Version: June 2014 [*)]
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(not up-to-date and unofficial version; mandatory is the current German version)

Technical Rules for Hazardous Substances	Process- and substance-specific criteria (VSK) for identifying and assessing inhalation exposure	TRGS 420

The Technical Rules for Hazardous Substances (TRGS) reflect the state of the art, the state of occupational 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 the rules and adapts them in line with development. The technical rules are announced by the Federal Ministry of Labour and Social Affairs in the Joint Ministerial Gazette (GMBI).

These technical rules set out in concrete terms the requirements of the Hazardous Substances Ordinance within their scope of application. If the technical rules are adhered to, the employer can therefore assume that the corresponding requirements under the ordinance have been fulfilled. If the employer chooses another solution, that solution must achieve at least the same level of safety and health protection for employees.

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[*)] The new version includes, in particular, the following adaptations:
a) Adaptation of TRGS 420 to the wording of the Hazardous Substances Ordinance. Process- and substance-specific criteria must at least describe inhalation exposure (compliance with occupational exposure limits). In addition, statements on dermal and oral hazards, as well as fire and explosion hazards, can be included in process- and substance-specific criteria. These must be expressly referred to within the scope of application of the process- and substance-specific criteria.
b) In future, it will also be possible to have process- and substance-specific criteria for carcinogenic hazardous substances with acceptable and tolerable concentrations according to TRGS 910. The conditions are described for process- and substance-specific criteria with exposure levels “in both the green and the yellow region” (see number 2.4 of TRGS 420).
c) The period for reviewing process- and substance-specific criteria has been extended from 3 to 5 years.

1 Scope of application

(1) These technical rules apply to the compilation of “process- and substance-specific criteria” (VSK) according to specified criteria and describe the way in which process- and substance-specific criteria are to applied by the employer.

(2) Within the framework of the risk assessment, process- and substance-specific criteria provide the employer with practical specifications for defined activities involving hazardous substances. They include a description of suitable protective measures and specifications for checking their effectiveness, which ensure compliance with:

1. the occupational exposure limits according to TRGS 900 “Occupational exposure limits”; or
2. in the case of substances without an occupational exposure limit, the assessment criteria identified in the process- and substance-specific criteria according to number 5.3 (1) and number 5.4.2 of TRGS 402 “Identification and assessment of the risks from activities involving hazardous substances: inhalation exposure”.

(3) In addition to the specifications according to paragraph 2, process- and substance-specific criteria may also contain specifications for how employers can adhere to the requirements of the Hazardous Substances Ordinance with regard to dermal and oral or fire and explosion hazards.

(4) Proposals for process- and substance-specific criteria can be drawn up by, for example, manufacturers, companies, professional associations, the federal states or the accident insurance institutions and then submitted to the AGS for decision-making and/or publication by the Federal Ministry of Labour and Social Affairs.

(5) Requirements for the application of process- and substance-specific criteria by the employer can be found in number 3. The prerequisites and requirements for drawing up process- and substance-specific criteria can be found in number 4.

2 Explanations

2.1 General

(1) Process- and substance-specific criteria describe the state of the art, the state of occupational hygiene and the protective measures for defined activities involving hazardous substances, taking account of the nature, degree and duration of inhalation exposure.

(2) In addition, they may describe the necessary protective measures, the state of the art and the state of occupational hygiene for further uptake pathways (e.g. oral uptake or dermal hazards) that are significant for assessing exposure or for possible fire and explosion hazards. The additional handling of these hazards must be expressly referred to within the scope of application of the process- and substance-specific criteria.

(3) If the protective measures described in process- and substance-specific criteria are implemented, the inhalation exposure does not exceed designated assessment

criteria. The following are used as assessment criteria:

1. occupational exposure limits;
2. assessment criteria for carcinogenic hazardous substances that have been announced in TRGS 910 “Risk-related concept of measures for activities involving carcinogenic hazardous substances” pursuant to article 20 paragraph 4 of the Hazardous Substances Ordinance (see number 5.3 of TRGS 402 for more information on this); and,
3. in the case of hazardous substances without an OEL, other assessment criteria according to number 5.4.2 of TRGS 402, along with the justification for using them for the assessment.

(4) Future workplace measurements can be dispensed with if, within the framework of the risk assessment, the employer determines that the measures of the process- and substance-specific criteria have been implemented.

