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Technical Rules for Hazardous Substances	Recommended course of action for determining the state of the art	TRGS 460

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

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.

Contents

1 Scope of application

(1) These technical rules describe a step-by-step approach to the determination of the state of the art by the AGS, which can be used in compiling Technical Rules, for example. It also provides assistance to companies and supervisory authorities for deciding whether systems meet the state of the art.

(2) These rules set out article 2 paragraph 12 of the Hazardous Substances Ordinance in concrete terms.

(3) Some examples of the approach are published at www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS-460.html.

2 Determining the state of the art – procedural recommendation –

The AGS can determine the state of the art by applying the five steps listed below (Fig. 1).

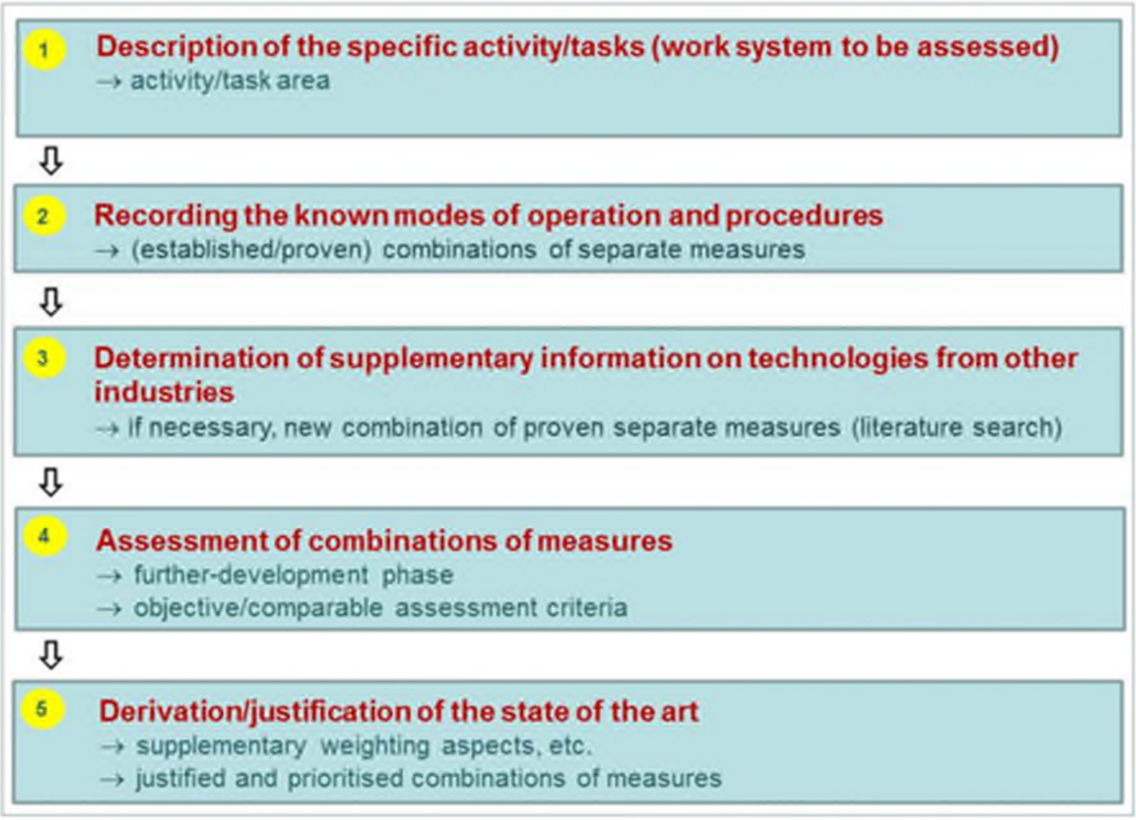


Fig. 1 Five steps to determining the state of the art

2.1 Step 1 – Description of the activity in the work system that is to be assessed

2.1.1 Aim – Step 1

In the determination of the state of the art, it is to be clarified in the first step whether the modes of operation and procedures to be compared are used for the same workplace activity or not. Only modes of operation and procedures that are used to perform the same activity can be compared with one another.

2.2.2 Explanation

(1) In practice, activities can be performed through different modes of operation and procedures. These depend on, among other things, the industry to which the company belongs, the company size (industry, trades), and the relevance of this activity (main or auxiliary activity). Especially when many different processes were considered, it can be assumed that at least one of the practised modes of operation and procedures corresponds to the state of the art.

(2) The clear description of these activities involving hazardous substances (scope of application of the Hazardous Substances Ordinance) is therefore a prerequisite for comparing the various modes of operation and procedures that have been proven in practice. So that this description is clear and comprehensible for all those concerned, it is to be pre-

pared according to specified criteria and in a standardised, specialised framework (= work system). The necessary delimitation of the work system (i.e. which aspects are to be considered and which are not) is shown in Fig. 2-1 of the scientific background paper (Annex 2).

(3) The work system[1] encompasses two levels:

1. the production flows ("daily" processes) that are subject to hazardous-substances legislation and, on the other hand,

2. the life cycle of the system(s) ("one-off" processes).

In workplace practice, the term "work task" is often equated with the term "activity".

(4) The following aspects (non-exhaustive list) describe the activity within the work system and represent a recommendation and guidance on delimiting the activity from other activities.

1. Aim of the activity (clearly identified work task), e.g. "Processing mineral materials (brick factory) with hand-operated work equipment".
2. What industry is this activity usually assigned to?
3. Is the activity performed
   a) within the framework of proper operation, including setup, or
   b) exclusively in the event of a breakdown or during maintenance?
4. What substances (hazardous substances) are used or are formed during the activity?
5. What are their properties?
6. What protective measures are present (e.g. extraction near to the source, air-conditioning measures)?
7. What types of exposure arise during the activity? For how long is this activity usually carried out (e.g. for a short time/length of shift)?
8. What work equipment is used for the activity (including a description and reference to the degree of automation)?
9. What specific qualification requirements are prescribed for employees carrying out the activity (e.g. competence in fumigation)?
10. What activity-specific hazards and exposures are present according to the results of the risk assessment?
11. Other requirements for the activity.

2.2 Step 2 – Recording the known modes of operation and procedures

2.2.1 Aim – Step 2

(1) The aim is to depict the modes of operation and procedures (including the company's own existing solution) which are customary (i.e. practically implemented) in the respective industry using the practical aid.

[1]Including static work systems, i.e. those without time components.

(2) The practical aid is available to the user as a blank document (see Annex 1). It is used to transmit the modes of operation and procedures in a standardised written form and to describe them appropriately.

2.2.2 Explanation

(1) In this step, the customary modes of operation and procedures – that are used for the same activity – are systematically recorded. The customary modes of operation and procedures are the combinations of individual measures that are used/known in practice. These are inseparably connected to the use of certain work equipment, implements, materials, energy, etc. As a result, these are often accompanied by specific exposure levels, required protective measures and also, as the case may be, conflicting protection issues, etc.

(2) For example, the following current sources can be used to identify the customary modes of operation and procedures:

1. substance and process-specific Technical Rules, e.g. TRGS 505 “Lead”;
2. regulations and industry rules from the German Social Accident Insurance (DGUV);
3. supplementary comparison methods (e.g. the column model according to TRGS 600 “Substitution”, Annex 2 No. 1 to that document);
4. state guidelines/information documents from the law-enforcement authorities;
5. (harmonised) standards, pre-standards;
6. scientific documents, expert reports;
7. articles from industry and trade journals;
8. information documents from the industrial associations/guilds/chambers of trade;
9. other standardisation products (e.g. VDI Standards, DIN SPEC).

