

**The new version of TRGS 600 supersedes TRGS 440.**

**Edition: August 2008**

<b>Technical Rules for Hazardous Substances</b>	<b>Substitution</b>	<b>TRGS 600</b>
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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 scientific knowledge relating to the requirements concerning the placing on the market and handling of hazardous substances. The

**Committee on Hazardous Substances (AGS)**

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

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## 1 Scope

(1) Under Sections 7 Subs. 1, 9 Subs. 1, 10 Subs. 1 and 19 Subs. 2 of the Hazardous Substances Ordinance (GefStoffV) the employer has the duty to determine, test and decide on substitution and to document it. The present TRGS is intended to support the employer

1. in avoiding activities involving hazardous substances,
2. to replace hazardous substances by substances, preparations or processes which are not hazardous or less so under the relevant conditions of use or
3. to replace hazardous processes by less hazardous ones.

(2) If the employer establishes within the context of the risk assessment that there is a low hazard according to the criteria of Section 7 Subs. 9 GefStoffV (see also Number 6.2 of TRGS 400 "Risk assessment for activities involving hazardous substances"), the Hazardous Substances Ordinance does not demand any substitution check or any substitution.

(3) The aim of the substitution is to eliminate or reduce to a minimum the hazard arising from all activities involving hazardous substances, including maintenance work and operating and monitoring activities. With regard to the protection of workers during activities involving hazardous substances, the primary measure to be taken by employers within the framework of information gathering and risk assessment under the Hazardous Substances Ordinance (Section 7 GefStoffV, see also TRGS 400) is to check substitution possibilities and implement them according to the criteria described in greater detail in Number 5 of this TRGS taking account of their reasonable nature.

(4) The substitution solution must as a whole reduce the hazards arising from hazardous substances at the workplace. At the same time it should not lead to any increase in other hazards at the workplace or to any increased impairment of other assets to be protected.

(5) The substitution check according to the specifications of this TRGS must also be applied if it is planned to use new substances and processes for economic or technological reasons.

(6) The TRGS does not describe the requirements set in the context of the Regulation (EC) No. 1907/2006 (REACH) regarding the assessment of substitution solutions within the framework of the authorisation and restriction procedure.

(7) Annex 1 contains a flow chart with the individual steps to be followed when determining and implementing substitution solutions. For illustration purposes Annex 1 contains in addition a simplified case example for this procedure.

## 2 Definitions

This TRGS uses terms as they are defined in the "Begriffsglossar zu den Regelwerken der Betriebssicherheitsverordnung (BetrSichV), der Biostoffverordnung (BioStoff) und der Gefahrstoffverordnung (GefStoffV)"<sup>1</sup> ["Glossary of Terms for the Regulations of the Plant Safety Ordinance (BetrSichV), the Biological Agents Ordinance (BioStoff) and the Hazardous Substances Ordinance (GefStoffV)] of the AGS and ABS.

## 3 Determination of substitution possibilities

(1) The determination of substitution possibilities is part of the information gathering for the risk assessment according to Section 7 Subs. 1 GefStoffV. In the case of activities involving hazardous substances, the employer must always determine the substitution possibilities, unless the hazard present is only minor (see Number 1 Para. 1).

(2) Information sources for the determination of substitution possibilities are listed below (for more precise details and sources see Annex 4 No. 5):

1. TRGS on substitute substances (TRGS 600 ff.),
2. sector- or activity-specific aids which incorporate statements on substitution, e.g.
  - a) BG/BGIA recommendation with statements on substitution,
  - b) information systems, e.g. product codes and publications of the public accident insurance institutions and the federal states,
  - c) other sectoral regulations (e.g. issued by trade associations),
3. safety data sheet (especially paragraph 7 therein) and additional information from suppliers and/or manufacturers, e.g. technical specifications,
4. information and experience reports from networks with other employers, technology transfer bodies, positive/negative lists from expert source,
5. information on substitution solutions from other regulatory domains, e.g. from REACH,
6. others, e.g. standards.

(3) To determine the substitution possibilities the employer must review the sources according to Paragraph 2 (Nos. 1-3). In particular he should ask the supplier about less hazardous solutions when purchasing. In order to prepare far-reaching decisions, in-depth searches/checks may be necessary, using in addition the sources according to Paragraph 2 (Nos. 4-6). Far-reaching decisions may be necessary in particular where there is

1. an elevated hazard or
2. a large number of endangered persons.

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<sup>1</sup> [www.baua.de/nn\\_57220/de/Themen-von-A-Z/Gefahrstoffe/Glossar/Begriffsglossar.pdf](http://www.baua.de/nn_57220/de/Themen-von-A-Z/Gefahrstoffe/Glossar/Begriffsglossar.pdf)

#### 4 Guiding criteria for the preselection of substitution possibilities with good prospects

(1) Where, in the course of information gathering, a number of substitution possibilities are determined, guiding criteria for the preselection of substitution possibilities with good prospects are meaningful if it is not possible to resort to model solutions according to Number 3 Para. 2 (Nos. 1–2). A preselection is particularly helpful if it is not possible, where a number of possibilities are established, to check them all with the same priority according to Numbers 5.1 and 5.2 with respect to their technical and health-related suitability. If, in the information gathering, only a few substitution possibilities are found, the preselection can be skipped.

(2) As criteria for a preselection of substitution possibilities consideration must be given both to the hazard features and the release potential based on the physico-chemical properties and the conditions of the process and of use (Paras. 3–5). When a decision is being taken on what possibilities have to be investigated further, all criteria must be considered as a whole and also include any consideration of the hazard to the skin (Number 4 Para. 6). Since the criteria of the preselection are intended for cases where many possibilities have to be scrutinised, the criteria are not finely differentiated. It is certainly conceivable that possibilities which, in the preselection, initially do not appear to have good prospects will be taken up again at a later stage in the check of substitute substances.

(3) The risk due to the health hazard properties of the substance can be reduced by substitution along the series in the respective line<sup>2</sup>:

1. substances with a low occupational exposure limit (OEL) > substances with a higher occupational exposure limit (with comparable substance properties and exposures, the ratio of occupational exposure limit to vapour pressure is relevant, for example, in the case of liquids),
2. systemic effect: highly toxic(T+) > toxic(T) > health hazard (Xn) > none of these features,
3. corrosive/irritant effect: corrosive (C) > irritant (Xi) > none of these features,
4. carcinogenic, mutagenic, toxic to fertility (cmr) > not cmr.

(4) The risk due to the physicochemical properties of the substance can in principle and in the context of the preselection be reduced by substituting along the series in the respective line:

1. extremely flammable (F+) or pyrophorous (F,R17) > highly flammable (F) > flammable (R 10) > none of these features,
2. combustion-enhancing (O) > not combustion-enhancing,
3. explosive (E) > non-explosive.

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<sup>2</sup> In the following paragraphs ">" should be taken to mean "greater risk expected than with ...".

(5) The release potential of a hazardous substance into the atmosphere at the workplace can in general be reduced by substitution along the series listed in the respective line:

1. large quantity > small quantity,
2. process with wetting of large areas > process with wetting of small areas,
3. gas > liquid > paste,
4. dust-producing solid > non-dust-producing solid,
5. sublimating solid > non-sublimating solid,
6. low boiling point (high vapour pressure) > high boiling point (low vapour pressure),
7. open process > closed process,
8. process at high temperatures > process at room temperature,
9. process under pressure > unpressurised process,
10. process involving generation of aerosols > aerosol-free process,
11. solvent-bearing systems > aqueous systems, etc.

(6) With regard to skin exposure the criteria for the preselection of substances, preparations or working processes may deviate in individual cases from those already mentioned and they must be individually checked or adjusted accordingly. This concerns in particular the criteria for the release potential. Here properties which lead to an increased release into the atmosphere can certainly have the opposite effect on the dermal exposure. For example pastes remain longer on the skin than liquids or gases. On the other hand a high vapour pressure reduces the dwell time on the skin and higher temperatures make skin contact easier to avoid than use at room temperature. When comparing the risks from skin contact, the criteria of TRGS 401 (especially in Numbers 3 and 4) should be referred to.

(7) When looking at the situation as a whole in the preselection procedure, the employer must weigh up all the guiding criteria against one another in order to establish with which substances and under what process and use conditions overall an elimination or minimisation of risk can be expected. For example, in a particular case a generally lower risk may apply with the use of a substance involving more hazardous properties which is available in a non-dust-producing form or which has a very low vapour pressure than one with less hazardous properties, but which is only available on the market in dust-producing form or which has a considerably higher vapour pressure.