2.2 Process- and substance-specific criteria for hazardous substances with an occupational exposure limit

Application of process- and substance-specific criteria for hazardous substances with an occupational exposure limit (OEL) allows the employer to assume compliance with the OEL. Workplace measurements or other suitable investigative methods are therefore not usually necessary (article 7 paragraph 8 or article 10 paragraph 2 of the Hazardous Substances Ordinance).

2.3 Process- and substance-specific criteria for hazardous substances without an occupational exposure limit

Application of process- and substance-specific criteria for hazardous substances without an OEL pursuant to article 7 paragraph 9 of the Hazardous Substances Ordinance allows the employer to assume compliance with the requirements of the Hazardous Substances Ordinance for inhalation exposure with regard to the measures that are to be taken and the effectiveness check.

2.4 Process- and substance-specific criteria for category 1A or 1B carcinogenic hazardous substances without an occupational exposure limit

(1) Application of process- and substance-specific criteria for category 1A or 1B carcinogenic hazardous substances without an OEL allows the employer to assume compliance with the requirements of the Hazardous Substances Ordinance for inhalation exposure with regard to the measures that are to be taken and the effectiveness check provided the acceptable concentrations according to TRGS 910 are not exceeded. This relates in particular to regular workplace measurements and the further measures set out in article 10 paragraphs 2 to 4 of the Hazardous Substances Ordinance. The exposure level achieved by these measures is to be described in the process- and substance-specific criteria.

(2) Process- and substance-specific criteria for category 1A or 1B carcinogenic hazardous substances without an occupational exposure limit may be applied for the purpose of identifying exposure provided they ensure compliance with the tolerable concentration according to TRGS 910. In this case, the employer must additionally implement the measures pursuant to article 10 paragraphs 3 to 5 of the Hazardous Substances Ordinance, as well as examining further measures for minimising exposure and drawing up an action plan for ensuring that the acceptable concentration is not exceeded.

2.5 Process- and substance-specific criteria for mixtures of hazardous substances

In practice, several hazardous substances (with or without an occupational exposure limit) usually occur simultaneously in the workplace. If mixtures of substances are taken into account in the process- and substance-specific criteria, the employer can assume that the related requirements of the Hazardous Substances Ordinance for inhalation exposure are met with regard to the measures that are to be taken and the effectiveness check.

3 Applying process- and substance-specific criteria

(1) Within the framework of the risk assessment, the employer examines whether the activities described in the process- and substance-specific criteria are performed at its company and whether the specified process- and substance-specific conditions for these activities are observed and met. If the employer determines that the requirements of the process- and substance-specific criteria are met, it can apply the result in its risk assessment. The process- and substance-specific criteria are not applicable if the activities they describe are carried out with substances other than those stated.

(2) The employer must document the application of process- and substance-specific criteria within the framework of the risk assessment. The documentation must contain at least the following information:

1. the applied process- and substance-specific criteria;
2. a description of the hazardous substances, activities and procedures (e.g. type of exposure; spatial conditions; type, number and location of the workplaces, as well as of neighbouring workplaces; nature and location of the technical ventilation system; number of employees, incl. the duration of their exposure; type of personal protective equipment);
3. the timing and nature of the necessary effectiveness checks.

(3) The person applying process- and substance-specific criteria must check at least annually whether the requirements for its working area remain valid without change and document the result of this check. This applies in particular with regard to changes in procedures, as well as with regard to checking the effectiveness of the technical protection devices, whose perfect operation is a prerequisite for applying the process- and substance-specific criteria. The check also includes examining whether the process- and substance-specific criteria remain valid without change.

4 Drawing up process- and substance-specific criteria

4.1 General

(1) As a basis, drawing up process- and substance-specific criteria requires the presence of a representative description of activities and protective measures according to the state of the art, as well as data on the level of inhalation exposure according to number 4.2.

(2) Methods for checking the effectiveness are to be specified in process- and substance-specific criteria.

(3) When describing the activities and protective measures, the employer must take account of the requirement to reduce the risk to a minimum (article 9 paragraph 1 of the Hazardous Substances Ordinance), as well as the obligation to adhere to the order of the protective measures (article 7 paragraph 4 of the Hazardous Substances Ordinance).

(4) Where relevant, measures may additionally be described for avoiding a dermal hazard, fire and explosion hazards, or oral uptake. Reference is to be made to this within the scope of application of the process- and substance-specific criteria.