(3) It is also advisable to designate these sources of information according to their origin, in terms of a potential territorial restriction, e.g. the description of a mode of operation and procedure that is not designated as a European standard, but rather only as a British standard.

(4) Determining the state of the art may require a more in-depth process of gathering information than is needed for the risk assessment pursuant to article 6 of the Hazardous Substances Ordinance. Detailed research requirements are to be met depending on the specialisation of the modes of operation and procedures to be compared. In this regard, however, it is important to take into account the reasonableness of the effort.

(5) Using the practical aid (Annex 1) is recommended for describing the necessary assessment parameters. On the one hand, this template, which was designed to aid completion, summarises the required assessment and/or comparison criteria in a clear form. On the other hand, the modes of operation and procedures that are to be compared at a later stage can be entered directly into this practical aid. Querying the assessment criteria by using the practical aid makes clear which criteria, if any, must be determined at a later stage (e.g. exposure levels) in order to corroborate a comparison of the modes of operation and procedures in step 4 in respect of technical content. Further assessment parameters can be added easily.

2.3 Step 3 – Determining supplementary information on technologies from other industries

2.3.1 Aim – Step 3

Description of customary modes of operation and procedures in other industries but which are used for the same activity, e.g. comparison of the modes of operation and procedures of the activity “transfer of dust-forming chemicals” in the chemical industry and the food-stuffs industry.

2.3.2 Explanation

(1) Whereas step 2 determined and listed the customary modes of operation and procedures, step 3 looks “beyond the horizon” at other industries and therefore at other technologies. This includes looking at the branch of industry from the point of view of trades and vice versa.

(2) In this way, potential innovative strength of other industries is used to transfer sustainable and already implemented modes of operation and procedures (or even just individual measures/aspects) to one's own industry and thus to further develop the state of the art here too.

(3) The resulting combination of individual measures from customary – and, as the case may be, cross-industry – measures with aspects of the determined modes of operation and procedures is not, however, aimed at achieving complete redevelopments of modes of operation and procedures, but rather combines tried-and-tested measures previously belonging to various industries into one solution.

(4) It should be noted at this point that only procedures that have already been implemented into workplace practice and that have been tried and tested can be considered as either customary or cross-industry modes of operation and procedures.

(5) This clarification serves to clearly delimit the state of the art from the state of science and technology (a different level of protection and measures!). The latter is aimed at qualitative further development, e.g. by including procedures that have been derived scientifically but that have not yet been applied in practice. The determined cross-industry modes of operation and procedures are also to be transferred to the practical aid. The reasonableness of the required effort can be used as a cut-off criterion.

2.4 Step 4 – Assessment of the combination of measures/comparison

2.4.1 Aim – Step 4

In this step, the compiled modes of operation and procedures are to be compared with one another. For this purpose, the assessment parameters and criteria must be individually weighted by a group of experts that is either internal (e.g. relevant technical departments in cooperation with the occupational-safety committee) or industry-wide (organised by, for example, guilds, chambers of trade, trade or industry associations).

2.4.2 Explanation

(1) The weighting of the individual assessment parameters may vary from one case to the next but it should be possible to justify it (e.g. technical or socio-economic justification). It is advisable to conduct this weighting, as well as the subsequent comparison, in an expert group consisting of several persons from as many different fields as possible and not to leave it to a single person's way of thinking.

(2) Due to their legally binding force, the following assessment principles are to be strictly adhered to and weighted accordingly:

1. principle of substitution,
2. minimisation of exposure,
3. restrictions and prohibitions on use,
4. compliance with national threshold values and other assessment criteria (e.g. pursuant to article 20 paragraph 3 of the Hazardous Substances Ordinance),
5. reliability of measures (e.g. ranking of measures: technology before organisation).

2.4.3 Explanation

(1) As a rule, an inherently safe measure is to be assessed higher than a protective measure that takes effect as an addition (retrofitted into the workplace).

(2) A small number of measures with high availability can achieve a greater increase in safety than a large number of measures with low availability.

(3) Adding measures arbitrarily is not always sensible, as these measures can give rise to new sources of hazard (interactions) and can therefore be linked to lower reliability of the overall system.

(4) A small increase in safety for a potentially high investment is to be examined critically – with a view to the efficient implementation of measures.

(5) The process described here for determining the state of the art is primarily focused on the Hazardous Substances Ordinance. Assessment parameters from other areas of protection (e.g. patient protection, environmental protection, patent protection, fire protection, product safety, protection of specific groups of persons) can also be important in individual cases, e.g. due to their legally binding force or legal obligation.

(6) The modes of operation and procedures should be assessed taking account of the listed mandatory assessment principles and with the inclusion of further assessment parameters in consideration of the proportionality of the effort entailed in the measure and the increase in safety.

(7) If the combination of measures leads to obvious interactions or new hazards, these are to be evaluated by means of a comparison. For this purpose, a risk assessment must be made of the “new” mode of operation and procedure before the comparison is conducted. These results then supplement the information (assessment parameters) in the practical aid (Annex 1), e.g. with regard to the necessary protective measures (ranking), the exposure level, or the duration of exposure in normal operation. The state of the art can be further developed by combining measures.

2.5 Step 5 – Identifying and justifying the state of the art

2.5.1 Aim – Step 5

The decision-making process, in which at least one mode of operation or procedure of the state of the art is explained, is to be justified, and the individual weighting is to be set out in a comprehensible manner.

2.5.2 Explanation

(1) It is advisable to furnish the identification of the state of the art with an issue date.

(2) Not every small change/improvement of the procedure automatically leads to a new definition of the state of the art (see Annex 2 “Scientific background paper” for further information).

Annex 1 to TRGS 460
Practical aid (matrix for the user)

Date of revision/time of determination:				
WORK TASK:				
PROCESS DESCRIPTION/ **ASSESSMENT CRITERIA:**	**PROCESS A** **Short title:**	**PROCESS B** **Short title:**	**PROCESS C** **Short title:**	**PROCESS D** **Short title:**
Profile (activity, industry)				
A - Description of the WORK SYSTEM				
a1) **Details of the WORK SYSTEM** (e.g. workplace/working environment,work equipment, ventilation technology, qualifications of the employees)				
a2) **Details of the PRODUCTION FLOW** (e.g. raw materials, other materials, possible material changes, material properties)				
B - SYSTEM OPERATION				
Quality of the AVAILABLE DATA (usable/additional data required):				
b1) **NORMAL OPERATION** - Exposure data - Peak exposures				
b2) **Foreseeable MISUSE** - Exposure data - Peak exposures				

PROCESS DESCRIPTION/ ASSESSMENT CRITERIA:	PROCESS A Short title:	PROCESS B Short title:	PROCESS C Short title:	PROCESS D Short title:
b3) **MAINTENANCE processes** - Exposure data - Peak exposures				
b4) **Possible BREAKDOWNS** - Exposure data - Peak exposures				
b5) **FIGURES (or link)** (sketches/photos/functional drawings)				
C - ASPECTS of ASSESSMENT RELATING to HAZARDOUS SUBSTANCES LEGISLATION				
c1) **RELIABILITY of the existing protective measures** (e.g. voluntary nature of the measure) acc. to T-O-P ranking				
c2) **Type and level of assessment criterion** (e.g. OEL, BLV, MAK, DNEL)				
c3) **Assessment of inhalative exposure**				
c4) **Assessment of dermal exposure**				
c5) **Assessment of physical/ chemical hazard**				