(8) Low-emission forms of use (see also TRGS 500) can be regarded as less hazardous processes in the meaning of Section 9 Subs. 1 GefStoffV. The use of low-emission forms of use should reduce the exposure to the extent that would be achieved by technical, organizational or personal measures according to Section 9 (2) or closed systems according to Section 10 Subs. 1 GefStoffV.

## **5 Decision on substitution**

(1) Those substitution possibilities which have been found in the preselection to have good prospects can be examined even more closely with respect to their technical, health-related and physicochemical suitability by applying the criteria and methodological aids given below in Numbers 5.1 and 5.2. Number 5.3 describes the regulatory specifications and operational decision-making criteria for the corporate implementation of substitution possibilities found.

(2) For substitution decisions in the context of the Hazardous Substances Ordinance safety and health are the primary concern in the integrated decision according to the criteria of the following sections, but in a specific case it may be necessary and relevant to the decision to consider other assets worthy of protection.

### **5.1 Criteria for technical suitability**

(1) Substitution recommendations given in the information sources according to Number 3 Para. 2 Nos. 1 and 2 for certain uses are normally suitable technically. If the employer deviates from these recommendations despite comparable workplace conditions of use, he must give his reasons in writing.

(2) In other cases the technical suitability of a substitution possibility must be assessed by the user of the relevant substance or process in relation to the individual case. The matters to be considered here include the following:

1. the state of the art (Section 3 Subs. 10 GefStoffV),
2. the function of the substance (auxiliary substance in the production process or indispensable component of the product/process or raw material of the manufacturing process or indispensable constituent of the product),
3. the technical consequences of the substitution on the company's own production process and product quality,
4. the resulting technical consequences for the downstream processing/use of the product in the value chain and
5. the effects of the substitution on the product properties and the quality of the end product (including consumer acceptance, conformity with standards, loss of authorisations).

(3) Authorisation under REACH does not replace the workplace substitution check according to GefStoffV for activities involving hazardous substances. The employer must then notify the European Chemicals Agency of the use of the authorised substance under Article 66 of the Regulation (EC) 1907/2006 (REACH).

### **5.2 Criteria for the health and physicochemical risk**

(1) The substitution solution must reduce overall the risks from hazardous substances at the workplace. At the same time it should not result in any increase in other risks at the workplace or to a greater impairment of other assets worthy of protection.

(2) Substitution solutions found on the basis of information sources according to Number 3 Para. 2 Nos. 1–3 normally lead to a lower risk to the health and safety of workers.

(3) If it is not possible when deciding on the suitability of a substitution possibility to make use of the general recommendations or if the assessment of the risk is not absolutely clear, reference should initially be made to specific estimation models, and in particular those mentioned in Annex 2 (column and effect factor model). It should be said that preparations cannot be clearly estimated in every case with the help of the models and that the assessment of preparations requires specific knowledge (for example the ability, where relevant, to identify the critical constituents relevant to the decision).

(4) When applying the models, information must be available on the properties of the substances or preparations. This includes in particular the classification and labelling of the hazardous substances. If information is available from, for example, the manufacturer, the person placing the product on the market, the client or other bodies, the employer may take over these classifications and assessments if he has no other knowledge at his disposal.

(5) When applying the models the following fundamental checks or assessments must be available as a minimum:

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

(6) It is possible to establish whether tests or assessments have been conducted by reference to the safety data sheet (section 11 "Toxicological Details"), or this must be determined elsewhere, in particular by enquiry to the supplier. If the information according to Paragraph 5 Nos. 1–5 cannot be determined, at least the following properties must be assumed – depending on what information is lacking

1. hazardous to health (labelling with R20, 21 or 22),
2. skin irritant (labelling with R38),
3. suspected mutagenic change (labelling with R68),
4. skin sensitising (labelling with R43).

(7) The substitute substances must be capable of being assessed just as well with regard to these toxicological endpoints as the substance being replaced. This also applies to preparations if the safety data sheet does not make any qualified statements concerning the hazardous properties (see notice on hazardous substances 220 "Safety Data Sheet", Number 6.11 Para. 9).

(8) With the same priority as the health-related properties, consideration must be given to the physicochemical properties which can give rise to fire and explosion risks. In particular a check must be made with substitution whether substances and preparations can be used which cannot form explosive mixtures.

(9) It should be checked whether the safety data sheet (section 9 "Physical and Chemical Properties") contains corresponding details and safety characteristics concerning the flammable, explosive, potentially explosive or combustion-enhancing properties. For example, the following details must be checked in the safety data sheet:

1. boiling point,
2. vapour pressure,
3. density ratio in relation to air (gases and vapours),
4. lower and upper explosion limits,
5. flash point,
6. ignition temperature,
7. self-ignition temperature,
8. pyrophorous properties,
9. burn-up rate,
10. maximum gas development rate when there is a reaction with water,
11. grain size distribution (what is relevant is the fine grain fraction smaller than 500  $\mu\text{m}$ ),
12. combustion-enhancing potential as compared to the reference mixture or active oxygen content in the case of organic peroxides,
13. exothermic decomposition energy,
14. test results for the thermal sensitivity (BAM steel shell test according to EG A.14 or Koenen test following test methods according to the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, indicating the test series), impact sensitivity and friction sensitivity.

(10) Further instructions can also be given in the safety data sheet in section 5 "Measures to Fight Fire" and section 7 "Handling and Storage".

(11) If no physicochemical details are available or if the plausibility check seems to suggest that details are lacking, for example an indication of the flammability in the case of a highly volatile organic solvent, these must be asked about as part of the information gathering. If it is not possible to give any indications in this respect, it must be assumed that the corresponding properties are present.

(12) In addition to applying the models for the health assessment and examination of the physicochemical properties, a more detailed, thorough test of possible substitute solutions may be necessary, depending on the complexity of the specific case (see Annex 4 No. 1 B and C). Apart from a thorough search of the sources according to Annex 4 No. 5, it may then also be necessary to involve experts.

(13) Consideration could also be given to ecotoxicological parameters, including for example the release and propagation potential in the environment, the coefficient of

distribution between water and n-octanol ( $\log P_{OW}$ ) as well as the persistence and bioaccumulation potential (PBT, vPvB).

### 5.3 Decision on the realisation of substitution

(1) It can be assumed that substitution possibilities according to Number 3 Para. 2 Nos. 1–2 are basically suitable at the workplace. The employer must therefore normally implement them.

(2) In the case of activities involving hazardous substances which are toxic, highly toxic, carcinogenic, mutagenic or toxic to fertility (categories 1 and 2) substitution must be implemented if alternatives are technically practicable and lead to an overall lower risk to workers.

(3) If no activities are conducted involving substances which are toxic, highly toxic, carcinogenic, mutagenic or toxic to fertility, or if there are no substitution possibilities according to Para. 1, the employer may take the integrated decision taking into account the economic assessment criteria (see also Annex 1 "Flow Chart"). Annex 3 "Criteria for the Realisation of Substitution" contains instructions as to what aspects the employer should consider in his deliberations.

(4) The substitute solution must be used if the workplace-related factors tested in accordance with Annex 3 are mainly affected in a positive sense. Higher costs of a substitute solution can also be accepted.

## 6 Documentation

(1) The result of the test for substitution possibilities must be documented. If there is a low risk according to the criteria of Section 7 Subs. 9 GefStoffV (see also Number 6.2 of TRGS 400) the Hazardous Substances Ordinance does not specify substitution. Consequently if there is a low risk, it is not necessary to document the determination of substitution possibilities. But a voluntary documentation can, for example, facilitate the application of the existing solution in other parts of the company or it can demonstrate to third parties that the employer is behaving in a responsible manner.

(2) It is appropriate to document the result of the test for substitution possibilities in conjunction with the documentation of the other parts of the risk assessment (see TRGS 400). No specific form is specified. One possibility is, for example, to supplement the list of hazardous substances by adding further columns/boxes showing the time at which the check was conducted, the result and the source of additional documents. The results of the substitution test can be described using standard sentences, e.g.:

1. Possibilities for substitution are ...
2. No possibilities for substitution.
3. Solution is already a substitute solution.

