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Announcement on Hazardous Substances	Using REACH-information for health and safety at work	Announcement 409

The Announcements on Hazardous Substances 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 (BMAS) in the Joint Ministerial Gazette (GMBl).

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Scope

The present catalogue of questions and answers has to be seen in a REACH and OSH context. Its primary aim is to ensure that the contents of the safety data sheet are put to effective use for occupational safety and health purposes. The safety data sheet is the central tool for information transfer under REACH communicating more information than the previous safety data sheets.

It is addressed at employers as the persons responsible for all health and safety concerns. It is meant to enable employers to effectively use any additional information that REACH will provide for meeting their OSH responsibilities. This includes the identification of interfaces with the set of technical rules under the German hazardous substances legislation.

The questions and the answers are worded so as to reflect the various positions represented in the Committee on Hazardous Substances. But unlike a technical rule, the catalogue of questions and answers cannot be considered to enjoy presumption effect. However, some of the key statements in this catalogue are to be included in the technical rule TRGS 400 at a later stage.

The catalogue of questions and answers is not an exhaustive list of interfaces between the REACH Regulation and the German hazardous substances legislation. Adjustments and amendments will follow as soon as final information on specified aspects is available.

Catalogue of questions

The core issues of this catalogue of questions and answers are the following:

- What new information will REACH provide to the employer?
- How can this new information be used for health and safety purposes?
- Where are the interfaces between risk assessments and the exposure scenarios in the extended safety data sheet (eSDS)?
- What information does REACH not supply?

The catalogue of questions and answers does not cover REACH issues that are not related to safety and health at work; information on such issues can be obtained from numerous sources (cf. helpdesks). When referring to classification and labelling we follow the terminology of the GHS Regulation (EC No. 1272/2008, CLP Regulation).

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1 The safety data sheet (SDS) as the central tool for information transfer under REACH

Since 1 June 2007 safety data sheets have been regulated by the provisions of Regulation (EC) No. 1907/2006 (called the REACH Regulation in short).

Under REACH the safety data sheet is even more important than it was before. This applies in particular to the "extended safety data sheet" (eSDS) because of its direct link with the chemical safety report according to Article 14 of the REACH Regulation which specifies that the information in the safety data sheet must be consistent with the data in the chemical safety report. The eSDS is a safety data sheet that includes in an annex one or more exposure scenarios (ES) that have to be prepared under certain conditions in the framework of the chemical safety report as specified in the REACH Regulation. Since 1 June 2007 the safety data sheet has to be accompanied by an exposure scenario if the relevant substance has already been registered.

Article 31 of the REACH Regulation in conjunction with Annex II stipulates that a safety data sheet has to be supplied to downstream users or distributors

- when a substance or mixture meets the criteria for classification as dangerous in accordance with the CLP Regulation (EC) No. 1272/2008 or with Directives 67/548/EEC or 1999/45/EC, or
- meets the criteria for a PBT or vPvB substance, or
- when the substance as such or when present in a mixture has been placed on the candidate list[2] to be published by ECHA according to Article 59 (10) and this substance exceeds the concentration limits specified in Article 56 (6) of the REACH Regulation, or
- at the request of a downstream user, for mixtures that are not classified as dangerous, but contain at least one substance posing human health or environmental hazards, at least one PBT- or vPvB-substance or one substance on the candidate list above the concentration limits pursuant to Article 31 (3) of the REACH Regulation or one substance for which there is a Community workplace exposure limit.

The supplier has to ensure that the safety data sheet is technically correct and complete. The safety data sheet must enable users to take the necessary measures

[1] See transition periods for the registration requirements pursuant to Article 23 of the REACH Regulation.

regarding the protection of human health, workplace safety and the environment. Attention shall be paid to the fact that any actor in the supply chain shall help to identify intended uses in the context of the registration and include them in the safety data sheet. This applies to all stages of the lifecycle of the substance as resulting from manufacture and identified uses. The identified risks and the resulting risk management measures (RMMS) must also be included in the safety data sheet.

To ensure that the safety data sheets are useful in practice it is essential to have close communication between all actors, from manufacturers to users, on specific information provided in the chemical safety reports and in the safety data sheets, particularly as regards information on use, exposure and risk management measures.