PROCESS DESCRIPTION/ ASSESSMENT CRITERIA:	PROCESS A Short title:	PROCESS B Short title:	PROCESS C Short title:	PROCESS D Short title:
D - OTHER ASPECTS of the ASSESSMENT				
d1) **Conflicting assessment criteria from occupational safety and health** (e.g. protection objectives)				
d2) **Other national or standardised targets** (Consequences: limiting of the process)				
d3) **Existing patent protection** (Consequences: limiting of the process)				
d4) **Assessment aspects from other protection areas** (e.g. consumer, environmental, patient protection)				
d5) **Socio-economic and economic aspects of assessment** (see TRGS 600)				
E - Other COMMENTS/NOTES on the ASSESSMENT CRITERIA used				
F - REFERENCES/SOURCES				

PROCESS DESCRIPTION/ ASSESSMENT CRITERIA:	PROCESS A Short title:	PROCESS B Short title:	PROCESS C Short title:	PROCESS D Short title:
JUSTIFICATION for the ASSESSMENT (e.g. possible weighting of the assessment criteria)				
RESULT of the ASSESSMENT				
USAGE INSTRUCTIONS, where appropriate				

Annex 2 to TRGS 460
Scientific background paper

1 Initial situation and aim of the subject

The term “state of the art” is intended to allow relevant stakeholders to keep their workplace in step with constantly changing technological progress (level of knowledge) and the current legal requirements.

“State of the art” is an indeterminate legal concept with historical roots in engineering sciences. It is an essential and accepted element of the lexicon of German engineering tradition.

Currently, it appears to be generally accepted that the “state of the art” does not offer stakeholders a quantifiable target but rather a criterion or assessment aid for defining measures or specifying requirements.

The term is used in various protection-related fields of law (environmental protection, product safety, occupational safety), as well as in other areas such as patent law.

Above all, technical committees, the experts appointed to them and case-law are responsible for the technical-content related and sector-specific interpretation of the term “state of the art”, alongside the staff to which it is addressed.

To this day, the so-called Kalkar judgement of the Federal Constitutional Court (BVerfG) on 8th August 1978 on the use of atomic energy[2] forms an important basis for the interpretation of the different protection levels.

For example, the court stated in 1978 that:

> *"… given the complex and multifaceted problems presented by technical issues and processes, it is not generally possible for [the legislature] to define in detail all of the safety-related requirements that the respective systems or items are to meet. In fields [...] where constant innovations are likely due to rapid technical development, the legislature would also have to bring these up to date on an ongoing basis if it had in fact laid down a detailed regulation."*

In its judgement, for the purpose of further clarification, the court formulated the following three clauses of technology in greater detail and compared them with one another (increasing safety level):

- generally accepted rules of technology,
- state of the art,
- state of science and technology.

The laws and regulations of occupational-safety legislation are fundamentally based on the state of the art. In the Hazardous Substances Ordinance, the requirement to comply with the state of the art is based on the following definition (article 2 paragraph 12):

> *"The state of the art means the state of development of advanced processes, equipment or modes of operation which make it appear certain that a measure is suitable in practical terms for protecting the health and safety of workers. In the determination of the state of the art, reference shall be made in particular to comparable processes, equipment or modes of operation which have been successfully tested in practice. The same applies with respect to the requirements regarding occupational medicine and workplace hygiene."*

[2] BVerfGE 49, 89 Kalkar I, Order of the Second Senate on 8th August 1978 -- 2 BvL 8/77,

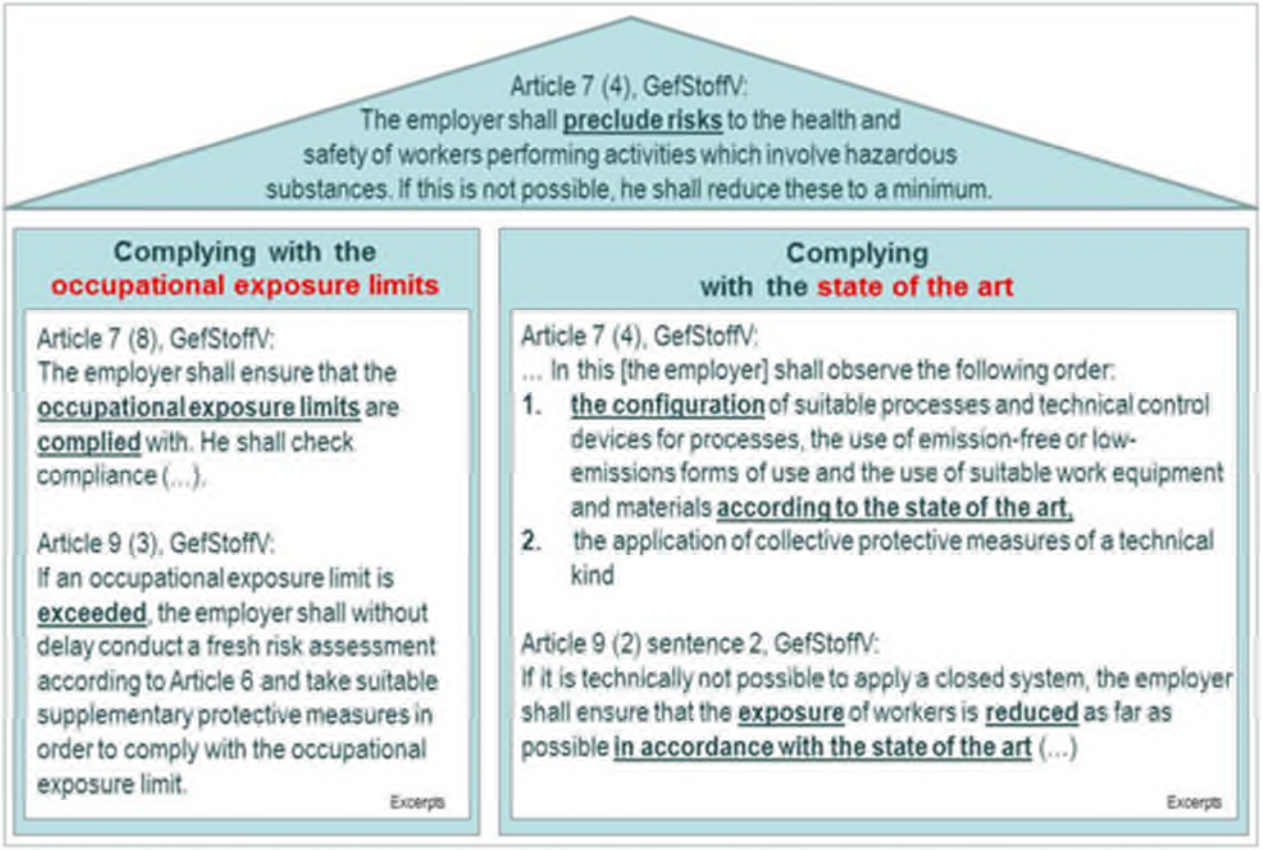


Fig. 1-1 Protection strategies of the Hazardous Substances Ordinance for conforming with the ordinance

Evidence of compliance with the Hazardous Substances Ordinance can be provided through two different protection strategies; see Fig. 1-1. Here, the quantitative, left-hand pillar – compliance with occupational exposure limits (OELs) – is given precedence; needs for action are identified in the event of non-compliance with the OEL.

If no OEL has been published for the substance that is envisaged for the activity (e.g. in the case of carcinogenic substances), the strategy in the right-hand pillar – compliance with the state of the art – is to be implemented in the workplace. The requirement to comply with the state of the art is also aimed at the planning/design of the work system (see Chapter 3 onwards). This means that, already in the basic obligations pursuant to article 7 paragraph 4 of the Hazardous Substances Ordinance, the state of the art (hereinafter abbreviated as SOTA) must be applied as a priority in the design of suitable processes, incl. technical control devices, the application of emission-free or low-emission forms of use and the use of suitable work equipment and materials.