(3) If the substitution test reveals for activities where additional protective measures have to be taken under Section 10 GefStoffV that there are possibilities for substitution and these are not implemented, the reasons for this must be documented. This

can be done in the form of standard sentences such as

1. Substitute solution technically not suitable because ...
2. Substitute solution does not adequately reduce risk because ...
3. Substitute solution operationally not suitable at the workplace because ...
4. Substitute solution initiated; repeat test by ...

(4) If a technically practicable substitution with less hazardous substances or processes is not implemented for business reasons, the issues considered on which the test were based must be documented in a verifiable way. Annex 3 is suitable for this purpose, for example.

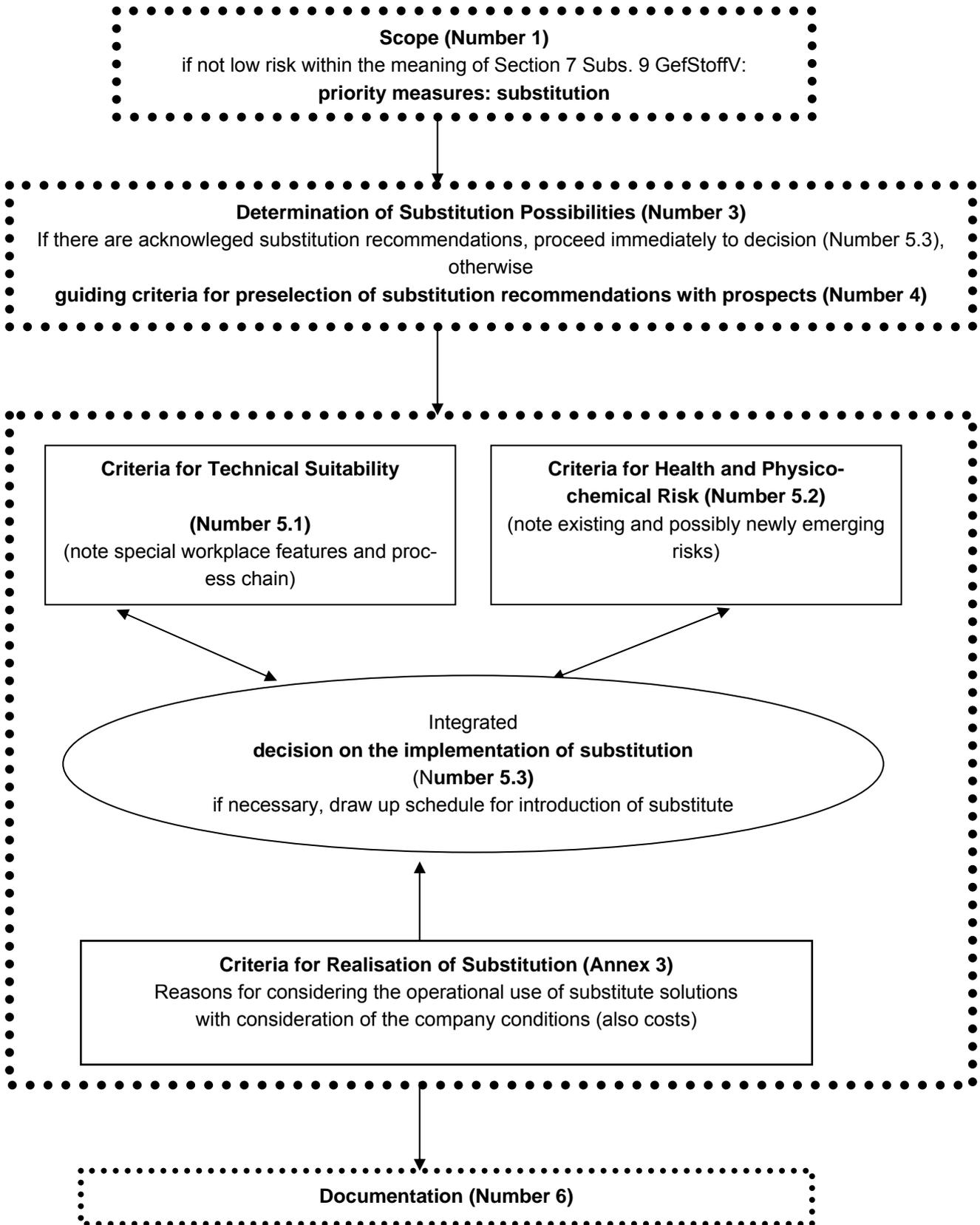
(5) If, in the test for substitution possibilities for activities where protective measures have to be taken under Section 10 GefStoffV, no substitution possibilities are identified, the sources where searches have been conducted must be named briefly.

(6) The employer who is responsible for activities involving substances and preparations which are carcinogenic, mutagenic or toxic to fertility (categories 1 and 2) must notify the competent authorities on request of the result of the substitution test and the cases of substitution.

(7) For a detailed documentation or as a replacement for freely formulated reasons, it is appropriate to apply Annex 2 "Comparative Assessment of the Health and Safety Hazards (Column and Effect Factor Model)" and in particular also Annex 3 "Criteria for the Realisation of Substitution – Reasons for considering the operational use of substitute solutions". These and other documents can be filed separately.

**Annex 1 to TRGS 600**

**1.1 Substitution Flow Chart**



## 1.2 Example of brake cleaning in automotive workshops

### 1 Preliminary remarks

(1) In this annex it is shown taking a practice-based example how the TRGS can be applied to a concrete substitution test. The example cannot claim to have tested all conceivable possibilities or to give a comprehensive and binding description of the selection and weighting of the assessment criteria. But it makes clear how the test steps described in the TRGS follow successively on from one another and what considerations are basically appropriate.

(2) At present searches conducted by the Berufsgenossenschaften (institutions for statutory accident insurance and prevention) in the metalworking industry reveal that in most automotive maintenance shops test petrols with a low boiling point and free of aromatic compounds are used to clean brakes as part of the maintenance work.

(3) Most products come under the category of highly flammable (flash point < 21° C) or extremely flammable (flash point < 0°C). On account of their positive cleaning properties – fast cleaning with no residues – they are used by many companies.

### 2 Risk assessment of the existing solution: cleaning with highly volatile solvents

<p><b>Health risk</b> Release of solvents into the atmosphere at the workplace, 5 compressed gas packs at 400 ml/shift Skin contact with degreasing solvents</p>
<p><b>Risks due to physicochemical properties (here: fire and explosion hazards)</b> Explosion hazard due to highly or extremely flammable solvents Fire hazard due to cleaning cloths and solvent slurries</p>
<p><b>Environment:</b> (not a concern of GefStoffV but operationally relevant) Emission of solvents into the environment</p>
<p><b>Other risks:</b> (not a concern of GefStoffV, but operationally relevant)</p>
<p><b>Decision:</b> There is a health and safety risk. A substitution solution should be aimed at.</p>

### 3 Determination of substitutions possibilities (Number 3 TRGS 600)

(1) There is no single, recognised activity- or sector-specific solution according to Number 3 Para. 2 Nos. 1-2 of the present TRGS.

(2) The following can be considered as possible alternative solutions to replace highly volatile brake cleaners:

1. Change of working process
  - a) Mechanical cleaning with brush and compressed air (former practice),
  - b) Mobile water-based cleaning facility (hot brake washer),
2. Use of substitute substances
  - a) Low-volatility, hydrocarbon-bearing brake cleaner, FP > 55°C, refillable spray can, compressed air as propellant.

(3) Mechanical cleaning with brush and compressed air causes high dust levels and yields inadequate cleaning results, and it is listed and described in the table only to provide an exhaustive set of examples.

#### **4 Substitution test**

##### **4.1 Note criteria for existing and possibly newly emerging risks (Numbers 4 and 5.2 TRGS 600)**

(1) Here the criteria from Number 4 of TRGS or the column model from Number 5 can be selected and applied. In the case of substances which are difficult to assess in health terms, the effect factor model can also be applied. In this example when determining substitution possibilities only a few were found. A formal "preselection" with the help of the grid of criteria from Number 4 of TRGS is therefore not necessary in this example.

(2) Under the Occupational Safety and Health Act other risk factors than substance-bound ones must be considered. The considerations in the line "environmental risk" do not result from requirements arising through the Hazardous Substances Ordinance, but are relevant for the operative decision and have therefore been included in the following table.

(3) The solution with good prospects should be examined and the results recorded.

