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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 definite scientific knowledge relating to activities involving hazardous substances including their classification and labelling. The

Committee on Hazardous Substances (AGS)

establishes the rules and adapt them to the current state of development accordingly. The TRGS rules are announced by the Federal Ministry of Labour and Social Affairs (BMAS) in the Joint Ministerial Gazette (GMBI).

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Annex 1: Proposal for a procedure to be followed in the risk assessment for activities involving hazardous substances

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1 Scope

(1) TRGS 400 describes procedures for gathering information and the risk assessment according to Section 7 GefStoffV. It incorporates the specifications of the German Hazardous Substances Ordinance (Gefahrstoffverordnung) within the framework specified by the German Occupational Safety and Health Act (Sections 5 and 6 ArbSchG).

(2) 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. This is the case if

1. a risk assessment is supplied by the manufacturer or the person placing the product on the market according to Section 7 Subs. 7 GefStoffV,
2. process- and substance-specific criteria (VSK) according to TRGS 420 are described,
3. substance- and activity-related TRGS have been drawn up, or
4. sector- or activity-specific aids are available whose quality corresponds to a risk assessment supplied with the product.

(3) TRGS 400 is supplemented in particular by

1. TRGS 401 "Risks resulting from skin contact – determination, assessment, measures" and
2. TRGS 402¹ "Determination and assessment of the risks from activities involving hazardous substances: inhalative exposure".

(4) Under Section 3 Subs. 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) Information requirements for the downstream users in the chain of responsibility according to the regulation (EC) 1907/2006 (REACH) are not considered in TRGS 400.

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)"² ("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, expert for the performance of the risk assessment, risk, risk assessment, hazardous substances index, skin contact, risk assessment supplied with the product, physicochemical action, protective measures, effectiveness of the protective measures.

¹ The references in this TRGS relate to the new version of TRGS 402, which is currently in preparation.

² www.baua.de/nn_57220/de/Themen-von-A-Z/Gefahrstoffe/Glossar/Begriffsglossar.pdf

3 Principles for the conduct of the risk assessment

3.1 Organisation and responsibility

(1) The risk assessment is the systematic determination 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 systematic procedure is shown in Annex 1.

(3) The risk assessment must be conducted anew if there are any major modifications to the activity. The reasons for this may be:

1. The introduction of new hazardous substances in working areas,
2. Modifications to activities, working procedures or protective measures,
3. New knowledge gained on the properties of hazardous substances (e.g. labelling, safety data sheet, TRGS 905 "List of carcinogenic, mutagenic or toxic-to-reproduction substances", TRGS 906 "List of carcinogenic activities or procedures according to Section 3 Subs. 2 No. 3 GefStoffV" and TRGS 907 "List of sensitising substances"),
4. Results from the regular effectiveness check of protective measures according to Number 7,
5. Amendments to the Hazardous Substances Ordinance and the technical regulations (e.g. establishment of occupational exposure limits in TRGS 900),
6. Knowledge gained from occupational health care.

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

(5) The employer may delegate the conduct of the risk assessment to one or more expert persons or obtain expert 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.

(6) Experts according to Section 7 Subs. 7 GefStoffV for the performance of the risk assessment are persons whose specialist training or experience give them adequate knowledge of activities involving hazardous substances and who are familiar with the regulations to the extent that they can assess the working conditions prior to commencement of the activity and can evaluate or check the protective measures specified for implementation during 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. If the employer does not himself have the relevant specialist knowledge, he must obtain advice from expert persons such as the company doctor and the specialist for occupational safety and health. The risk assessment for activities for which precautionary examinations according to annex V GefStoffV must be provided or arranged for requires special knowledge of occupational medicine (e.g. on biomonitoring, the metabolism, the effect and the deposition

of dangerous substance) which the employer does not normally have.

(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 inhalative, dermal and physico-chemical 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,
7. concerning the documentation of the risk assessment under Number 8.

(8) Special requirements for the necessary expertise and the requisite equipment may be required according to Section 9 Subs. 6 GefStoffV for certain procedures for the assessment of inhalative exposure, and in particular for workplace measurements. These requirements are described in TRGS 402.