With this “two-pillar model”, the Hazardous Substances Ordinance differs from other individual ordinances implementing the Occupational Safety and Health Act (ArbSchG) in that it places the two protection strategies parallel to one another (compliance with the occupational exposure limits and compliance with the state of the art). This cannot be achieved in other individual ordinances implementing the Occupational Safety and Health Act because in those ordinances the SOTA is primarily aimed at the requirement to ensure that threshold values (e.g. noise limits) are not exceeded.

However, mixing both protection strategies under the Hazardous Substances Ordinance has proven problematic with regard to companies' desire for legal certainty.

Supplementary instruments or guidance must be offered to the users of the law with reference to the specific activity in order to allow them:

- to identify their concrete, company-specific modes of operation and procedures in a comprehensible manner;
- to assess the customary and cross-industry modes of operation and procedures in a comprehensible manner; and, as a result,
- to compare these modes of operation and procedures with the aim of determining the state of the art and to implement it in the workplace with due regard to the right to keep existing inventory/standards.

The statements in the Technical Rules for Hazardous Substances (TRGS) represent a central form of guidance in the national hazardous-substances legislation. In this regard, the task of identifying the state of the art – particularly within the framework of compiling Technical Rules – and of describing it with reference to the specific activity falls to the Committee on Hazardous Substances (AGS) in accordance with article 20 paragraph 3 of the Hazardous Substances Ordinance.

Pursuant to article 7 paragraph 2 of the Hazardous Substances Ordinance, these descriptions assert the principle of presumption. This means that the ordinance's protection objectives are achieved if these technical and/or organisational modes of operation and procedures are implemented. The person applying the technical rules is, in general, guided by the understanding that this link between technical rule and presumption of conformity has unrestricted validity aside from the ordinance.

The conceptual definition of the state of the art according to article 2 paragraph 12 of the Hazardous Substances Ordinance contains numerous statements and a great deal of textual support intended to assist the recipient in their concrete workplace activity.

It was determined within the framework of a brief study (online survey) at Bergische Universität Wuppertal[3] whether this legislative conceptual specification is comprehensible and helpful to the relevant technical experts in advising the employer. Here, one aim among others was to ascertain how much room for technical and application-specific interpretation is given to this conceptual specification by the experts – who are, at the same time, the persons to whom the Hazardous Substances Ordinance is addressed. As a result of the analysis, it was determined that, among other findings:

- 57% of experts were able to classify “state of the art” into its conceptual environment; and
- 54% of experts consider a process “successfully tried in practice” to be a measure or decision for the purpose of their own company’s success (e.g. by reviewing effectiveness). (Excerpt)

Compared to the legal definition of the SOTA (Hazardous Substances Ordinance), the point of view of the surveyed experts with regard to the interpretation and meaning of the term covers a very diverse spectrum of interpretation. This diversity of interpretation has proven problematic in that it makes it harder for the employer to derive concrete workplace processes and to compare solutions, and, as a result, leads to an individual solution that lacks transparency. An “isolated solution” of this kind cannot adequately offer the desired legal certainty to the employer or to the persons to whom the Hazardous Substances Ordinance is addressed.

[3] Anonymous online survey of 237 occupational-safety stakeholders within the framework of:
DUNKEL, S.: “Ermittlung und Bewertung der Deutungsvielfalt der Technikklausel Stand der Technik” [Determination and assessment of the diversity of interpretation of the 'state of the art' clause of technology] (unpublished), Bergische Universität Wuppertal, Safety Engineering/Occupational Safety Group, Wuppertal 2009

It is therefore helpful for the implementation of this requirement of the Hazardous Substances Ordinance to thematically delimit or confine the field of application of the state of the art, underpinning this with technical and methodological clarifications and assistance in deriving comprehensible and measurable decisions.

With this scientific background paper (Annex 2 to TRGS 460), the aim is to substantiate the recommended course of action of these technical rules from a technical and methodological standpoint.

In addition to this positioning concerning technical content, another objective is to minimise existing "areas of uncertainty" in the determination of the SOTA at company level.

In the long term, this is linked to the desire to develop a common understanding of the technical clause "state of the art" on the basis of a considered perception of the problems on the part of the stakeholders.

2 Introduction to the subject

The state of the art (SOTA) describes a workplace procedure through a bundle of real measures. This aggregation of measures depicts a technical level in a process-dependent manner. In general, it exists for every technical process[4] in definable system boundaries (work system) and can usually be determined and described, e.g. for the

- contactless application of biocidal products;
- extraction of hardwood dusts with a capture efficiency of xx%;
- stress-relief heat treatment for reduction of residual stress in steel;
- welding of cast-aluminium materials in shipbuilding; or
- manual removal of asbestos-cement panels.

The measures generally consist of separate technical and/or organisational measures. In this regard, the state of the art is in principle independent and detached from the legal permissibility of a solution, e.g. within the framework of occupational safety and health regulations. The practicable (protection) level of the SOTA that has been proven in practice does not, in principle, apply any ranking or weighting to the proportions of technical and organisational measures. These proportions can vary depending on the individual case, i.e. the SOTA can be realised through a high proportion of technical and lower proportion of organisational measures or, equally, through a high proportion of organisational measures and a significantly lower proportion of technical measures.
The SOTA is therefore the de facto description of practicable, means-oriented action without reference to a risk convention. This does not in principle affect the T-O-P (Technology – Organisation – Personal) model that is to be practised in occupational safety for the additive evaluation and decision-making process for determining the state of the art, however, it should be taken into account that a higher proportion of technical protective measures is generally associated with greater reliability.

Conversely, the concrete company-specific modes of operation and procedures, as well as the modes of operation and procedures that are customary in the respective industry, are operating conditions in the company that can actually be found in practice on site (see Fig. 2-1). They also describe a bundle of technical and/or organisational measures.

[4] A technical process is, in general, the implementation of a technology with all technical and organisational requirements (measures). In the context of engineering sciences, the general concept of a process includes processes, facilities or modes of operation.

In accordance with the applied processes, the details of these modes of operation and procedures (combination of separate measures) can exhibit a vastly different technical and organisational level.