4.2 Requirements for inhalation exposure

4.2.1 Drawing up process- and substance-specific criteria based on workplace measurements

(1) The following requirements must be met:

1. a validated measurement method exists;
2. there are a sufficient number of representative workplace measurements for these working procedures/activities.

(2) The criteria are to be based on measurement results obtained in working areas according to the state of the art at normal capacity utilisation with regard to working and production conditions during different shifts and taking account of seasonal influences. Unfavourable conditions should also be taken into account in this process, e.g. start-up and shutdown processes, repair, maintenance and cleaning work, or high levels of capacity utilisation. In particular, account is also to be taken of exposure peaks and mixtures of substances.

(3) Reports on workplace measurements that have been taken should satisfy the requirements of annex 1 to TRGS 402. In this regard, particular account must be taken of precise details of the working and production conditions, including the system capacity and the degree to which this is utilised.

(4) No generally applicable rule can be drawn up for the minimum number of measurements required; rather, this must be specified on an individual basis depending on the validity and values of the measurement results, their distribution and the special technical conditions in the workplace. Findings are assessed using the 95^{th} percentile of the measured value distribution.

(5) For drawing up process- and substance-specific criteria, it is recommended to use at least 24 representative workplace measurements from as many companies as possible, taking three average shift values at each. A smaller number of measurement results may also be sufficient if the evaluation indices are low and the individual values are highly clustered, or if the working conditions exhibit little change in the long term. For example, 12 working area analyses from various companies with three average shift values from each will suffice if all measurement values are ≤ ½ • OEL.

(6) Fewer measurements may suffice if combined with other suitable investigative methods in accordance with number 4.2.2.

(7) If average shift values have been obtained based on a reduced exposure duration, then the measurement values relating to the exposure duration must be stated in addition to the measurement results. It may also be necessary to state the extent to which a reduced exposure duration is typical for the working procedure. Sufficient information must be present on compliance with the conditions associated with short-term values. In case of variations in the exposure conditions, the result must be sufficiently backed up by short-term measurements.

4.2.2 Drawing up process- and substance-specific criteria without workplace measurements

Depending on the individual case, the following are considered to be suitable investigative methods:

1. calculations of exposure using reliable models;
2. information on procedures that lead to a minimisation of the hazard in comparison with prior or other procedures;
3. information on procedures that are recognised to exhibit a high degree of safety in comparison with other procedures;
4. investigations carried out in practice or on test stands (model investigations), especially for the purpose of identifying procedures with a lower hazard level;
5. results relating to procedures that have shown themselves to be reliable and advanced in the opinion of the relevant expert circles.

If process- and substance-specific criteria are drawn up without workplace measurements, evidence is to be given of the validity of the investigative method in addition to the description of exposure.

4.3 Requirements relating to other hazards

(1) In addition to inhalation exposure, the following may also be considered when drawing up process- and substance-specific criteria:

1. dermal exposure in case of hazardous substances that are skin-resorptive or harmful or sensitising to skin (see TRGS 401 “Risks resulting from skin contact – identification, assessment, measures”);
2. other possible uptake pathways (e.g. oral uptake); and
3. fire and explosion hazards.

(2) If the fire and explosion hazards are taken into account in the process- and substance-specific criteria, an assessment is to be made in particular of the information required pursuant to article 6 paragraph 4 of the Hazardous Substances Ordinance, and the measures are to be described for meeting the requirements of article 11 of the Hazardous Substances Ordinance, taking account of the process- and substance-specific conditions.

4.4 Additional requirements

The AGS reviews process- and substance-specific criteria and adapts them to the state of the art at least every five years.

4.5 Organisation of process- and substance-specific criteria

4.5.1 Specification of the scope of application

Process- and substance-specific criteria must include all information that is necessary for their application. They should, if possible, be geared towards broad applicability and be comprehensible and practicable for the user. The description of the scope of application must indicate the procedures, hazardous substances and exposure situations to which the process- and substance-specific criteria are applicable and under what operating conditions. At the same time, these must be clearly distinguished from procedures and hazardous substances that are not subject to the process- and substance-specific criteria.

4.5.2 Procedure-specific conditions

The text must provide a sufficiently accurate description of the procedures to which the process- and substance-specific criteria are applicable and must specify and describe in detail the technical protective measures, e.g. measures against emissions, extraction systems and their collection devices, or ventilation equipment and its airflow.

4.5.3 Substance-specific conditions

Process- and substance-specific criteria must clearly specify the substances, groups of substances, mixtures, products and usage quantities to which they apply.