(9) 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 (Section 17 GefStoffV).

3.2 Identical working conditions

(1) Basically the employer must conduct his own risk assessment for all activities involving hazardous substances. Where the working conditions are identical it is sufficient to assess one workplace or activity (Section 5 Subs. 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. Other risks, such as those arising from work equipment, biological agents or noise, should be taken into account within the meaning of the Occupational Safety and Health Act when establishing this. The activities must be comparable in terms of the risks, exposure conditions, working sequences 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 servicing or maintenance.

(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 determine 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 substitution (except for low-risk activities),
4. on possible and existing protective measures and their effectiveness,
5. on conclusions drawn from precautionary occupational medical examinations conducted.

(2) The most important information sources for the risk assessment concerning activities involving hazardous substances are the label identifying the hazardous substances and preparations, the safety data sheet and a possible risk assessment supplied with the product.

(3) The safety data sheet includes among other things details of:

1. the name of the dangerous substance, manufacturer or person placing it on the market,
2. dangerous constituents of preparations,
3. classification: dangerous properties and R phrases (section "Potential hazards"),
4. first-aid measures and fire-fighting,
5. measures to be taken in the case of unintentional release,
6. measures to be taken with respect to handling and storage,
7. occupational exposure limits according to TRGS 900, biological limit values according to TRGS 903 (section "Exposure limit and personal protective equipment"),
8. limitation and monitoring of exposure, e.g. references to TRGS or substance- or activity-related aids,
9. nature and quality of necessary personal protective equipment,
10. physical and chemical properties,
11. toxicological details, including references to dangerous properties not yet tested.
12. labelling under EC law and relevant protective regulations, including TRGS 905 (section "Regulations").

Reference should be made to the notice on hazardous substances 220 "Safety data sheet".

(4) The safety data sheet must be reviewed to establish any obviously incomplete or erroneous data, especially in the sections "potential hazards" "handling and storage", "exposure limitation and personal protection equipment" and "regulations". If necessary the person placing the product on the market must be asked to supply any information lacking 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 regarding 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 not bearing hazard symbols and whose label contains the indication "Safety data sheet available to professional users on request" it must be arranged that the information is obtained. In addition, for substances and preparations for which it is not mandatory under the statutory provisions to supply a safety data sheet, it may be demanded of the person placing them on the market that he supply the information itemised in Subs. 3, if such information is necessary for the risk assessment.

(6) The information accessible without problem to the employer encompasses:

1. Technical Rules for Hazardous Substances (overview at www.baua.de),
2. information on the packing, instructions for use, technical specifications which describe the knowledge gained from notification, risk assessment and 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, protection guidelines),
4. sector-related hazardous substance and product assessments 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 in 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), BGIA substances database (GESTIS), information system for hazardous substances (IGS) of the state of North Rhine-Westphalia,
6. simple measures concept for hazardous substances (EMKG) of the Federal Institute for Occupational Safety and Health.

4.2 Hazardous substances

(1) The criteria for deciding whether a chemical agent must be treated as a dangerous substance are described under Section 3 Subsection 3 of the Hazardous Substances Ordinance. The following paragraphs explain this definition.

(2) Substances and preparations classified by the manufacturer or person placing them on the market as dangerous are hazardous substances. This also includes chemical substances and preparations not bearing hazard symbols, but which may be assigned to one or more risk features according to Section 4 GefStoffV, e.g. flammable substances and preparations marked with the R phrase 10.

(3) Substance, preparations or intermediates manufactured by the employer himself must be classified by him with the help of TRGS 200.

(4) 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 marked as hazardous substances or preparations, 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).

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

(6) 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),
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.

(7) In the context of the risk assessment substances must be treated as hazardous substances if basic tests or assessments with respect to dangerous properties have not been performed, or only partly:

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

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

(8) If it is not possible to gather information according to Subsection 7, in the risk assessment protective measures must be laid down for these substances on the basis of the property

1. harmful to health (R20, 21 or 22),
2. skin irritant (R38),

3. suspected mutagenicity (R68) and
4. skin sensitisation (R43)

This also applies to preparations where the safety data sheet does not make any qualified statements on the dangerous properties (see notice 220 "Safety data sheet" Number 6.11 Para 9).