<b>Risks</b>	<b>Current solution/practice</b>	<b>Alternative 1</b>	<b>Alternative 2</b>	<b>Alternative 3</b>
<b>Designation</b> (substance or process)	Highly volatile brake cleaner	Low-volatility brake cleaner	Brush and compressed air	Hot brake washer
<b>Characterisation</b>	HC cleaner flashpoint < 21°C, propellant gas: propane/butane	HC cleaner, flashpoint > 55°C propellant gas: compressed air	Manual mechanical cleaning	Facility with hot water (low-pressure) as cleaning agent
<b>Health risk due to dermal and inhalative exposure</b>	Inhalative exposure due to hydrocarbon vapours and aerosols, 5 compressed gas packs at 400 ml/shift. Skin contact with degreasing solvents.	Inhalative exposure due to hydrocarbon vapours and aerosols (lower exposure than with highly volatile cleaner), the dermal exposure (degreasing) is greater than with highly volatile cleaner.	No cleaning agents characterised as hazardous substances are used, but high release of fibre dust which is harmful to health	No hazardous substances are used. Brake dust is bonded. Low skin contact.
<b>Risks due physicochemical properties</b> (here: fire and explosion hazards)	Fire and explosion hazard due to highly and extremely flammable solvents and propellant gas	<i>Fire and explosion hazard due to flammable solvents lower than with FP &lt; 21°C. Fire hazard due to cleaning cloths and solvent residues</i>	None	None
<b>Environmental risk</b> (not a subject of GefStoffV, but operationally relevant)	Emission of solvents into the environment	Lower emission of solvents into the environment than with FP < 21°C. Collecting vessel necessary	Extraction and expert disposal of fibre dust necessary	Cleaning of effluent necessary
<b>Other risks:</b> (not a subject of GefStoffV, but operationally relevant)			Noise (compressed air)	Steam, hot water, risk of scalding due to manual handling
<b>Decision</b>	High risk due to vapours and aerosols of highly volatile hydrocarbons	Lower risk due to HC than with current solution	High inhalative risk due to fibre dust	No risks from hazardous substances to be expected

## 4.2 Select criteria for the technical suitability (Number 5.1)

Assess solutions with prospects according to the relevant criteria selected and record results; note special operational features and process chain.

(Check of important technical parameters, check of the possibility of dispensing with certain properties, possibly new qualification requirements or space requirement)

Technical assessment	Current solution/practice	Alternative 1	Alternative 2	Alternative 3
<b>Designation</b>	Highly volatile brake cleaner	Low-volatility brake cleaner	Brush and compressed air	Hot brake washer
<b>Technical requirement:</b> Clean, dry brakes fulfilled?	Yes	Yes, but longer drying time than with FP < 21°C	Yes, but poor cleaning effect with oily contaminants	Yes, organisational changes necessary
<b>Suitability in the process chain</b> here in particular: manufacturer specifications for brake cleaning	Suitable	Suitable	Limited suitability	Suitable
<b>Realisable in existing premises</b>	No, special explosion-proof room required! (BGR 157)	Yes, but collecting tray required	Yes	Yes
<b>Remarks:</b>		Residues from cleaner remain longer on the vehicle and in the working area		More elaborate handling required (collecting tray, electrical connection, ...)
<b>Decision</b>	Technically suitable, but special room required	Technically suitable	Limited suitability	Technically suitable

### 4.3 Criteria for the realisation of substitution (Number 5.3 and Annex 3 TRGS 600)

#### Reasons for considering the operational use of substitute solutions

For the remaining solutions under consideration all influencing factors of Annex 3 are examined and the appropriate sub-points are completed. It is documented qualitatively whether effect of the substitute solution is very positive (++), positive (+), negative (-), very negative (--) or neutral (0). For a number of conceivable substitute solutions the table could be extended or established a number of times. Quantification can be described in separate documents.

#### Tabular comparison of the substitute solutions for highly flammable brake cleaners

Influencing factors	Change through substitute solution		
	++/+/0/-/--	++/+/0/-/--	Remark
	Hot brake washer	Low-volatility brake cleaner	
<b>Material costs</b>	++ Material costs lower	0 High material consumption	
<b>Equipment costs</b> – investment costs – energy costs	-- - approx. € 3,000 is almost made up for in the long term by low material costs	- 0 collecting tray (approx. € 300) refilling station (approx. € xxx)	The total costs depend very much on the number of daily (monthly/annual) cleaning operations. The greater this number, the less the cost disadvantages of the hot brake washer as compared to the low-volatility brake cleaner.
<b>Labour costs</b>	- Working time longer by 20% equivalent to 2 min. per operation with 20 operations per day	0	
<b>Technical protective measures</b> – ventilation measures – fire/explosion protection	+ +	+ +	
<b>Personal protective measures</b>	+	+	
<b>Occupational health care</b>	0	0	
<b>Workplace measurements</b>	+	+	
<b>Transport costs</b> – freight tariffs, packing ...	0	0	
<b>Storage costs</b>	+	0	
<b>Disposal costs</b> – recycling, effluent, exhaust air	? Clarify effluent disposal	+	Empty spray cans no longer involved
<b>Costs for organisation</b>	0	0	Labour costs v. costs for organisation?
<b>Insurance costs</b>	0	0	
<b>Reduction of risk</b> (not described in costs)	+	+	
<b>Other influencing factors</b> (company-related factors not to be			

Influencing factors	Change through substitute solution		
	++/+/0/-/--	++/+/0/-/--	Remark
described in terms of costs			
– corporate image	+	+	
– employee satisfaction	0	0	
– sustainability/ planning reliability	+	0	
<b>Other relevant factors</b>			
– if necessary supplement by items related to company and specific cases			
<p><b>Final assessment:</b></p> <p><b>Short-term solution:</b> Replacement of the HC cleaner used to date (FP &lt; 21°C, propellant gas propane/butane) by HC cleaner FP &gt; 55°C, propellant gas compressed air.</p> <p><b>Medium-term solution (one year):</b> Check whether a hot brake washer can be procured</p> <ul style="list-style-type: none"> <li>– clarification of effluent disposal</li> <li>– comparison of costs as a function of quantities consumed</li> </ul> <p>In the short term the agent used to date will be replaced by one with a lower flashpoint because this is simple to implement and only involves a small investment. In the medium term (one year) the possibility of a hot brake washer should be re-examined – after clarification of the effluent question and a profitability calculation. If the outcome is positive, this substitute solution should be introduced, especially on account of the risk reduction and the long-term planning reliability.</p>			

## Annex 2 to TRGS 600

### Comparative assessment of the health and safety hazards (column and effect factor models)

#### 1 The column model

(1) With the column model (see table "Substitute substances check") it is possible to make a quick comparison of substances and preparations with reference to a small amount of information.

(2) A comparative assessment of a product and a potential substitute solution is conducted in the five columns separately for the two solutions:

1. acute and chronic health hazards (the columns "acute health hazards" and "chronic health hazards" as a single column),
2. environmental hazards,
3. fire and explosion hazards,
4. risks from release behaviour
5. risks due the process.

(2) The evaluation of the results should take account of the following criteria:

1. Comparative assessments may invariably only be conducted within a column and on no account within a line.
2. It may only be applied if the manufacturer has assessed the substances or preparations (with view to the health risk at last regarding acute toxicity, skin irritation, irritation of the mucous membranes, mutagenic potential and skin sensitisation) on the basis of data and experience available including any gaps in data (see safety data sheet chapters 9 and 11) and has declared that there is no reason to expect on the basis of this assessment any hazardous features going beyond the classification (especially with a view to toxicity in the case of repeated application).
3. In the column "acute health hazards" a special feature must be noted for the R phrases 20, 21, 22, 23, 24 and 25: if these R phrases arise in combination with the R phrase 48, the relevant substances/products are assessed as being one risk stage higher. This then involves chronic health hazards.
4. Basically small differences in the risk stages are only an argument for a substitute substance if the data for the substitute substance is approximately as good as that for the substance to be substituted.
5. If the potential substitute solution performs better in all five columns than the product or process used, the level of risk has been clarified beyond doubt.
6. A difference of one risk stage can occasionally mean, if contrary reasons are present, that the substitute substance will not be used.
7. If there are differences of two or more risk stages, there must be important reasons for not using the substitute substance.
8. But the normal case will be that the potential substitute product performs better

in some columns and does worse in one or two columns. Then it is the responsibility of the user to assess which risk features, i.e. which columns, have the greater weight in a specific case.

