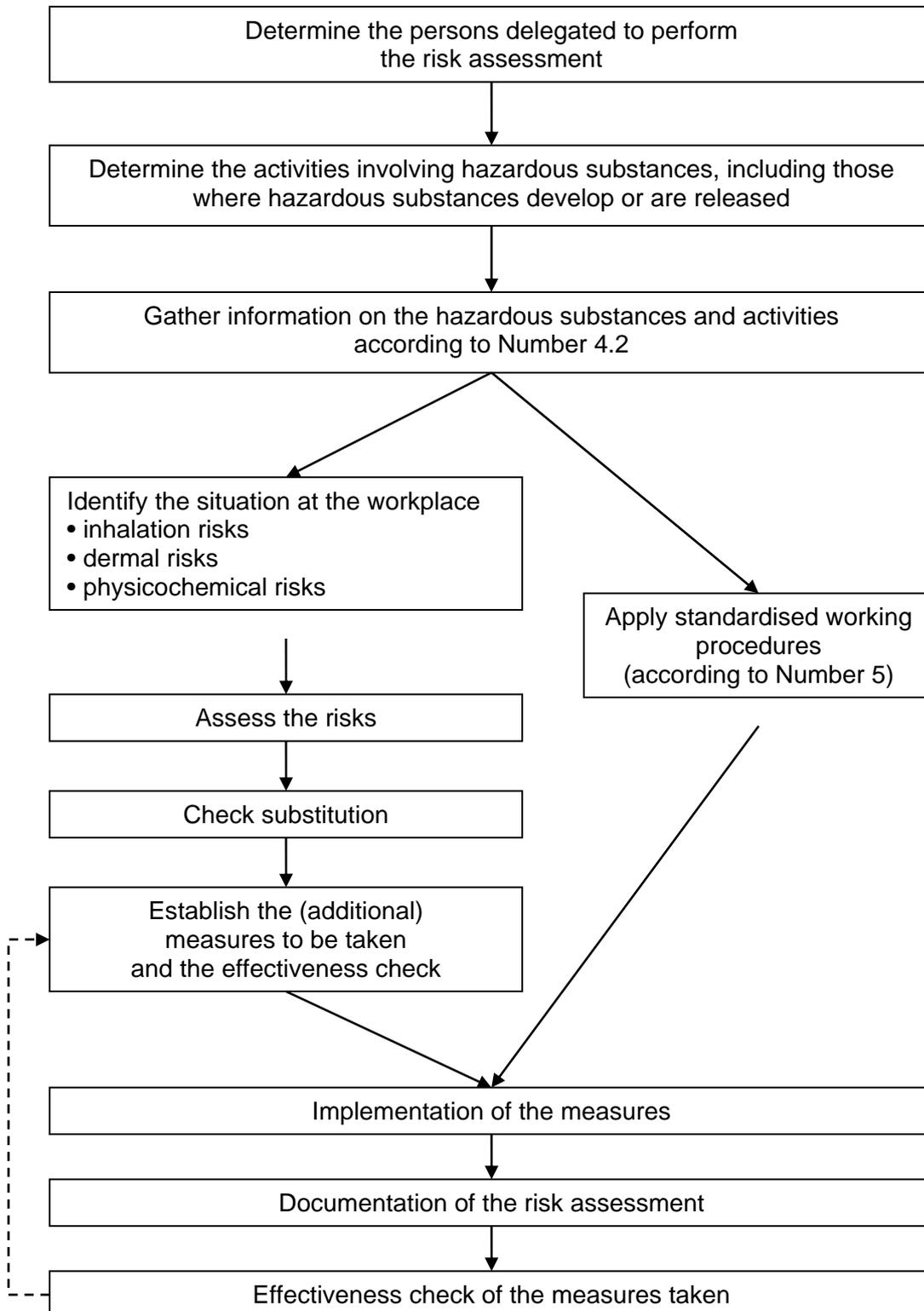
- [1] TRGS 201 “Labelling for activities involving hazardous substances” (in preparation)
- [2] BekGS 220 “Safety data sheet”
- [3] BekGS 408 “Application of GefStoffV and TRGS upon entry into force of CLP”
- [4] BekGS 409 “Use of the REACH information for occupational safety and health”
- [5] TRGS 710 “Biomonitoring”