4.5.4 Assessment criteria

The process- and substance-specific criteria must always indicate:

1. the possible exposure level;
2. the assessment criterion (OEL; assessment criteria for carcinogenic hazardous substances announced in TRGS 910 pursuant to article 20 paragraph 4 of the Hazardous Substances Ordinance; or other assessment criteria according to

number 5.4.2 of TRGS 402, stating their origin and the justification for using them for the assessment).

4.5.5 Application instructions

(1) Process- and substance-specific criteria must include application instructions for the employer. These include that the employer must do the following if applying the criteria:

1. Check annually whether the criteria remain valid without change.
2. Check annually whether the operational prerequisites for applying the criteria remain valid without change in its working areas.
3. Document the results of its workplace investigation.
4. Carry out functional testing of the protection equipment at specified intervals. The type of testing is to be stated.

(2) Furthermore, process- and substance-specific criteria should identify the further duties that exist on the part of the employer pursuant to the Hazardous Substances Ordinance.

4.5.6 Process- and substance-specific criteria – structure

The text for process- and substance-specific criteria is based on the following structure:

1. scope of application;
2. gathering information and risk assessment;
3. protective measures;
4. parameters for checking effectiveness;
5. measurement data, calculation models (as an annex; stored in a database if necessary).

5 Adoption of process- and substance-specific criteria

(1) Process- and substance-specific criteria are adopted into TRGS 420 based on a decision by the AGS in accordance with the flow chart in Figure 1. The prerequisite for this is the presence of exposure descriptions according to the requirements of these technical rules, including a specification of the protective measures associated with the process- and substance-specific criteria and the check of their effectiveness.

(2) In the case of hazardous substances without assessment criteria according to number 2.1 paragraph 3, the AGS may, if necessary, evaluate the exposure on an occupational health/toxicology basis and document it in the process- and substance-specific criteria.

(3) Proposals for process- and substance-specific criteria are to be directed to the

management of the AGS:

Committee on Hazardous Substances (AGS)
- Management -
Federal Institute for Occupational Safety and Health (BAuA)
PO box 17 02 02
44061 Dortmund
Email: ags@baua.bund.de

Proposals should already be coordinated with the AGS before investigation programmes begin.