- a) If, for example, it is not possible to exclude ignition sources during product processing, greater attention will be paid to the fire and explosion features and the release behaviour of the products.
  - b) If large quantities of waste are generated during processing, a greater weighting is given to the environmental risks etc.
9. In any case the user must document the result of the substitution check in a suitable way.
- (3) In the column model no assessment is conducted taking account of the constituents. With this pragmatic approach certain disadvantages are tolerated which arise, for example, from the existence of classification limits for preparations.

## Substitute substances check

Product name	1 Risk	2a acute health hazards (single impact, e.g. chemical accident)	2b chronic health hazards (repeated impact)	3 environmental hazards <sup>1)</sup>	4 fire and explosion hazards <sup>2)</sup>	5 hazards due to release behaviour	6 hazards due to process
very high risk	<input type="checkbox"/> highly toxic substances/preparations (R26, R27, R28) <input type="checkbox"/> substances/preparations which can form highly toxic gases in contact with acid(R32)	<input type="checkbox"/> carcinogenic substances of the categories 1 or 2 (Carc.Cat.1, K1, Carc.Cat.2, K2, R45, R49) <input type="checkbox"/> mutagenic substances of the categories 1 or 2 (Mut.Cat.1, M1, Mut.Cat.2, M2, R46) <input type="checkbox"/> preparations which contain carcinogenic or mutagenic substances of the categories 1 or 2 in a concentration of $\geq 0.1\%$	<input type="checkbox"/> substances/preparations with the hazard symbol N and the hazard designations R50, R51, R53, R54, R55, R56, R57, R58, R59 <input type="checkbox"/> substances/preparations of the water hazard class WGK 3	<input type="checkbox"/> substances/preparations with explosion hazard (R2, R3) <input type="checkbox"/> extremely flammable gases and liquids (R12) <input type="checkbox"/> self-igniting substances/preparations (R17)	<input type="checkbox"/> gases <input type="checkbox"/> liquids with a vapour pressure of $> 250$ hPa (mbar) (e.g. dichloromethane) <input type="checkbox"/> dust-generating solids aerosols	<input type="checkbox"/> open working <input type="checkbox"/> possibility of direct skin contact <input type="checkbox"/> large-area application	
high risk	<input type="checkbox"/> toxic substances/preparations (R23, R24, R25) <input type="checkbox"/> highly corrosive substances/preparations (R35) <input type="checkbox"/> substances/preparations which can form toxic gases in contact with water or acid (R29, R31) <input type="checkbox"/> skin-sensitising substances (R43, Sh) substances which sensitise respiratory tracts (R42, Sa) <input type="checkbox"/> preparations which contain substances that sensitise skin or respiratory tracts in a concentration of $\geq 1\%$ (in the case of gases $\geq 0.2\%$ )	<input type="checkbox"/> substances toxic to reproduction of the categories 1 or 2 (Repr.Cat.1, Re1, Rf1, Repr.Cat.2, Re2, Rf2, R60, R61) <input type="checkbox"/> preparations which contain substances toxic to reproduction of the categories 1 or 2 in a concentration of $\geq 0.5\%$ (in the case of gases $\geq 0.2\%$ ) <input type="checkbox"/> carcinogenic substances of the category 3 (Carc.Cat.3, K3, R40) <input type="checkbox"/> mutagenic substances of the category 3 (Mut.Cat.3, M3, R68) <input type="checkbox"/> preparations which contain carcinogenic or mutagenic substances of the category 3 in a concentration of $\geq 1\%$ <input type="checkbox"/> substances which can accumulate in the body (R33)	<input type="checkbox"/> substances toxic to reproduction of the category 3 (Repr.Cat.3, Re3, Rf3, R62, R63) <input type="checkbox"/> preparations which contain substances toxic to reproduction of the category 3 in a concentration of $\geq 5\%$ (in the case of gases $\geq 1\%$ )	<input type="checkbox"/> substances/preparations without the hazard symbol N, but with the hazard designations R52, R53 <input type="checkbox"/> substances/preparations of the water hazard class WGK 2	<input type="checkbox"/> highly flammable substances/preparations (R11) <input type="checkbox"/> substances/preparations which form extremely flammable gases with water (R15) <input type="checkbox"/> combustion-enhancing substances/preparations (R7, R8, R9) <input type="checkbox"/> substances/preparations with certain properties (R1, R4, R5, R6, R7, R14, R16, R18, R19, R30, R44)	<input type="checkbox"/> liquids with a vapour pressure of 50...250 hPa (mbar) (e.g. methanol)	
average risk	<input type="checkbox"/> substances/preparations which are harmful to health (R20, R21, R22) <input type="checkbox"/> substances which can accumulate in breast milk (R64) <input type="checkbox"/> corrosive substances/preparations (R34, $\text{pH} \geq 11.5$ , $\text{pH} \leq 2$ ) <input type="checkbox"/> substances which are harmful to the eyes (R41) <input type="checkbox"/> non-toxic gases which may cause asphyxiation due to air displacement (e.g. nitrogen)	<input type="checkbox"/> substances toxic to reproduction of the category 3 (Repr.Cat.3, Re3, Rf3, R62, R63) <input type="checkbox"/> preparations which contain substances toxic to reproduction of the category 3 in a concentration of $\geq 5\%$ (in the case of gases $\geq 1\%$ )	<input type="checkbox"/> substances/preparations without the hazard symbol N, but with the hazard designations R52, R53 <input type="checkbox"/> substances/preparations of the water hazard class WGK 2	<input type="checkbox"/> flammable substances/preparations (R10)	<input type="checkbox"/> liquids with a vapour pressure of 10...50 hPa (mbar), with the exception of water (e.g. toluene)	<input type="checkbox"/> closed working with exposure possibilities e.g. when decanting, sampling or cleaning	
low risk	<input type="checkbox"/> irritant substances/preparations (R36, R37, R38) <input type="checkbox"/> damage to the skin during wet work <input type="checkbox"/> substances/preparations which cause lung damage if swallowed (R65) <input type="checkbox"/> substances/preparations which damage the skin (R66) <input type="checkbox"/> vapours cause sleepiness and dizziness (R67)	<input type="checkbox"/> substances which are chronically harmful in other ways (no R phrase, but still a hazardous substance!)	<input type="checkbox"/> substances/preparations of the water hazard class WGK 1	<input type="checkbox"/> low-flammability substances/preparations, flash point 55...100 °C	<input type="checkbox"/> liquids with a vapour pressure of 2...10 hPa (mbar) (e.g. xylene)		
negligible risk	<input type="checkbox"/> substances which experience shows to be harmless (e.g. water, sugar, paraffin etc.)		<input type="checkbox"/> non-water-hazardous substances/preparations (nwg)	<input type="checkbox"/> noncombustible or very low-flammability substances/preparations (in the case of liquids flash point $> 100$ °C)	<input type="checkbox"/> liquids with a vapour pressure of $< 2$ hPa (mbar) (e.g. glycol) <input type="checkbox"/> non-dust-generating solids	<input type="checkbox"/> closed, tight system <input type="checkbox"/> closed system with extraction at the outlet points	

Assessment:

This product can be used

 /cannot be used  as a substitute for

Date:

Name:

Signature:

1) The water hazard class is only referred to as an assessment criterion in the case of substances/preparations which have not (yet) been classified with respect to environmentally hazardous properties.

2) Explosive dusts must be checked by a specialist in each individual case on account of their specific problems and are therefore not allocated to any of the risk stages given below.

(if, in the column "acute health hazards", the R phrases 20, 21, 22, 23, 24 and 25 arise in combination with the R phrase 48, the relevant substances/products are assessed as being one risk stage higher. This then involves chronic health hazards.)

## 2 The effect factor model

(1) With the following procedure it is possible to conduct a comparative risk estimation, although only with respect to the health hazard properties in substances and preparations for which neither a detailed and current toxicological assessment is available nor are there aids in the form of sector-specific solutions. In contrast to the column model, this is not based on classification of the preparation, but takes account proportionately of all constituents (as indicated by the safety data sheet).

(2) For the application of the effect factor model, at least details of the following health hazard properties of the substances or constituents of the preparations should be available: acute toxicity, skin irritation, irritation of the mucous membranes, mutagenic potential and skin sensitisation. In addition the toxicity with repeated application (administration) must be assessed. Details which are lacking with respect to these endpoints are assessed with corresponding W factor:

1. If there is no data or experience available on acute toxicity, skin irritation, irritation of mucous membranes or mutagenic potential and no air limit value has been fixed either, for these properties a W factor of 100 must be assumed.
2. If there is no data or experience available on skin sensitisation and if no air limit value has been fixed either, for this property a W factor of 500 must be assumed
3. If no data or experience is available for toxicity with repeated administration and if no air limit value has been fixed either, for this property a W factor of 100 must be assumed.