Miscellaneous

- [1] Lists of maximum workplace concentration values (MAK) and biological tolerance values for the workplace (BAT), Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area of the German Research Foundation DFG, Wiley-VCH-Verlag
- [2] Easy-to-use workplace control scheme for hazardous substances (EMKG), Federal Institute for Occupational Safety and Health (BAuA) (<http://www.baua.de/emkg>)

- [3] GESTIS – hazardous substances information system of the German Social Accident Insurance (<http://www.dguv.de/ifa/de/gestis/stoffdb/index.jsp#>)
- [4] GISBAU – hazardous substances information system of the Berufsgenossenschaft in the construction industry (<http://www.gisbau.de>)
- [5] GisChem – hazardous substances information system of the BG RCI (*Berufsgenossenschaft for raw materials and the chemical industry*) (<http://www.gischem.de/>)
- [6] Hazardous substances database of the Federal States (GDL, <http://www.gefahrstoff-info.de>)
- [7] Information system for hazardous substances (IGS) of the State Authority for Nature, Environment and Consumer Protection of North Rhine-Westphalia (LANUV) (http://www.lanuv.nrw.de/stoffdaten/stoffdaten_2.htm)

Annex 1 to TRGS 400

Proposal for a procedure to be followed in the risk assessment for activities involving hazardous substances

Annex 2 to TRGS 400

Checklist for the application of standardised working procedures according to Number 5.3

Numbers 1 and 2 letters a to e must all have been answered with "yes" in order to be able to apply the standardised working procedure. For any other numbers which may have been answered with "no" the employer must independently gather information according to Number 4 of this TRGS and take it into account when laying down the protective measures.

A checklist expanded to include the column "Chapter in SDS or ES" can be found in Annex 2 of Announcement on Hazardous Substances BekGS 409.

		yes	no	Remarks
1	Are activities conducted in accordance with the information and stipulations given by the manufacturer/legal entity responsible for placing on the market?			If no, an independent risk assessment must be conducted by the employer.
2	Does the standardised working procedure contain information on the following points:			
	a. dangerous properties of the substances or mixtures			Is information given on the classification and labelling of the product and the constituents? Are indications given as to whether risks can be expected which go beyond the labelling? Number 4.2 Para 7 of TRGS 400 applies accordingly. If there is a lack of checks or evaluations, are the dangerous properties assumed for the recommendation of protective measures Number 4.2 Para 8?
	b. occupational exposure limits (OEL) and biological limit values (BLV)			Are the limit values of TRGS 900 and 903 respectively given (safety data sheet)? For hazardous substances without OEL or BLV this point is not relevant.
	c. information from the manufacturer/legal entity responsible for placing on the market on health protection and safety			Is the safety data sheet available? Are details given of the framework conditions for the safe use of the product (e.g. concrete details of personal protective equipment, ventilation)? Remark: If there is a need to use protective gloves and no makes are specified, the employer must determine them himself.
	d. extent, nature and duration of exposure taking account of all exposure routes			Are the inhalation exposure at the workplace and, where relevant, the skin exposure described?
	e. physicochemical effects			Is information available on the flash point and, where relevant, explosion limit values etc.?
	f. working conditions and procedures including work equipment and quan-			Are concrete details given of the working conditions and the process in which the product is

	yes	no	Remarks
tity of the hazardous substance			used? Where relevant, the employer must add information on, for example, the quantity of product used.
g. possibilities of substitution			Are details given of why no harmless or less dangerous products or processes can be used? If this is not the case, the employer must himself check possibilities for substitution.
h. effectiveness of the protective measures taken or to be taken			Is assistance provided in checking the effectiveness of the protective measures described (e.g. compliance with the limit values)? The effectiveness of the protective measures employed operationally must be checked by the employer.
i. conclusions drawn from occupational medical examinations conducted			Normally this information is not part of a standardised working procedure, but has to be identified independently by the employer (see Number 5.1).
³ Are all operating states according to Number 4.3 Para 1 considered?			Normally these are not contained in the standardised working procedures

SDS = Safety data sheet

ES = Exposure scenario in the extended safety data sheet