(9) New substances used in scientific laboratories or for scientific or product- and process-oriented research and development (according to Article 3 No. 22 of the Regulation (EC) 1907/2006) must be treated in the risk assessment, beyond the specifications of Para 8, as toxic hazardous substances if there is no knowledge available as to dangerous properties.

(10) Hazardous substances can also be dust (including fumes), gases, vapours or mist released during activities and which, for example, arise due to interaction with work equipment (TRBS 2210) or due to incidents and accidents. 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.

(11) If no information or only incomplete information is available on the dangerous properties of hazardous substances under Para 10, the employer must determine the constituents and their dangerous properties at least with the help of the following information sources:

1. List of hazardous substances classified as dangerous in Annex I of the Directive 67/548/EEC ("Legal classifications"),
2. TRGS 905 "List of carcinogenic, mutagenic or toxic-to-reproduction substances",
3. TRGS 906 "List of carcinogenic activities or processes according to Section 3 Subs. 2 No. 3 GefStoffV",
4. TRGS 907 "List of sensitising substances",
5. TRGS 900 "Occupational exposure limits",
6. TRGS 903 "Biological limit values",
7. sources with new scientific knowledge, e.g. the current list of the senate commission of the DFG for the assessment of agents which are harmful to health ("MAK list").

In addition the information sources according to Number 4.1 Para 6 should be referred to for the assessment. Often the manufacturer or supplier of chemical products or work equipment can provide support as part of his customer service.

(12) If it is not possible to determine adequate information for the dust (including fumes), gases, vapours or mist released during activities, at least the dangerous properties according to Para 8 must be assumed as present for the purpose of the risk assessment.

(13) If third parties 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.

(14) 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),
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 I of the Directive 67/548/EEC,
4. indications that toxicological or occupational medical knowledge is lacking concerning major dangerous properties for the hazardous substance ("gaps in data"),
5. properties of the hazardous substance which may lead to a risk to the safety and health of workers at work, but not to a classification (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.

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, cleaning, maintenance, repair, clearance and demolition jobs, storage, transport, disposal and possible operational malfunctions. 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/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 nature, extent, duration and course of the exposure to hazardous substances due to inhalation or skin contact, where relevant also to oral intake with deficient hygiene,
5. existing protective measures, e.g. technical protective equipment such as enclosure, source extraction, ventilation equipment, organisation protective measures, personal protective equipment such as respirator, chemical 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. sources of hazardous substances in the surrounding area with time and duration of a potential release (in the working area or from adjacent installations),
3. probability of the occurrence of hazardous substances which may lead to the danger of fire or explosion (TRGS 720, TRGS 721),
4. 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 on 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 determine whether substances or processes are available which have a lower health risk than those being considered (see Number 6 and TRGS 600 "Substitution"³).

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.

4.6 Conclusions from precautionary occupational medical examinations carried out

(1) In the case of activities for which precautionary examinations must be provided or arranged under Annex V GefStoffV, the examining doctor must be involved in the risk assessment. This is essential because, owing to the physician's confidentiality obligation, the employer does not have the knowledge and normally also not the expertise to draw conclusions from precautionary occupational medical examinations⁴.

4.7 List of hazardous substances

(1) A list must be kept of the hazardous substances determined. It should give an overview of the hazardous substances used in the plant and must refer to the related safety data sheets. Hazardous substances which only give rise to a low risk according to Number 6.2 do not have to be included in the list of hazardous substances.

³ Currently in preparation

⁴ A technical rule "Occupational Health Care" specifying these provisions more concretely is currently in preparation.

(2) The list must be kept up to date and must be made accessible to all workers concerned and their representatives with the reference to the safety data sheets. 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) If a safety data sheet is available the following information is sufficient in the list of hazardous substances:

1. Name of the hazardous substance (e.g. product or commercial name from the safety data sheet) and
2. Reference to the place where the safety data sheet is kept.

This also applies to hazardous substances not subject to mandatory labelling according to Number 4.2 Para 4 provided information of a safety data sheet is available in terms of extent and quality of the risk and protective measures. The information should be incorporated in the collection of data safety sheets.