(3) It is thus possible to apply the effect factor model even when not all details relating to health hazard properties are available.

(4) The effect factor model relates only to toxic properties. Physicochemical properties, environmental hazards, and exposure and application conditions are not taken into account. These must be assessed separately in decisions concerning a substitute substance (for example with the column model).

### 2.1 The effect factor (W) for substances

(1) W is described by the corresponding hazard instructions (R phrases) and by health hazards which have not yet been accorded an R phrase (e.g. skin resorptivity, pH, K3).

(2) Account must be taken in each case of all substances used, arising or released in the existing solution or substitute solution.

(3) The W factor of a substance can appropriately only be used in a comparison with the W factor of another substance. The W factors have been obtained from the classification criteria and the level of the air limit values in the same way as for classified substances (F. Kalberlah, H. Wriedt: Bewertung und Fortentwicklung der Regelungsetzung: Anwendbarkeit der TRGS 440; publication series of BAuA, research report Fb 784, Dortmund/Berlin, 1998).

Effect factors (W)	
R45, R46, R49, M1, M2, K1, K2	50,000
R26, R27, R28, air limit value <sup>3)</sup> <0.1 mg/m <sup>3</sup>	1,000
R32, R60, R61, R <sub>E</sub> 1, R <sub>E</sub> 2, R <sub>F</sub> 1, R <sub>F</sub> 2	
R35, R48/23, R48/24, R48/25, R42, R43, Sh, Sa, Sah <sup>4)</sup>	500
R23, R24, R25, R29, R31, R34, R41, H <sup>2)</sup>	
R33, R40, R 68, K3, M3, pH<2 bzw. >11.5 <sup>1)</sup>	100
R48/20, R48/21, R48/ 22, R62, R63, R <sub>E</sub> 3, R <sub>F</sub> 3	50
R20, R21, R22	10
R36, R37, R38, R65, R67	5
R66, classified (but none of the criteria mentioned) or with AGW >100 mg/m <sup>3</sup>	1
substances known to have a low health risk	0
Air limit value of between 0.1 and 100 mg/m <sup>3</sup>	100/GW <sup>3)</sup>

- 1) If  $W_Z < 100$  applies for the preparation, the effect potential with a pH in the preparation of <2 or >11.5 must be assumed to be  $W = 100$ , where the pH was not assessed on the basis of tests because it is not relevant to an assessment.
- 2) With an H classification in the MAK list or TRGS 900 without a corresponding R phrase,  $W=100$  must be selected. If one of the R phrases 20, 21 or 22 is available, the effect potential must be selected in accordance with this R phrase.
- 3) Use the maximum value for W in each case (from the most critical R phrase or 100/GW). Where effects taken as a basis for an R phrase provide a major justification for the level of the air limit value, the judgement can be made via 100/GW and this R phrase does not need to be taken into account. This can be taken from the reasons for the air limit values.
- 4) With a classification as Sh, Sa or Sah in the MAK values list or TRGS 900 without a corresponding R phrase,  $W=500$  must be selected. If one of the R phrases R 42, R 43 or R42/43 is available, the effect potential must be selected in accordance with this R phrase.

(4) If no data or experience is available with respect to skin sensitisation or chronic toxicity for the substance to be substituted and for the substitute substance, and both have only been accorded the effect factor on the basis of the lacking data or experience, this endpoint and the corresponding effect factor will not be taken into account.

(5) In the case of substances with a number of the properties listed the property with the highest value must be referred to. Combination phrases – where these are not listed in the table – must be regarded as a compilation of individual R phrases, e.g. R39/26 as R39 and R26. R68 is only referred to for an assessment if it does not appear in a combination phrase.

## 2.2 The effect factor ( $W_Z$ ) for preparations

(1)  $W_Z$  is basically obtained by adding the W factors for the constituents according to the proportion of the preparation they account for.  $W_Z$  for preparations with the constituents A, B, C, ... the ideal approach is to calculate with the formula

$$W_Z = W_A \times P_A + W_B \times P_B + W_C \times P_C + \dots$$

where  $P_A, P_B, P_C, \dots = \text{percentage}/100$ .

(2) The  $W_Z$  may not be determined on the basis of the preparation's labelling. It is appropriate for the W factor of preparations to be determined by the supplier or manufacturer, since the latter has more exact knowledge of the composition of the preparation. It should be possible to comprehend the level of the W factor from the information in the safety data sheet.

(3) If the user still has to calculate  $W_Z$  from the data in the safety data sheet, for concentration ranges (e.g. 10-25%) the highest value (here 25%) must be taken for the calculation. Even if a total content of 100% is obtained in doing this (e.g. substance A 10–25%, substance B 75–90%), there should be no recalculation down to 100%. If the total content for the substances given in the safety data sheet is less than 100%, the figure must be extrapolated accordingly.

(4) With multi-component products the effect factors of the component with the higher  $W$  factors must be referred to for a comparison with a substitute solution (in the case of containers involving forced mixing, the mean value of the components' effect factor must be used).

### **2.3 Assessment of the $W$ factors**

(1) The effect factor model relates to toxic properties. Where decisions are to be taken on substitute substances, the physicochemical properties, environmental hazards, and exposure and application conditions must be assessed separately.

(2) The use of a substitute solution must be checked all the more closely, the greater the quotient from the effect factors of the existing solution and the substitute solution.

(3) Basically small differences in the effect factors are only an argument in favour of the substitute substance if the data situation for the substitute solution is similarly positive to that for the substance to be substituted.

(4) With a ratio of effect factors for substance used to substitute substance of less than 10, other reasons for the use of the substitute substance should be used. If the effect factor of the product used is at least ten times as great as that of the substitute product, there must be important reasons for not using the substitute substance.

## **Annex 3 to TRGS 600**

### **Criteria for the realisation of substitution:**

#### **Reasons for considering the operational use of substitute solutions and for an extended assessment**

##### **1 Reasons for considering the operational use of substitute solutions**

(1) The following remarks are intended to provide employers in particular with reasons for considering the operational use of substitute solutions (see Number 5.3 of the TRGS). The check is conducted when it has been established that the changes envisaged

1. actually reduce the substance-related risk (see Number 5.2) and
2. are technically suitable (see Number 5.1).

(2) The following table shows relevant operational factors (with sub-points given as examples) which experience shows may be influenced by the use of substitute substances and substitute processes.

(3) In terms of the business aspect a distinction is drawn typically between variable and fixed costs. The table gives the user indications of which costs may possibly be influenced by the substitute solution.

(4) The allocation of the cost blocks in terms of variable and fixed fractions depends mainly on the organisation of the company and must be individually adjusted accordingly. Thus fixed costs, for example a change in personnel requirement due to the use of sub-contractors or similar, may under certain circumstances be variabilised, whereas storage costs may possibly represent fixed costs through an investment in a new warehouse.

(5) In addition to the costs, the table contains other factors which are difficult to register in terms of cost, but which may quite definitely be relevant for decisions with a long-term effect. Whether, in what direction and to what extent influencing factors are affected by the intended substitute solution depends essentially on the individual parameters of the companies (e.g. handling of other hazardous substances, work organisation, technical standard etc.).

(6) The influencing factors shown can basically be applied to all kinds of substitute solutions, in other words for

1. the use of substitute substances and/or
2. the application of substitute processes.

(7) In most cases it is sufficient to describe the influencing factors qualitatively (positive influence/no influence/negative influence). It is important that all factors be considered and that the relevant sub-points be selected and documented, even if they prove not to be relevant in the specific case or if there is no change in the factor. A comparison of selected individual costs (e.g. price of the substance currently used as against that of the substitute substance) is typically not sufficient.

Table: Reasons for considering the operational use of substitute solutions

As far as possible all influencing factors should be considered and relevant sub-points selected. For each influencing factor, where relevant broken down according to sub-points, it should at least be documented qualitatively whether the impact of the substitute solution is positive (+), negative (-) or neutral (0). If there are a number of conceivable substitute solutions the table may be extended or multiplied.