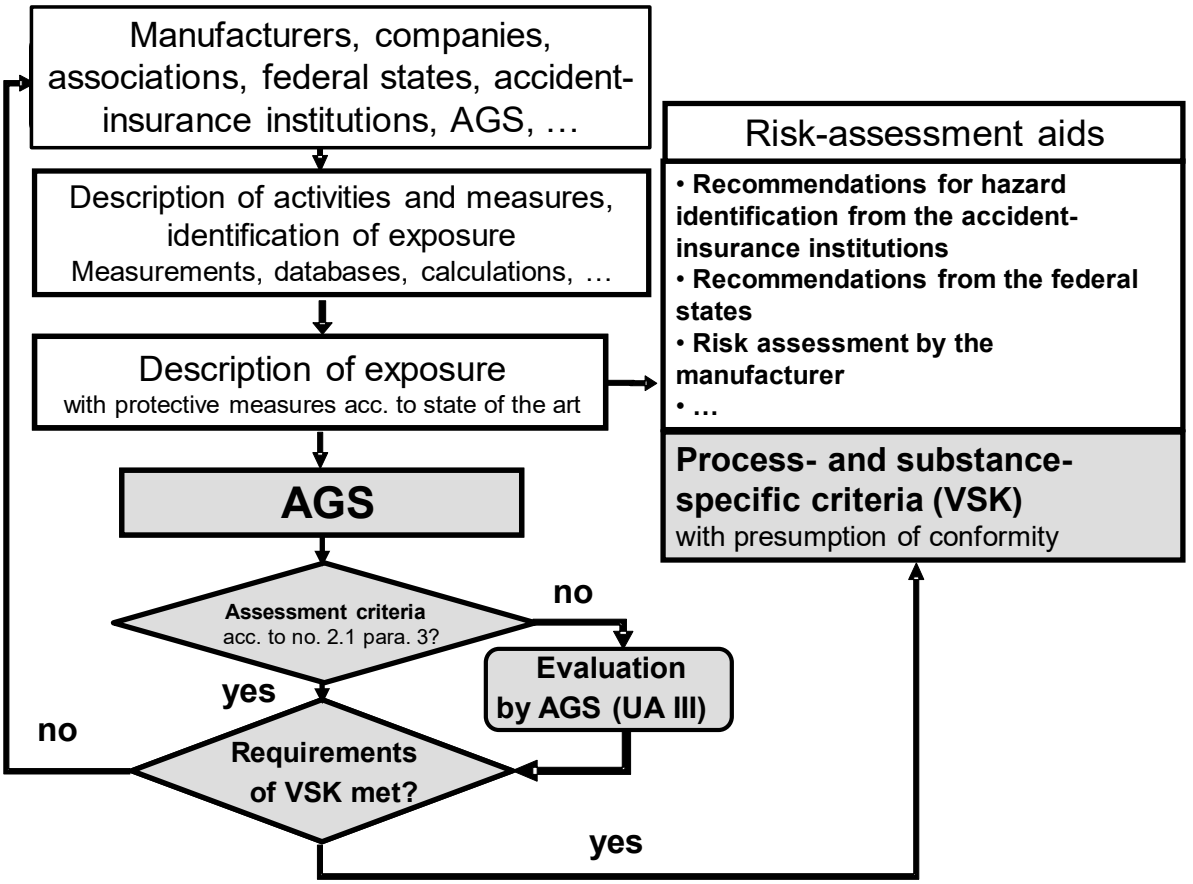


Figure: Drawing up process- and substance-specific criteria – flow chart

(4) The following documentation is usually needed to draw up process- and substance-specific criteria:

1. the detailed description of the working procedure, including the protective measures that are to be provided;
2. the type and amount of hazardous substances used, with details of the emission sources if necessary;
3. the precise definition of the area of application for the procedure;
4. the associated working instructions for the employees, including conduct in case of malfunctions;
5. results of performed investigations (e.g. risk assessments, exposure descriptions, calculations or measurement reports according to TRGS 402);
6. a statistical analysis of the investigation results with a summarising evaluation;
7. the proposed text of the process- and substance-specific criteria.

(5) The standardised working procedures adopted by the AGS as process- and substance-specific criteria are listed in the annex to TRGS 420 with an indication of the respective source.

Annex to TRGS 420

List of standardised working procedures recognised as process- and substance-specific criteria by the AGS

No.	Title	Edition/source
1	Soft soldering with soldering iron on electric and electronic assemblies or their individual components (iron soldering)	BGI 790-014, June 2008 *www.dguv.de/bg-bgia-empfehlungen* or *www.dguv.de/bgia,* web code d3483
2	Process- and substance-specific criteria in the application of low-temperature steam formaldehyde processes for sterilisation in health care facilities	Annex 5 to TRGS 513, GMBl no. 28 p. 575 of 14.7.2008 *www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/pdf/TRGS-513.pdf*
3	Handling solvents in screen printing (LV24) Guideline for risk assessment pursuant to the Hazardous Substances Ordinance – process- and substance-specific criteria, TRGS 420	Committee of the Länder for Occupational Safety and Health (LASI) of 24.3.2009 – ISBN: 3-936415-60-9 *http://lasi.osha.de/de/gfx/publications/lasi_publications.php*
4	Process- and substance-specific criteria “Optometry work”	*http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Arbeiten-mit-Gefahrstoffen/pdf/VSK-Augenoptiker.pdf*
5	Practical instructions for good working practice Textile recycling – activities involving hazardous substances and biological agents in the recycling of textile waste	*http://www.baua.de/nn_12322/de/Themen-von-A-Z/Gefahrstoffe/Arbeiten-mit-Gefahrstoffen/pdf/Textilrecycling.pdf*
6	Practical instructions for good working practice Plastic recycling – activities involving hazardous substances and biological agents in the mechanical recycling of plastics	*http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Arbeiten-mit-Gefahrstoffen/pdf/Kunststoffverwertung.pdf*
7	Practical instructions for good working practice Exposure of workers to solvents in the industrial cleaning of metals	*www.baua.de/dok/4530052*

No.	Title	Edition/source
8	Practical instructions for good working practice Paper recycling – activities involving hazardous substances and biological agents in the treatment of paper waste	*www.baua.de/dok/2731428*
9	Practical instructions for good working practice Motor vehicle recycling – activities involving hazardous substances in the recycling of motor vehicles	*www.baua.de/dok/2369450*
10	Exposure description Application of the stripping method for removing lead-containing coatings on wood and preparation for subsequent recoating within the framework of renovation measures on construction sites	*http://www.risan.cc/vsk_abbeizverfahren.html*