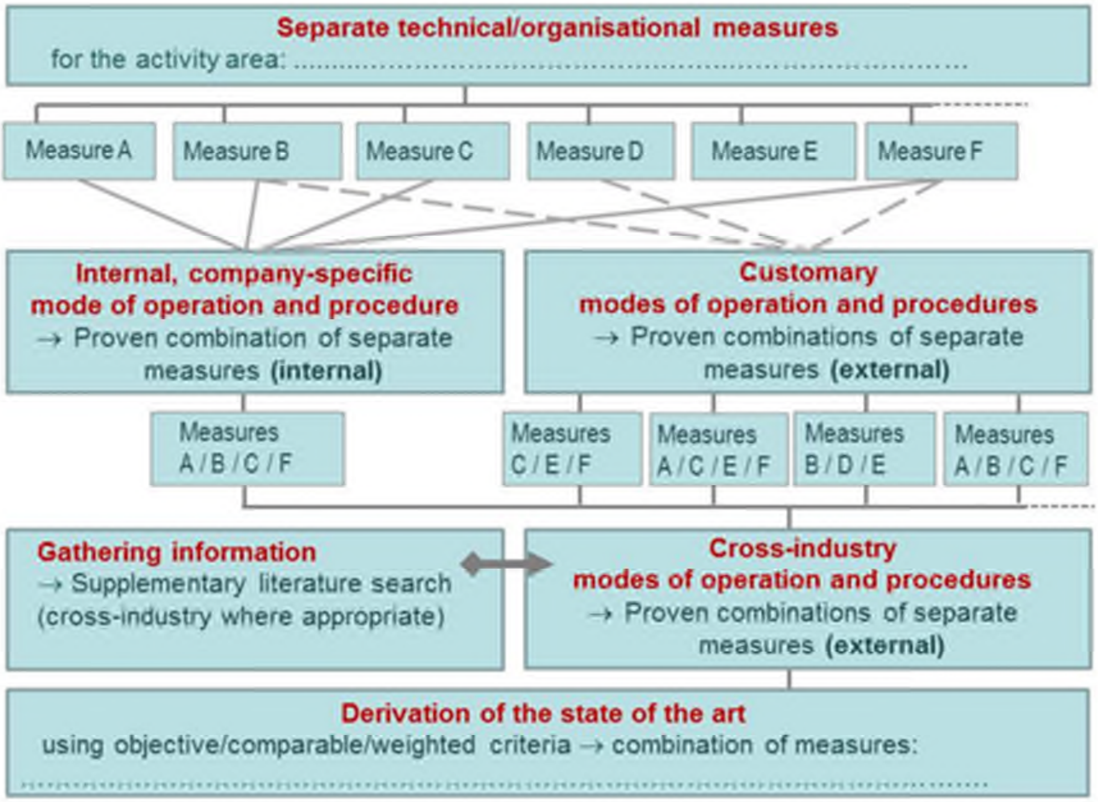


Fig. 2-1 Basic approach to determining the state of the art

In principle, the following applies:

The SOTA is abstracted from the process operators' concrete, customary modes of operation and procedures. Exceptions are possible that necessitate the implementation of a cross-industry SOTA based on the assessment criteria used, the proportionality and the increase in safety.

The legislator specifies in laws and ordinances what technical (protection) level the addressee must strive for, realise and/or demonstrate; for example, it issues occupational safety-policy rules for the replacement of products containing asbestos or for activities involving ammonium nitrate and organic peroxides. The legislator can therefore require the SOTA as a protection objective (e.g. closed system) but cannot define the SOTA in terms of its practical execution (the concrete bundle of measures). The fact that the legislator sets this requirement does not automatically lead to a change of the SOTA. Establishing a legal requirement of this kind can, however, promote or encourage the further development of the SOTA in a targeted manner. The improvement rule pursuant to the Occupational Safety and Health Act represents such a requirement.

In addition, there is a special arrangement in the Hazardous Substances Ordinance in which the legislator also demands compliance with the SOTA as a protection strategy for those envisaged substances for which no occupational exposure limit has been established.

The interface between the two requirements (state of the art/law) lies in the portrayal of the current SOTA in the regulations, technical rules or technical specifications, and above all in the harmonised standards (product safety/machine safety).

Therefore, the existing SOTA at the time of specification – with its capacity for description and determination – becomes the convention, the stipulation in the legal construct, even though its specific characteristic/quality is fundamentally independent of the regulation.

Both technical rules (non-legislative regulation of occupational safety) and product-specific harmonised standards (manifestations of product-safety legislation) describe the SOTA at the time of their publication. Since these publications are compiled based on consensus, the acceptance by professionals exists at this point in time with regard to suitability in the above sense.

Through the scope of application of the respective regulation (e.g. the Hazardous Substances Ordinance), the SOTA takes on a technical connection and therefore requires a specialised work system with static and dynamic components.

3 The static work system model

3.1 The 2D model

In order to determine the SOTA required in the Hazardous Substances Ordinance in a comprehensible manner, it is first necessary to define the work system (with a focus on the activity) for the company-specific mode of operation and procedure. This static description of the work system allows transparent delimitation of the activities that must be included in the determination of the company-specific mode of operation and procedure, as well as in the subsequent determination of the SOTA.

The two-dimensional work system (see Fig. 3-1) considers:

- the production flows (“daily” processes) that are subject to hazardous-substances legislation, on the one hand; and
- the life cycle of the system(s) (one-off processes), on the other.

In addition to this, higher-level framework conditions (e.g. infrastructures, employees) are to be considered.

The production flow, as the horizontal axis,

> describes the materials and energy fed into the work system, the processing within the work system, the generated output/product residues, and the resulting waste.

The life cycle, on the vertical axis,

> relates to the work equipment and systems that are included in the work system, which are planned, realised and commissioned and then, after use, decommissioned, dismantled and disposed of.

The work system encompasses the following work-system elements:

- the spatial workplace;
- the work implements contained therein (e.g. solder);
- the work equipment and processes (e.g. systems, machinery, means of transport, tools);
- the employees with their individual characteristics, dispositions and qualifications (incl. for the work task to be performed); and

- the environment and/or the environmental conditions.

Activities as defined by article 2 paragraph 5 of the Hazardous Substances Ordinance, which may or may not correspond to the intended use, are carried out in work systems according to the work task that has been set and the defined workflow.