(4) For hazardous substances without safety data sheet or comparable information it is recommended that the following information be included:

1. name of the hazardous substance and
2. indication of the dangerous properties of relevant constituents (health risk taking particular account of carcinogenic, mutagenic and toxic-to-reproduction properties (TRGS 905, TRGS 906) and of fire and explosion hazards).

(5) The minimum information in the list of hazardous substances is normally not sufficient for a risk assessment. It is therefore recommended that this be extended to include essential information such as

1. chemical agents used (regardless of the assessment as hazardous substance),
2. classification (dangerous properties, R phrases),
3. occupational exposure limits (OEL),
4. workplaces, areas or activities concerned,
5. Details of quantities of hazardous substances.

The list of hazardous substances can constitute part of the documentation under Number 8.

5 Risk assessments with specified measures (standardized working procedures)

5.1 Principles

(1) The risk assessment can be simplified if

1. a risk assessment is supplied by the manufacturer or person placing the product on the market,
2. a substance- or activity-specific TRGS has been published, and in particular

- process- and substance-specific criteria (VSK) according to TRGS 420 and
3. the specific measures or procedures can be found in a sector- or activity-specific aid according to Number 5.4.

These specifications are described as standardised working procedures and must be applicable directly to the activity being assessed.

(2) In the risk assessment a check must be made to establish whether the standardised working procedures are already being applied in the case of the activity involving hazardous substances which is being assessed. Otherwise the measures lacking must be laid down and implemented in accordance with the standardized working procedure prior to commencement of the activity.

(3) Application of the risk assessment with the standardised working procedure does not release the company concerned from the obligation

1. to keep the list of hazardous substances and to document the risk assessment,
2. to draw up operating instructions, to give courses of instruction and to provide consultations relating to occupational medicine/toxicology,
3. to take the necessary precautions for accidents, incidents and emergencies,
4. to take measures of occupational health care and
5. 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 Risk assessment supplied with the product

(1) Under Section 7 Subs. 7 GefStoffV the employer may take over risk assessments provided by the manufacturer or person placing the product on the market. Annex 2 includes a checklist to be applied to risk assessments thus provided.

(2) For a risk assessment supplied with the product under the Hazardous Substances Ordinance the following framework conditions apply:

1. it relates to a use described by the manufacturer or person placing the product on the market,
2. it is a voluntary service provided by the manufacturer or person placing the product on the market, including in terms of its nature and scope,
3. it contains references to information according to Number 4 which the employer must still determine independently for the risk assessment,
4. alongside the description of use it also contains statements relating to Number 2 letters a to e of Annex 2, giving the application conditions assumed and the related, concrete protective measures. Reference may be made here to sector- and activity-specific aids.

(3) A safety data sheet may be used as a risk assessment supplied with the product if the information given in it meets the specifications of Number 5.2 here and of Annex 2. This also applies with respect to a relevant exposure scenario based on a substance safety assessment according to Article 14 or 37 of the Regulation (EC) 1907/2006 (REACH) from the manufacturer or importer of a chemical substance or a

preparation which is available, for example, as an annex to the safety data sheet. The requirement is also met if it is recommended in the safety sheet that measures from substance- or activity-specific TRGS according to Number 5.3 or from sector- or activity-specific aids according to Number 5.4 be taken, indicating the source. With the use of authorised biocidal products and insecticides, account must also be taken of additional manufacturer information (labelling, instructions for use).

- (4) If the employer takes over a risk assessment supplied with the product, he must
1. check whether his activity is conducted in accordance with the information and stipulations provided by the manufacturer or person placing the product on the market and
 2. take account of any other information he has to complete his risk assessment (e.g. results from precautionary occupational medical examinations, product quantity used, effectiveness of protective measures taken). The specifications concerning the gathering of information under Number 4 must be adhered to here (see also Annex 2).
- (5) When applying a risk assessment supplied with the product the employer will invariably remain responsible for the risk assessment relating to the respective activity.