Influencing factors		Change due to the substitute solution ++/+/0/-/-- or estimate of costs	Remarks
<b>variable costs:</b>			
1.	<b>Costs for substance used</b> Where relevant take account of costs for auxiliaries and consumables.		
2.	<b>Storage costs</b>		
3.	<b>Transport costs</b> e.g. costs for packing, freight rates etc.		
4.	<b>Disposal costs</b> e.g. costs for recycling of materials, and for treatment of waste, effluent and exhaust air		
5.	<b>Energy costs</b>		
6.	<b>Insurance costs</b> Etc.		
<b>fixed costs:</b>			
7.	<b>Costs for R&amp;D</b> Development and adjustment of the substitute solution in the value chain		
8.	<b>Plant costs</b> Investments in the production plant		
9.	<b>Personnel costs</b> e.g. salaries, costs for further training, etc.		
10.	<b>Costs for risk management:</b> – technical measures – organisational measures – personal measures e.g. structural measures, ventilation measures, where relevant need for additional personnel, workplace measurements, personal protective equipment, etc.		
11.	<b>Costs for occupational health care</b>		
12.	<b>Costs for work management systems and for the fulfilment of statutory conditions</b> e.g. ISO certification, hazard substances register, registrations, licences, etc.		
13.	<b>Distribution costs</b> etc.		
<b>other influencing factors</b> (where relevant company-related factors not describable in terms of cost):			
	a. public perception, company image, etc.		
	b. employee satisfaction, motivation, etc.		
	c. advantageous product labelling, quality seal, etc.		
	etc.		
<b>other relevant factors</b> (if necessary supplement on a company- and case-related basis)			

<b>final assessment:</b>	
–	substitute solution operationally not suitable because ...
–	substitute solution introduced ....
–	new check by ....
–	or free text

(8) On the basis of a qualitative description of the influencing factors it is possible in many cases to make a clear decision. Otherwise individual or multiple factors should be examined more closely.

(9) If none of the influencing factors changes towards the negative, the advantage of the substitute solution is obvious. The changes envisaged must be initiated without delay.

(10) Even if individual influencing factors are affected negatively, the substitute solution may still be advantageous as a whole. If a majority of the factors are affected negatively, it will depend on the operational parameters what relative weight will be accorded to the positively and negatively affected factors in the final decision. It is not possible to formulate rigid assessment rules.

(11) It must be emphasized, however, that higher costs incurred for a substitute solution may not automatically result in a "do not use" assessment. In particular if the substances to be replaced trigger a high risk, the reduction of risk must be given greater weight.

## 2 Reasons for considering an extended assessment

(1) For far-reaching decisions (e.g. substitution objectives beyond the company, development of new product lines, group-wide restrictions (black lists)) the company-related criteria described above are not sufficient.

(2) Apart from the assessment of health and physicochemical risks and of the technical suitability of the substitute solution, the environmentally related, social and economic impact over a product's whole life cycle is important.

(3) The results of an extended assessment should accompany the development of product or process alternatives where far-reaching decisions are being taken. Extended assessments should examine a large number of criteria, balanced in terms of the life cycle, and they should thus give a holistic assessment of possible consequences of product substitutions. They can also analyse previously ignored negative or positive effects of the existing processes through the entire value chain.

(4) To take account systematically and in a comparable fashion as many relevant aspects as possible, a large number of parameters must be covered and expressed in terms of figures. For this purpose it is now possible to make use of efficient and tried-and-tested expert methods capable of analysing social and economic consequences in the preparatory phase.

(5) Before using expert methods, it should be checked whether and how the models cover the economic, ecological and social criteria, convert them into figures and assess them. To facilitate sustainable decisions, it is very important that these criteria be applied at all relevant stages of a substance's life cycle.

(6) The models should take account of the following stages of the life cycle:

1. manufacture, extraction and transport of the raw material,
2. further processing of the raw material to make products,
3. use or consumption of the products, including the care and maintenance effort,
4. recycling, commercial utilisation or disposal of substance or products.

(7) Basically relevant criteria include, for example, the toxicological profile of the input substances and/or intermediates, the energy consumption, emissions, the ecotoxicological profile, the availability of the substances, and depending on the problem many other and more specific criteria. The social effects considered for the extended assessment can also be described in terms of a number of criteria, according to the problems involved. The relevant points may, for example, be: the number of the workplaces connected with the product or substance, the quality of work or the health hazards typically linked to this work.

(8) Depending on the number of phases of the substance's life cycle which are examined and the data available or used, differently far-reaching descriptions of the substance and of the chances and risks involved in its use are possible.

(9) Expert models can support decisions on substitution or on building up a product line in the fields of marketing, research, strategy and also policy. For this purpose they must be capable of presenting their results in a transparent form and plausibly.

(10) One example of such an expert model is SEEBalance®. This model visualises its results in a special three-dimensional presentation, a cube called SEECube®. In the three-dimensional space, the economic assessment is shown on the first axis, the environmental assessment on the second and the social assessment on the third. Overall advantageous alternatives are then shown in the right-hand upper quadrant and they represent the preferred alternatives for the substitution decision. In this way different alternatives can be sorted and prioritised at a glance. In the course of the next few years such expert models will presumably be developed further and applied more intensively in the framework of REACH. What needs to be checked is how far such models can also be used for the requirements of this TRGS (see for example [http://www.baua.de/nn\\_54910/de/Themen-von-A-Z/Gefahrstoffe/Tagungen/Substitution/pdf/Vortrag-04.pdf](http://www.baua.de/nn_54910/de/Themen-von-A-Z/Gefahrstoffe/Tagungen/Substitution/pdf/Vortrag-04.pdf))

## **Annex 4 to TRGS 600**

### **Procedure adopted in the formulation of substitution recommendations for hazardous substances, activities or processes**

When formulating substitution recommendations, the content of the present TRGS must be observed. This annex contains, in addition to the specific procedures as described in the other annexes, basic aspects and aids for locating knowledge sources for specific substitution solutions with respect to hazardous substances.

#### **1 Analysis of the substitution task**

There are three different types of substitution.

##### **1.1 Replacement**

In the simplest case, substitution takes the form of a 1:1 replacement of a substance already in use by a different, non-hazardous or less hazardous substances or by a known process in which non-hazardous or less hazardous substances are used. Here it is often merely necessary to notify the companies involved so that existing solutions become common practice.

##### **1.2 Adaptation**

In the second case a 1:1 replacement is not possible, but reference processes and application procedures for the substitution solution from individual companies in the sector or transferable solutions from other sectors are available. The substitution is in many cases both a problem of information and a problem of acceptance on the part of those companies which have not as yet dealt with this substitution solution adequately. Often adaptation developments are necessary to enable reference processes to be transferred successfully to the majority of the companies involved in the particular sector. For this purpose a detailed technical search is necessary as is the performance of tasks relating to the transfer of technologies and knowledge. Often substitution cannot be implemented in a short time, comprehensively and definitively. But it can be initiated in the form of sub-tasks and concluded mostly in a medium-term process (orientation 3–7 years).

##### **1.3 Research and development**

The most difficult case arises when there are no substitution solutions or corresponding processes at all. Then more or less fundamental, laborious research and development tasks in the chemical or technical field are necessary. However, the procedures and assessment criteria described in this TRGS and its annexes can also be applied beneficially when dealing with such basic questions.

## **2 Problem definition – consideration of chances and risks with respect to substitution possibilities**

(1) An essential precondition for successful work is that a concrete task be set. If there are different substitution possibilities, their evident advantages and risks must be weighed up systematically and transparently. In addition to application of the criteria from Number 5 of this TRGS it is meaningful to identify possible driving and inhibiting influences for or against individual solutions (e.g. consumer acceptance, standardisation, patents). It is also absolutely essential in the problem definition phase to agree on the meaning of the terms to be used in the ensuing discussion.

(2) The great advantage of substitution is the possibility it provides of basically reducing the overall risk potential of chemical substances or processes. This can also reduce the effort required to comply with a large number of statutory and costly protective measures, which otherwise regulate the activities involving hazardous substances.

(3) Risks may arise from substitution when the possible effects of substitution solutions have not been adequately tested. This applies with respect to the technical effects which a substitution can always trigger as a change in the substance basis of a process or to the change in the risk spectrum which may be involved in substitution solutions (e.g. occupational safety and health, climate protection, consumer protection).