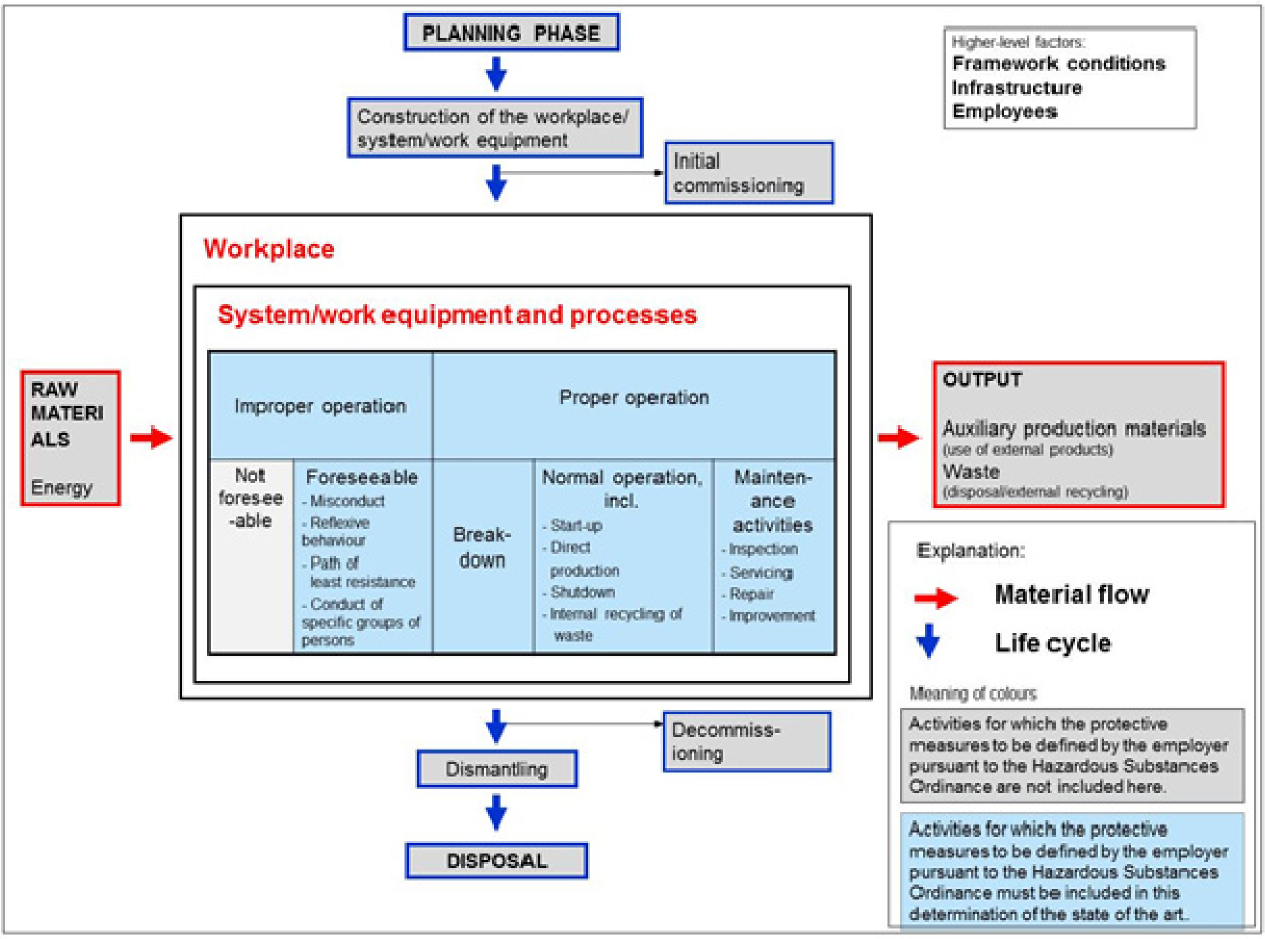


Fig. 3-1 Delimitation of the state-of-the-art work system in hazardous substances legislation

In this scientific background paper, the work task (an element of the work system) corresponds to the activity as defined by article 2 paragraph 5 of the Hazardous Substances Ordinance. Integrating the work-system elements allows the task to be unambiguously described and identified (e.g. transferring sodium hypochlorite solution from tanks into stationary storage containers, disinfecting areas in health-care facilities). This is a key prerequisite for the comparability of activities in the determination of the state of the art (particularly in the case of cross-industry modes of operation and procedures).

3.2 Work-system elements that fall within the definition of the SOTA

The scope of the definition of a “state of the art” in hazardous-substances legislation includes the work-system elements listed in the work system (see Fig. 3-2 or, in Fig. 3-1, the workplace boxes with a grey/blue background). Accordingly, activities involving hazardous substances are generally carried out in direct and inseparable conjunction with the work equipment/processes and facilities that are needed for the activities. The interaction of the work-system elements characterises the activities and, in principle, allows two types of activities to be differentiated:

- the proper use of hazardous substances, work equipment and working processes; and

- the improper but reasonably foreseeable use of, above all, work equipment in conjunction with materials, work implements/processes, and modes of operation.

The definition of a state of the art always relates to a closed work system for one activity. In this regard, upstream or downstream operations such as disposing of consumables or setting up the production system can, where applicable, be left out of the consideration for the state of the art of the production process.

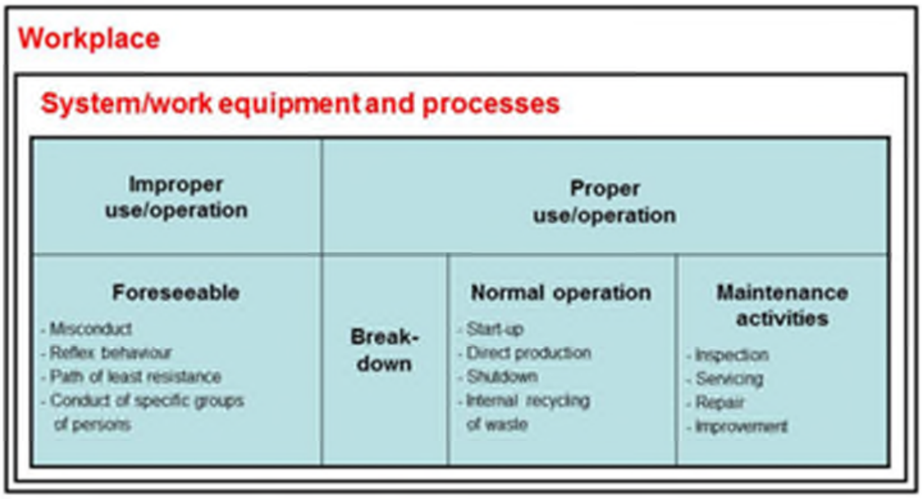


Fig. 3-2 The confined static work system (scope of application)

4 Introduction to the dynamic process level

In addition to the components of PRODUCTION FLOW and LIFE CYCLE, the presented work system, consisting of the specialised and customary modes of operation and procedures and the derived state of the art, is characterised and influenced by a further component: the TIME or DYNAMICS. The dynamics can take place on two levels.

4.1 Internal dynamics

The static work system (Fig. 3-2), as demarcated from the overall system (Fig. 3-1), can change in a company over the course of time. A new risk assessment is to be carried out if this change is brought about and influenced by internal company factors – e.g. staff changes, building modifications, new system components as a result of modified product dimensions, and modernisation of obsolete systems (upgrading) with new, more powerful components. These modifications are not usually decisive for the identification or further development of the SOTA and therefore will not be considered further. In individual cases, a modification of this kind can also change the SOTA.

4.2 External dynamics

The company's own work system (company-specific mode of operation and procedure) must be reassessed on the basis of gathered information if the work system needs to be modified as a result of external influences (with consequences for the entire industry), e.g. as a result of knowledge on new processes or technical innovations, or as a result of modified legal constraints (e.g. revision of the Hazardous Incident Ordinance [StörfallV]).

Modified market mechanisms can also provide the driving external force for economic reasons and can sustainably change the SOTA, e.g. due to rising raw-material prices.

For the employer, this requirement becomes formally identifiable through, among other things, new workplace standards, trade publications (e.g. scientific publications, industry information, association newsletters, etc.), announcements of new/modified regulations and rules, and the availability of technical innovations (e.g. processes) that are already in operation. In this regard, the time at which information becomes available can differ by varying degrees from the time of assessment of one's own work system (*ex ante*[5] assessment, problems relating to right to keep existing inventory/standards). For example, a decisive technical modification of one's own system or the system in question can, over the course of time, represent the underlying criterion for all other customary – i.e. SOTA-determining – modes of operation and procedures (internal dynamics lead to external dynamics – pioneering role).

The information-gathering process is used to evaluate all variables that influence the work system, with the aim of:

- mapping the changes in the work system (external dynamics);
- evaluating and assessing the available company-specific and customary modes of operation and procedures; and
- comparing the modes of operation and procedures with one another.

In this regard, it is important to clarify whether this determination in principle also necessitates or permits cross-industry comparisons, i.e. the inclusion of modes of operation and procedures from other industries with comparable processes, technologies, working practices and areas of activity that are associated with a significant increase in safety.

The limits and/or expansion of the determination are to be established not only in an industry-specific manner but also based on territory, i.e. it is to be clarified whether the situation calls for an internationally oriented gathering of information, a determination within the scope of application of European law, or simply a national determination with regard to the customary modes of operation and procedures. The size of the industry and also the nature of its penetration are possible criteria that provide grounds for territorial confinement.

It must also be stated whether modes of operation and procedures in industrial areas can be compared with modes of operation and procedures in non-industrial areas (e.g. in trades) but that are linked to the same activity, e.g. aluminium welding, in order to determine the SOTA. A differentiation is needed because, among other reasons, current safety-

[5] ***ex ante*** denotes a point in time prior to an action that is to be assessed. In an *ex ante* consideration, the assessment is based on the information that could be identified prior to the action. Conversely, an *ex post* consideration also takes into account factors that only became identifiable afterwards.