5.3 Application of a substance- or activity-related TRGS

- (1) If substance- and 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 Hazardous Substances Ordinance.
- (2) If process- and substance-specific criteria (VSK) on the basis of TRGS 420 have been published for an activity 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, and hazardous substance measurements to conduct the effectiveness check according to Number 7 are not necessary.
- (3) If there is any deviation from the specifications of a TRGS, reasons for this must be given and it must be documented in the risk assessment. The measures taken must ensure the protection and safety of workers in a comparable fashion.
- (4) For a series of chemical substances or groups of substances with dangerous physicochemical properties (e.g. explosive substances, organic peroxides, 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.

5.4 Sector- or activity-specific aids

(1) Sector- or activity-specific aids may be referred to when assessing risks for activities involving hazardous substances. They must be up to date, i.e. they must relate to the applicable version of the Occupational Safety and Health Act and the Hazardous Substances Ordinance.

(2) Sector- or activity-specific aids may be applied like a risk assessment supplied with the product by the manufacturer or person placing the product on the market in accordance with Section 7 Subs. 7 GefStoffV provided they fulfil the specifications described under Number 5.2 and in Annex 2.

6 Risk assessment without specified measures

6.1 Procedure

(1) If, for an activity involving hazardous substances, no measures have been specified as standardised working procedures according to Number 5 or if they are not practicable, they must be drawn up and laid down within the framework of the risk assessment. The basis is the assessment of the inhalative, dermal and physico-chemical (fire and explosion hazards) risks involved in the activity and other such risks due to the hazardous substance.

(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 is the case, for example, when work is performed with protective gloves and the wearer absent-mindedly touches his own face with them. 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 with the help of the information determined under Number 4. 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 on the basis of it are comprehensible.

6.2 Low-risk activities

(1) Low-risk activities are those where, owing 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 Section 8 GefStoffV to protect the workers. If more extensive measures according to Sections 9 to 12 GefStoffV are necessary, the activities concerned are not low-risk.

(2) For a low-risk activity within the meaning of Section 7 of the Hazardous Substances Ordinance, the following conditions must be met:

1. The hazardous substance used is not classified as toxic, highly toxic or carcino-

genic, mutagenic or toxic to reproduction (categories 1 and 2). TRGS 905 and TRGS 906 must be observed here.

2. The quantity of substance used during the activity must be small. 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 activity. At the same time the exposure must be low in terms of levels and duration. Inhalative and dermal fractions must be considered. For example, in the case of solid substances the inhalative exposure is normally low with low-emission use forms, such as pastes, waxes, granulates, pellets or master batches.
- (3) Activities involving hazardous substances in confined spaces and containers are invariably not low-risk activities.
- (4) 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 "corrosive" (R34, R35) an activity cannot be regarded as low-risk if it is not possible to prevent skin contact.
- (5) The following are examples of low-risk activities:
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.
- (6) Even an activity does not fulfil all the conditions under Subs. 2, the risk assessment may still stipulate measures which are largely in accordance with Section 8 GefStoffV. In such cases, however, other organisational requirements have to be complied with, especially those concerning the keeping of a list of hazardous substances, documentation of the risk assessment and occupational health care.

6.3 Dermal risk (risk due to skin contact with hazardous substances)

The procedure for assessing dermal risk in activities involving hazardous substances and for selecting suitable protective measures is described in TRGS 401.

6.4 Inhalative risk (risk due to the inhalation of hazardous substances)

(1) Methods and procedures for assessing the inhalative risk in activities involving hazardous substances and for checking the effectiveness of protective measures by means of the measurement of hazardous substances and qualified exposure estimates are described in TRGS 402.

(2) In the case of hazardous substances for which TRGS 900 sets an occupational exposure limit (OEL), a comparison of the exposure level will determine the need for additional protective measures. The duration of the exposure must also be taken into account (e.g. short-duration conditions). To determine the exposure level reference may be made to results from workplace measurements for comparable activities and to qualified exposure estimates.

(3) If activities involving hazardous substances are being conducted for which no occupational exposure limit has been set in TRGS 900, suitable assessment criteria must be laid down for atmospheric load at the workplace. It may be necessary for this purpose to conduct calculations or workplace measurements (see TRGS 402).