(4) One basic problem is that there is typically less information available on the new substance or new process than on the previous solution. This may concern the assessment of risk where test data may be missing (this will be improved by REACH) and also the assessment of the technical efficiency of the substitution solution in practice. While the effects of most occupational safety and health measures remain restricted to the company, the replacement of a substance can have an impact on the whole product or the whole value chain and hence also on suppliers or customers.

(5) A higher price and the effort involved in operational adjustments can also be obstacles in the initial introductory phase for substitution solutions. But an examination of the medium-term total costs for the product or process concerned is often a suitable means of putting this problem into perspective.

## **3 Involvement of specialists**

(1) In order to analyse and process various aspects it may be necessary to involve specialists with an adequate knowledge of different aspects of the substitution check and in formulating substitution solutions. Relevant qualifications may, for example, include knowledge of

1. risk due to substances – health, safety and environmental properties,
2. process engineering and practical production experience,
3. risk assessment and the effort required for protective measures,
4. the effects of substitution on the value chain (e.g. customer acceptance),
5. the content of standards and regulations.

(2) In addition information which is available throughout the whole process chain (e.g. manufacturers of machines, purchasers of products, pre-suppliers) should be used.

## 4 Sequence when formulating substitution recommendations

(1) Annex 1 "Flow chart" provides an orientation with respect to the sequence of the project stages in the formulation of substitution solutions. Assessment and decision-making aids for establishing work packages and for structuring the discussion are provided in Annexes 2 (Comparative assessment of the health and safety hazards) and 3 (Criteria for the realisation of substitution – Reasons for considering the operational use of substitution solutions and for an extended assessment). In the establishment of goals, different problem-solving approaches, where available, should be discussed with open result alongside one another. Sub-tasks, such as the health and environmental assessment, should be identified at an early stage, be allocated resources and scheduled.

(2) When drawing up substitution solutions it is particularly important to inform the specialist public early, since the merely putting the question can trigger innovative impulses and in the discussion often broaden again the information base.

## 5 References to knowledge sources

In addition to the involvement of specialists, a search should be conducted of generally available knowledge sources when formulating substitution solutions. Below are some examples of such knowledge sources. They require different things with respect to the user's prior knowledge, and some of them should only be used where adequate specialist qualifications are held. The following collection is not exhaustive (as at 1/2008).

### 5.1 Databases concerning substitute substances and substitute processes

1. Gefahrstoffe im Griff <http://www.gefahrstoffe-im-griff.de/8.htm> Structured portal with data sources on all questions of hazardous substance management; recommended starting point for the search; specific window "Substitute substances/Substitute processes" available; links and describes most of the relevant databases, also contains specific substitution recommendations
2. Gisbau <http://www.gisbau.de/giscodes/Liste/INDEX.HTM> Access through product groups for construction products and construction by-products; contains specific section on substitute substances - substitute products – substitute processes
3. BG-Druck und Papier <http://www.bgdp.de/pages/service/download/arbeitsicherheit.htm> Annually updated list with recommended and permissible washing and cleaning agents for offset printing and list of anti set-off spray powders
4. Portal for component cleaning <http://129.217.206.133/rc1/index.php> Access via key words: list of processes etc., helpful in substitution by change of process (co-ordinated by: Faculty of Machine Elements, University of Dortmund)
5. Cleantool [http://www.cleantool.org/de/teilereinigung\\_prozesse.php](http://www.cleantool.org/de/teilereinigung_prozesse.php) Access according to the criteria of material, mass, dimensions, geometry, annual throughput, dirt type and further treatment of the component. The metal cleaning processes can be compared using an integrated assessment tool.

6. OEKOpro chemical database <http://www.oekopro.de/search.php?l=DE> Access possible via uses – it is possible to locate different substances for an intended use, including details of industrial sectors
7. Cooling lubricants components on-line information system <http://www.fobig.de/arbeitsfelder/KSS.html> Access via substance; a working party consisting of representatives of the consumer association Verbraucherkreis Industrieschmierstoffe (VKIS), the trade association Verband Schmierstoffindustrie (VSI) and the trade union IG Metall (IGM) accompanied the development of the on-line information system
8. "CatSub" – catalogue with examples for substitution (in Danish) <http://www.catsub.dk/> sorted according to industrial sector; more than 230 examples of substitutions carried out, co-financed by the European Agency of Occupational Safety and Health in Bilbao
9. "Branchenregelungen" [http://www.arbeitsschutz-center.net/branchenregelungen/brachenregelungen\\_nach\\_produkten/branchenregelungen-branchen\\_produkte.html](http://www.arbeitsschutz-center.net/branchenregelungen/brachenregelungen_nach_produkten/branchenregelungen-branchen_produkte.html) Recommendations for hazardous substance management and good practice, arranged according to industrial sectors
10. Hat-Map Information on Hazardous Chemicals and Occupational Diseases <http://hazmap.nlm.nih.gov/> Toxicological information, but access possible via substance groups so that possible alternative substances are offered

## 5.2 Databases with substance information

1. GESTIS - substances database <http://biade.itrust.de/biade/lpext.dll?f=templates&fn=main-h.htm> Access via the substance; substance information; references to "good practice", some specific references to restrictions on use and substitute solutions
2. GSBL – Common substance data pool of the Federal Government and the Länder (federal states) <http://www.gsbl.de/> Access via the substance; substance information in the structure of the safety data sheet; references to uses, but none to substitute solutions
3. Substance databases of the Federal Republic of Germany <http://www.stoffdaten-deutschland.de/> Portal for databases; access via the substance; IGS-Publik contains substance data, uses, restrictions, but no specific recommendations for substitute solutions
4. BG Chemie – GisChem hazardous substances information system <http://www.gischem.de/> Access via the substance or some activities, product groups, sectors; substance information; some references to "good practice", no specific references to substitute solutions
5. GDL – hazardous substance database of the Länder (federal states) <http://www.gefahrstoff-info.de/> Access via the substance; linked to GESTIS; substance information; some practical aids for references to "good practice" at [http://lasi.osha.de/de/gfx/publications/lasi\\_publications.php](http://lasi.osha.de/de/gfx/publications/lasi_publications.php) no specific references to substitute solutions
6. euSDB safety data sheets – search <http://www.eusdb.de/> Access via product name

(exact or word fragment), substance or CAS: the database contains a search index for approx. 190 000 safety data sheets from various manufacturers primarily from the field of laboratory chemicals and gases, a good addition for an in-depth search, or in the case of missing or outdated safety data sheets

### 5.3 International databases (mostly on the effect of substances)

1. Chemicals | Human Health | Acute Exposure Guideline Levels (AEGs) | OPPT | US EPA <http://www.epa.gov/oppt/aegl/pubs/chemlist.htm> Substance information; access via the substance
2. ECB – ESIS (European Chemical Substances Information System) <http://ecb.jrc.it/ESIS/> Substance information; access via the substance; various databases on substance properties and occurrence in European regulations
3. IPCS INCHEM <http://www.inchem.org/> Substance information; access via the substance or CAS number: fast international access to an assessment of chemicals used worldwide which may also occur in the form of environmental and food contamination, very helpful as an aid to substitution decisions (co-ordinated by the Canadian Centre for Occupational Health and Safety (CCOHS), English and French)
4. Kemi PRIO [http://www.kemi.se/templates/PRIOEngframes\\_\\_\\_4144.aspx](http://www.kemi.se/templates/PRIOEngframes___4144.aspx) Substance properties; lists of undesirable substances; strategies for substitution but no specific recommendations
5. <http://toxnet.nlm.nih.gov/> Database portal for mostly toxicological information with access via the substance name, but also individual databases on the use of substances
6. KEMI Riskline <http://apps.kemi.se/riskline/index.htm> Substance information; access via the substance; only bibliographic database with exclusively peer reviewed information on environment and health
7. TOXNET <http://toxnet.nlm.nih.gov/> Databases on toxicology, hazardous chemicals, environmental health, and toxic releases (HSDB, Toxline etc.) substance information; access via the substance or CAS number: fast international access to an assessment of chemicals used worldwide which may also occur in the form of environmental and food contamination, very helpful as an aid to substitution decisions (co-ordinated by the National Library of Medicine of the USA, English)
8. Pubmed <http://www.ncbi.nlm.nih.gov/sites/entrez> Service of the U.S. National Library of Medicine including over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s.
9. OECD HPV-Database <http://cs3-hq.oecd.org/scripts/hpv/> DB tracks all High Production Volume chemicals through the process of investigation in the programme on the Investigation of Existing Chemicals