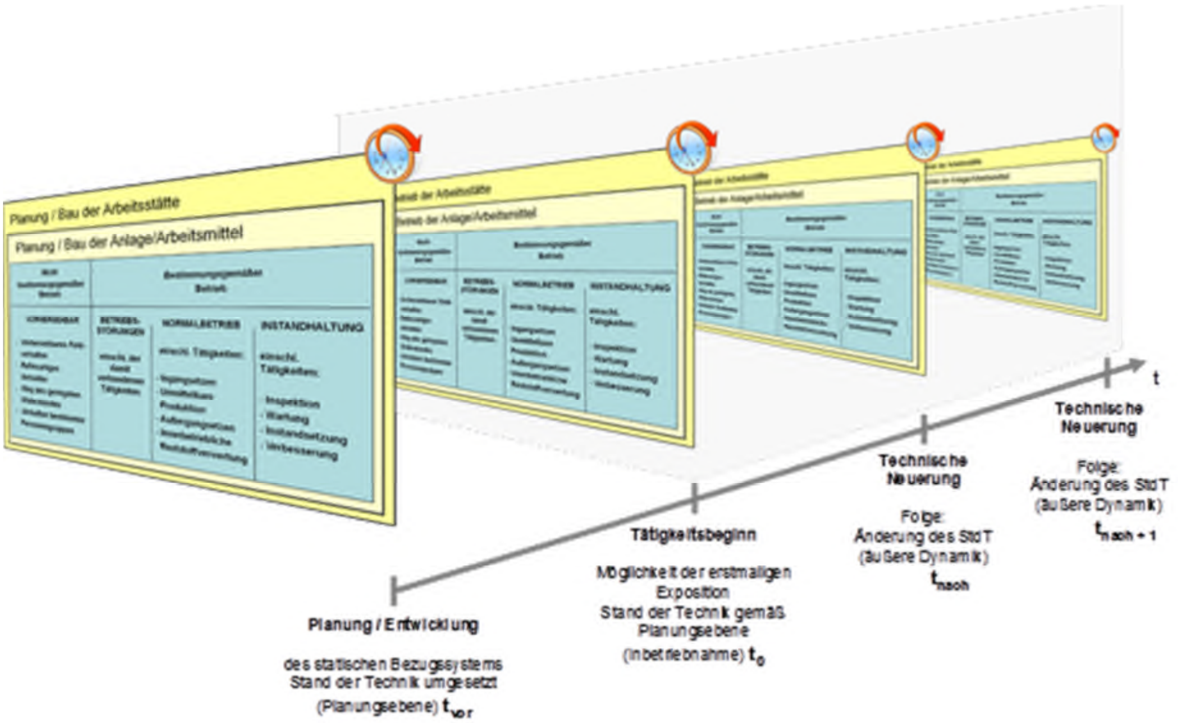
related knowledge (specialist knowledge) and the existing possibilities for making investments (e.g. within the framework of retrofits) are not generally comparable.

4.2.1 The dynamic work system at the time of planning t_{before}

The consideration of the life cycle of an item of work equipment, a process, or even a workplace starts already in the planning phase, i.e. outside of the confined static work system (see Fig. 3-1). In practice, the original composition and design of the work system (i.e. the practical implementation of the SOTA in a real work system) are definitively specified in this phase. At this point, the planned company-specific mode of operation and procedure corresponds to the SOTA. This point in time in the planning process is denoted as t_{before} ($t_{before} < t_0$); see Fig. 4-1.

4.2.2 The dynamic work system in the period under review $t_0 \rightarrow t_{after\rightarrow}$ $t_{after+1}$

The scope of application of the Hazardous Substances Ordinance is aimed at employees' activities involving hazardous substances. With the established activity-specific work system, the scope of application of the state of the art is also portrayed in the Hazardous Substances Ordinance.



Planning/development	Start of activity	Technical innovation	Technical innovation
of the static reference system State of the art implemented (planning level) $\mathbf{t_{before}}$	Possibility of initial exposure State of the art acc. to planning level (commissioning) $\mathbf{t_0}$	Consequence: modification of the SOTA (external dynamics) $\mathbf{t_{after}}$	Consequence: modification of the SOTA (external dynamics) $\mathbf{t_{after+1}}$

Fig. 4-1 Dynamic work system of the SOTA in the period under review $t_{before\rightarrow}$ $t_{after+1}$

The relevant turning point in the work system for the hazard due to hazardous substances is the time at which the activity begins and, therefore, the time of the first possible exposure. In the model, this is designated as t_0; see Fig. 4-1.

The process of external dynamics and the associated externally initiated assessment of the customary modes of operation and procedures can result in adaptation of the company-specific mode of operation and procedure and, therefore, adaptation to the SOTA (see Fig. 4-1, t_{after}, $t_{after+1}$). The point in time or the time window for assessment of the company's own work system depends on numerous beneficial and impeding influencing factors, e.g.:

- the influence of the media,
- the competition within the industry,
- the possibility of increasing effectiveness,
- the legally binding nature, and finally also
- the company philosophy.

A readjustment of the SOTA must at least lead to the same residual hazard in line with the legally binding stipulation of a protection objective or to a lower residual hazard (substance exposure, mechanical hazards, etc.) in line with the improvement rule.

Within the framework of the determination of possible processes, technologies and measures that determine the SOTA in the dynamic process, and that can therefore also modify it, it is necessary to include all industry-specific modes of operation and procedures and potential cross-industry alternatives in the multidimensional evaluation and subsequent decision-making process.

The multidimensional character of the evaluation process means decisions must be made on a case-by-case basis, especially if a hazard is to be minimised (e.g. minimising the exposure, making the measure more binding) at the expense of combating another hazard (increasing the thermal hazard) or another protection objective (e.g. relating to environmental or patient protection).

The inclusion of cross-industry modes of operation and procedures is especially advisable if:

- the industry is very small (e.g. only a few manufacturers of a speciality product in Germany);
- the work system is readily transferable to other industries (e.g. the activity “Filling tanks”: this work system is present in, among others, the chemical industry, the foodstuffs industry and the oil industry);
- the increase in safety or the innovation potential is very high.

Care should be taken to ensure that the customary modes of operation and procedures to be compared are not “preselected”. It is entirely possible that modes of operation and procedures are included in this determination phase that are suitable according to the regulatory area of hazardous-substance protection (occupational safety) but that are a priori impermissible based on regulations from other areas (e.g. technical specifications from environmental law requirements, standards from building law).

5 Decision-making aids/strategies for the evaluation process

The systematic comparison of the company-specific, customary and, where appropriate, cross-industry modes of operation and procedures (activity description, work system with production and material flow) can be fundamentally characterised by a formal level and a technical-content level.

5.1 Formal level

The formal level is realised by describing the company-specific and customary modes of operation and procedures using the assessment criteria provided.

The portrayal of both customary and potential cross-industry modes of operation and procedures necessitates an additional and, as the case may be, extensive information-gathering process (focused activity with hazardous substances).

Within the framework of this information-gathering process, account is to be taken of, among others, the following current sources (partial list):

- substance and process-specific Technical Rules, e.g. TRGS 505 “Lead”;
- regulations and industry rules from the German Social Accident Insurance (DGUV);
- supplementary comparison methods (e.g. the column model according to TRGS 600 “Substitution”, Annex 2 No. 1);
- state guidelines/information materials from the law-enforcement authorities;
- (harmonised) standards, pre-standards;
- scientific documents, expert reports;
- articles from industry and trade journals;
- information materials from the industrial associations/guilds/chambers of trade;
- other standardisation products (e.g. VDI Standards, DIN SPEC).

In addition, the necessary scope of information gathering is to be defined, e.g. through inclusion of European or even international solutions (territorial link).

Detailed research requirements are to be met depending on the specialisation of the modes of operation and procedures to be compared, e.g. through inclusion of test reports on successful testing in practice.