(4) Special instructions regarding the risk assessment and the stipulation of protective measures for activities involving hazardous substances which may lead to sensitisation when inhaled (e.g. labelling with R42) are given in TRGS/TRBA 406.⁵

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 hazardous substances must be taken into account.

(2) Fire and explosion hazards may arise, for example, as a result of

1. explosive substances,
2. combustible gases, solids and liquids (including water-mixable ones which are flammable), in particular extremely flammable, highly flammable or flammable ones within the meaning of Section 4 Subsections 3 to 5 of the Hazardous Substances Ordinance,
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 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 dangerous explosive atmospheres and the appropriate protective measures are given in TRGS 720, 721 und a22.

(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"),

⁵ TRGS/TRBA 406 "Sensitising substances for the respiratory system" is currently in preparation.

2. cryogenic or hot liquids, vapours and gases, e.g. molten metal, liquid nitrogen,
3. skin-dyeing agents or
4. adhesives (e.g. adhesion of fingers due to superglue).

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

6.6 Stipulation of protective measures

(1) As a result of the risk assessment the requisite protective measures must be laid down. The principles for preventing risks according to Section 8 GefStoffV must always be applied regardless of the risk assessment. They are described in greater detail in TRGS 500.

(2) Sections 9 to 11 of the Hazardous Substances Ordinance describe the protective measures for eliminating or reducing the possible health risk due to hazardous substances. The classification and labelling of the hazardous substance indicate those protective measures which have to be checked when stipulating them within the framework of the risk assessment to protect against dermal and inhalative risks. The final stipulation of the concrete protective measure is a result of the risk assessment in a particular case. It is therefore expressly pointed out that the establishment of the "protection level" is only an auxiliary instrument for deriving suitable measures, but not the result of the risk assessment. Establishment of the protection levels is not mandatory.

(3) For hazardous substances labelled Xn (harmful to health), Xi (irritant) and C (corrosive) measures must be laid down according to Section 9 GefStoffV. This applies not only to activities involving a low risk according to Number 6.2. If the assessment reveals

1. for the dermal risk according to Number 6.3 (TRGS 401) a high risk, or
2. for the inhalative risk according to Number 6.4 (TRGS 402 and TRGS/TRBA 406) that the measures according to Section 9 GefStoffV are not sufficient,

additional measures must be stipulated, where relevant also measures according to Section 10 GefStoffV.

(4) For hazardous substances labelled T (toxic) and T+ (highly toxic) measures must be stipulated according to Sections 9 and 10 GefStoffV. Taking account of the specific circumstances of the individual plant, such as production process, plant engineering and product quality, a check should be made in particular as to whether substitution or the use of a closed system can be implemented (see TRGS 500, TRGS 600). If neither substitution nor a closed system are technical feasible, state-of-the-art technical measures must be taken to exclude the risk or, if this is not possible, to reduce it as far as possible.

(5) For carcinogenic, mutagenic or toxic-to-reproduction hazardous substances of categories 1 or 2 additional measures must be laid down according to Section 11

GefStoffV if the occupational exposure limit (OEL) is not complied with or the work performed does not meet process- and substance-specific criteria (VSK). For a series of carcinogenic hazardous substances, technical rules give concrete specifications for the risk assessment and for the stipulation of measures to be taken.

(6) When laying down protective measures consideration must be given to prioritising substitution over technical and organisational measures and over the application of personal protective equipment. This also applies if a combination of technical, organisational and personal measures is laid down. The protective measures must be state of the art.

(7) The personal protective equipment must be checked for its suitability for the relevant hazardous substance and the activity. If no specific makes are given for the necessary protective gloves in the safety data sheet or other information sources, these must be determined from the information available (material, layer thickness etc.). Further details can be found in TRGS 401.

(8) 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 Para 2), supplementary protective measures according to Section 12 and Annex III No. 1 GefStoffV must be laid down to prevent fire and explosion hazards.

(9) In the case of activities involving hazardous substances which are not labelled or cannot be assigned to a danger feature, but which still may present a risk for the health and safety of workers, those measures according Sections 8 to 10 and 12 GefStoffV must be taken which are needed to protect workers.