The practical aid (see Annex 1) is used to describe the company-specific and customary modes of operation and procedures in a standardised fashion. The comparison that can be conducted in this way of the different modes of operation and procedures allows a comprehensible database or basis for assessment to be compiled for the objective of “Determining the state of the art”.

The preceding description of the work system supports the necessary characterisation of the work system with selected details. Examples include the topics of workplace, working environment, work equipment and ventilation technology, as well as details of the production flow. It also allows information to be added depending on the individual case, e.g. details of the specific separation technology or the ventilation system present.

The following assessment criteria can be used here:

- exposure data and peak exposures, taking account of different operating states;
- health- or risk-based assessment criteria;

- exposure times (permanent, e.g. over the entire shift/brief, e.g. transfers several times per shift/or sporadic, e.g. once a week as required);
- availability/effectiveness of the measures (proportion of automatic/voluntary solutions);
- conflicting assessment aspects;
- practical experience in the application of the modes of operation and procedures;
- modified hazard profiles (new hazards);
- regulations in other topic areas of occupational safety, e.g. workplace safety, workplaces, biological agents;
- other legal areas beyond the Hazardous Substances Ordinance that are to be considered, e.g. medical-device legislation, environmental law (hazardous-incident law), consumer-protection law, patent law;
- requirements or restrictions by standards, patents, processes according to GLP, GMP;
- economic and socio-economic aspects;
- other assessment aspects that are relevant to the decision, e.g. the quality of the output;
- successful testing of the mode of operation and procedure in practice etc.;
- acceptance by the persons carrying out or affected by the activity.

5.2 Technical/content level

In order to derive the SOTA from the portrayed company-specific and customary modes of operation and procedures, it is necessary to individually weight and evaluate the assessment criteria, as well as other aspects, within the framework of the technical-content level. The evaluation process results in a case-by-case decision based on weighted assessment criteria and the following aspects.

In this process, high priority is to be placed on legally enshrined factors (e.g. compliance with the occupational exposure limits or other national threshold and target values, the minimisation rule, usage in a closed system). Company philosophies, authorities' recommendations, etc. are also to be included within the framework of the weighting.

The consideration should also include identification of the “exposure data” assessment criterion. Unlike in the risk assessment, the remark “No data present”, which might accompany this, should not necessarily be assessed critically; nor should this considered mode of operation and procedure be withdrawn from the evaluation process.

Although trends are exhibited by, in particular, very new and advanced modes of operation and procedures that are included in the assessment of the SOTA (e.g. in relation to the expected exposure values/minimisation), these trends are not usually available in quantified form. With regard to the innovative strength of this measure and the further development of the state of the art, the producer of these innovative modes of operation and procedures should collect the necessary data promptly in order to drive forward its establishment in the market.

It is not advisable to derive the SOTA solely based on the specification of exposure percentiles (50th or 95th percentile). Although the further development of the SOTA necessitates continuous minimisation of exposure in line with the improvement rule (pursuant to the Occupational Safety and Health Act), the numerous influencing variables mean that the evaluation process is based on multiple assessment criteria, e.g. the level of technical and organisational measures, the effectiveness of the measures (in terms of their automatic/voluntary nature), the number of persons affected, protection objectives from other protection areas, etc.

A definable exposure level (or exposure band, as the case may be) can be achieved by applying a concrete level of measures. Consideration solely of exposure data and percentiles without a clear link to applied measures usually does not allow explicit conclusions to be drawn for the possible SOTA.

In addition, a weighting of measures in terms of the T-O-P model (Technology - Organisation – Personal) should be performed during the evaluation process of the company-specific and customary modes of operation and procedures. This follows the ranking-oriented approach of giving the technical protective measures priority over organisational or collective protective measures (e.g. use of PPE) because of the higher availability/effectiveness associated with technical measures and also their generally assumed greater reliability. In this regard, an automatic technical protective measure (e.g. integrated extraction, positive locking) is also to be given priority over a voluntary technical protective measure (e.g. flexible extraction). Current knowledge on the effectiveness of technical protective measures is to be included in the consideration.

The strategy of “the more measures, the safer it is” does not define the approach to linking technical, organisation and personal measures. In some cases, this way of thinking might even be counterproductive, i.e. associated with a decrease in the protection level (e.g. due to interfering air flows). The focus should be on consistent orientation towards achieving a recognisable increase in safety that is, at the same time, proportionate.

The point in time at which the SOTA is defined or derived can also be of central significance. Thus, a review after a so-called “technology push” can drive forward the establishment of the “new” SOTA in the industry. Furthermore, it is also possible to use the review of the customary modes of operation and procedures to identify the companies with a low standard of health protection if a SOTA has generally been established in the industry for a long time.

6 Classification of the state of the art into the hazardous-substances framework

6.1 Proportionality and right to keep existing inventory/standards

The dynamic component of the state of the art means that the SOTA is continuously changing and, as a rule, improving. Depending on the breadth of the concept of comparability, the SOTA can change very rapidly.

This dynamic also exists in other areas of hazardous-substances legislation. For example, the current occupational exposure limits (protection strategies; see Fig. 1-1) are to be applied at all times, even if they have been significantly reduced due to new findings.

Modification of the SOTA, however, generally also affects the construction of a system or the technical components of a process. Any change that becomes necessary to the company-specific or customary modes of operation and procedures can thus entail significant costs.

In terms of regulation, however, account is to be taken here of the principle of proportionality stemming from procedural law (especially, in the narrower sense, in the form of the criterion of reasonableness). In applying this criterion, it cannot be demanded in general that every old system be adapted to every modification. Here, it should be checked in each case whether the success achieved through adaptation is proportionate to the respective costs, especially if the costs entailed in the event of retrofitting to meet the SOTA are higher than for new systems.

Because of the criterion of reasonableness, it must always be checked before need for adjustment is determined whether there is not a right to keep existing inventory/standards for old processes/equipment (including old systems) or old modes of operation. Here, the criteria can once again vary. A right to keep existing inventory/standards is more likely to apply to a structural installation than to the way in which an extraction system is adjusted or to the type of filter used. However, even if there is a right to keep existing inventory/standards, a need may arise for supplementary measures, e.g. of technical or organisational nature.

6.2 State of the art and minimisation rule

Pursuant to the Hazardous Substances Ordinance, the employer must reduce any hazards to the health and safety of employees to a minimum insofar as these cannot be ruled out.

TRGS 500 defines the hazard as being reduced to a minimum if, for example, the SOTA is met. The SOTA, as it is described in these technical rules, ensures in particular the lowest overall hazard for employees.

The statements “Compliance with/implementation of the state of the art” and “Satisfaction of the minimisation rule” are therefore to be considered as equivalent.

6.3 State of the art and process- and substance-related criteria according to TRGS 420

Only those measurements that were determined in working areas meeting the SOTA may be used as representative measurements for the determination of process- and substance-related criteria (VSKs) in accordance with TRGS 420. Only for these activities with protective measures that meet the SOTA is it then checked whether the existing occupational exposure limit, if applicable, is also met.

In this respect, the VSK concept mixes the two pillars within the framework of the two-pillar model and implicitly requires compliance with both protection strategies; see Fig. 1-1.

6.4 State of the art and REACH

As a European regulation for the placing of chemicals on the market, REACH requires the establishment of exposure scenarios for identified uses (10 tonnes/year and up). The exposure scenario, which is also to be enclosed with the safety data sheet, must exhibit an exposure below the DNEL value defined in each case. A description is to be provided of the measures for minimising exposure that are necessary for this purpose.

The result of this approach is that REACH only requires compliance with “threshold” values in the sense of the two-pillar model (see Fig. 1-1). There is absolutely no need to take a SOTA into consideration.