7 Stipulations for checking 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.

(2) Technical protective measures, such as ventilation and extraction equipment, must be regularly checked with respect to their adequate functioning and effectiveness. This must be done at least every third year. For technical equipment intended to protect against inhalable dust a maximum deadline of one year applies under Annex III No. 2.3 Para 7. 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) In the case of hazardous substances for which TRGS 900 sets an occupational exposure limit (OEL), the effectiveness of the protective measures taken must be verified by means of workplace measurements or equivalent assessment procedures (Section 9 GefStoffV) or equivalent verification methods (Section 10 GefStoffV). This is not required if process- and substance-specific criteria (VSK) according to TRGS 420 are applied.

(4) In the case of workplace measurements the airborne concentration of the hazardous substance being monitored is determined directly (see TRGS 402). Equivalent assessment procedures or verification methods make it possible to conduct an alternative effectiveness check with the help of

1. calculations of the concentration of the hazardous substance (qualified exposure estimation) or measurements which make it possible to conclude indirectly the dangerous substance load, e.g. with the help of lead components (see TRGS 402) or
2. technical and organisational inspection specifications which relate to the measures laid down (see TRGS 500).

(5) For activities involving hazardous substances for which there is no occupational exposure limit, the effectiveness of the protective measures taken can be verified by means of suitable assessment methods. Suitable assessment methods describe good working practice and the related (maximum) level of exposure. They also contain statements as to how the effectiveness of the protective measures taken can be checked. This also includes technical performance criteria which can be checked by effectiveness measurements, e.g. the testing of technically closed system parts, functional elements and activities according to TRGS 500.

(6) If no suitable assessment methods are available, a measurement is required with which the exposure can be assessed in combination with the measure taken. This may be a measurement of the hazardous substance, of substance groups or of lead components.

(7) If the effectiveness check yields the result that the protective measures taken are not sufficiently effective, additional measures must be taken and the risk assessment conducted again. 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 regardless of the number of workers employed.

(2) The documentation regarding activities involving hazardous substances must, as a constituent part of the documentation according to Section 6 ArbSchG, 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 inhalative, dermal or physicochemical risks arising at the workplace,
4. the frequency of the activities, the duration of exposure and additional load 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. the instruction given to the workers and
7. the result of the check of possibilities for substitution (see TRGS 600). If this check reveals for activities for which the supplementary protective measures must be taken under Section 10 GefStoffV, that substitution is not possible fol-

lowing the principle of reasonableness, the considerations on which the check was based must also be verifiably documented.

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

(3) 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.

(4) A detailed documentation is not required if low-risk activities according to Number 6.2 are being conducted. In such cases the information under Subs. 2 Nos. 3 to 7 can be dispensed with. It must be documented that a low risk was ascertained.

(5) A documentation of the protective level is not required.

(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 Subs. 2.

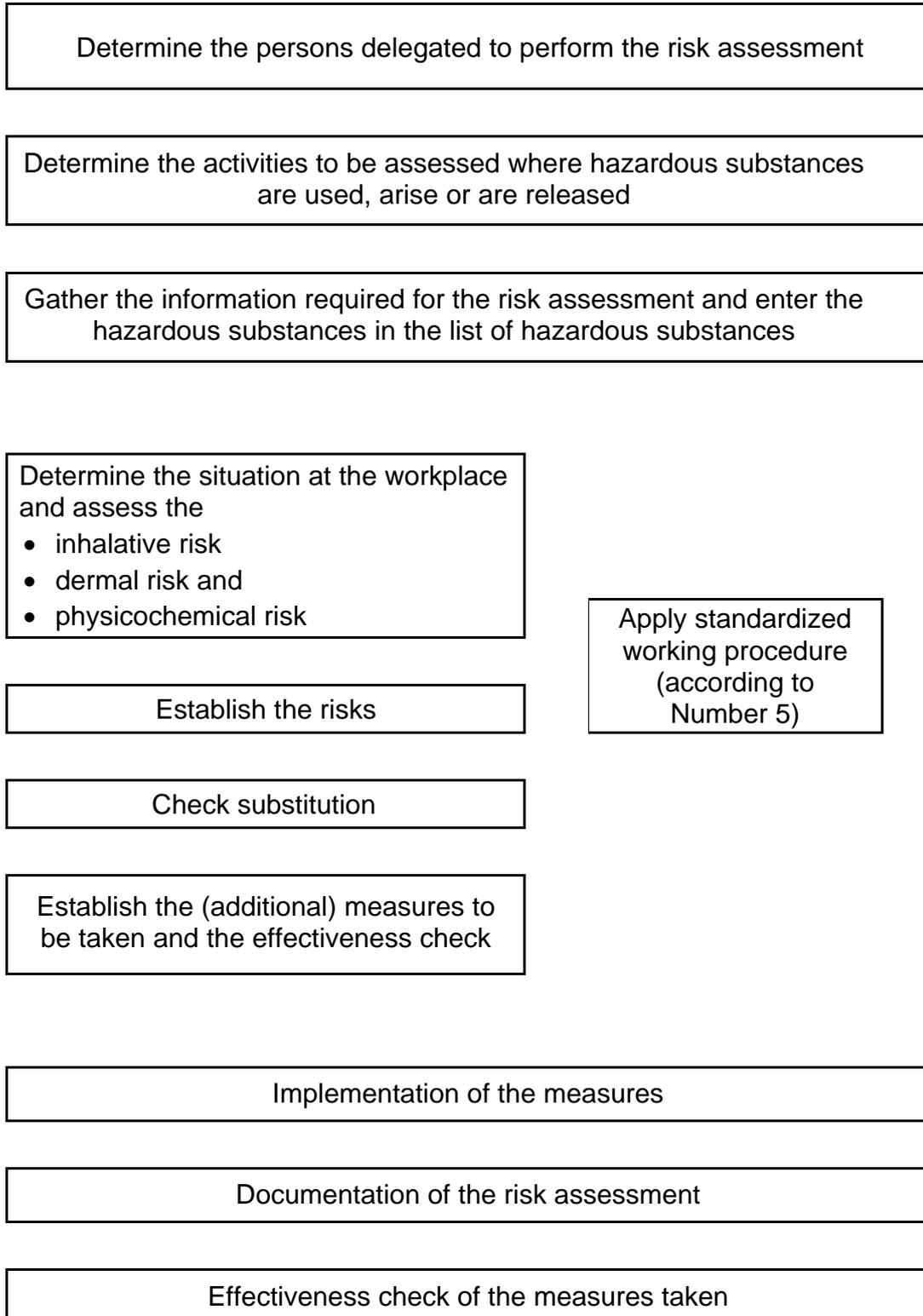
(7) It is recommended that the documentation of the risk assessment be kept for an extended period, especially in the case of activities involving carcinogenic, mutagenic or toxic-to-reproduction hazardous substances of categories 1 or 2.

(8) It should be pointed out that safety data sheets according to Regulation (EC) No. 1907/2006 (REACH) Art. 36 Section 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.

Annexes

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 risk assessment supplied with the product according to Section 7 Subs. 7 GefStoffV

Numbers 1 and 2 letters a to e must at least all have been answered with "yes" in order for the risk assessment supplied with the product to be applied as a standardised working procedure according to Number 5.2. 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.

	yes	no	Remarks
1 Are activities conducted in accordance with the information and stipulations given by the manufacturer/person placing the product on the market?			If no, an independent risk assessment must be conducted by the employer.
2 Does the risk assessment supplied with the product contain information on the following points:			
a. dangerous properties of the substances or preparations			Is information given on the classification and labelling (R/S phrases and danger symbol) 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 applies accordingly. If there is a lack of checks or assessments, 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/person placing the product 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 paths			Are the inhalative exposure at the workplace and, where relevant, the skin exposure described?
e. physicochemical effects			Are details given of the flash point and, where relevant, explosion limits etc.?
f. working conditions and procedures including the work equipment and the quantity of the hazardous substance			Are concrete details given of the working conditions and the process in which the product is used? Where relevant, the employer must add information on, for example, the quantity of product used.

	yes	no	Remarks
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 under the information and stipulations given in the risk assessment supplied with the product (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 health care examinations conducted			Normally this information is not part of the risk assessment supplied with the product, but has to be determined independently by the employer (see Number 4.7).