Question 1.1: What changes have been introduced for the safety data sheet?

Answer: As compared to the previous provisions (Directive 91/155/EC) the REACH Regulation has changed the requirements for safety data sheets in several points. In formal terms, this concerns the sequence of information on composition and ingredients (now section 3, previously heading 2) and on potential hazards (now section 2, previously heading 3). Substantive changes in the REACH safety data sheet that are particularly relevant under health and safety aspects are shown in the following table:

Table 1: Additional or extended SDS components with relevance for health and safety at work

Sub-section in the SDS	Additional or extended elements that may be contained in a SDS	Number of the question in this catalogue under which more detailed information can be found
1.1 3.2	Registration number for substances Registered substances in mixtures	1.3
1.2	Indication of (identified) use(s)	1.6
1.2	Uses which the supplier advises against	2.3
8.1	Exposure limits under the aspects of human health (DNEL and DMEL) and environment (PNEC)	3.1–3.7
8.2	Protection measures	2.5, 4.1–4.4
15.1	Authorisation, restrictions	6.3–6.6
Annex	Exposure scenarios	1.4, 1.5

For a complete overview of all new information in a safety data sheet, see the ECHA Guidance for Downstream Users[3]

[2] http://echa.europa.eu/en/candidate-list-table
[3] ECHA "Guidance for Downstream Users": http://echa.europa.eu/documents/10162/17226/du_en.pdf, Table 25, New information for the safety data sheet, pp. 123-124

Question 1.2: May a safety data sheet which does not comply with the REACH format be used for risk assessment by the employer?

Answer: Yes, it is important for the employer to locate in the safety data sheet and take into consideration the information that they require for the risk assessment in accordance with TRGS 400, irrespective of the formal format of the safety data sheet.

With the coming into force of the REACH Regulation on 1 June 2007, the EU Directive 91/155/EEC ceased to be effective. The provisions governing safety data sheets were adopted into Article 31 and Annex II of the REACH Regulation with barely any amendments to their content. Deviations from the new provisions played no role for the risk assessment until 1 December 2010, as they were formal in nature.

On 1 December 2010, the requirements for the safety data sheet were amended in various aspects – including with regard to content – by Regulation (EU) No. 453/2010. Transition periods are provided for with regard to sell-off and mixtures already on the market. From 1 December 2012 at the latest, safety data sheets must meet the specifications set out in Annex II of the REACH Regulation in the form as amended by Regulation (EU) No. 453/2010.

Question 1.3: What is the relevance of the registration number in the safety data sheet?

Answer: REACH requires that, for substances subject to registration, the registration number shall be mentioned under section 1 of the safety data sheet. This indicates whether the substance has been registered and – to a certain degree – according to what specifications. For substances that have been registered as a transported isolated intermediate, for example, the registration number begins with the digits 08. These substances may only be used under strictly controlled conditions, which the user must confirm to the supplier. The registration number as such does not imply other direct health and safety obligations.

Where classified substances that are present in a mixture have to be mentioned under section 3 of the safety data sheet, the respective registration numbers must be indicated, if available. This does not imply obligations for the users of mixtures.

Question 1.4: Why does my safety data sheet have no annex?

Answer: Not all safety data sheets need to have an annex. Only those actors in the supply chain who are required to prepare a chemical safety report

according to Articles 14 or 37 of the REACH Regulation place the relevant exposure scenarios in an annex to the safety data sheet (extended safety data sheets = eSDS).

The chemical safety report has to include exposure scenarios only where a substance

- is manufactured or imported in quantities of ≥ 10 t/a per manufacturer/importer and
- meets the criteria for classification as dangerous or as a PBT or vPvB substance.

There will be no eSDS for substances that have not yet been registered (registration deadlines may be as late as 2018 depending on the substance).

As the preparation of exposure scenarios is not required for mixtures, the associated safety data sheets need not contain an annex.

According to Article 31 (7) of the REACH Regulation any downstream user who is not required to prepare a chemical safety report (because he uses substances supplied from within the EU for their identified uses) shall include the exposure scenarios, and add other relevant information, when compiling his own safety data sheet for identified uses. He may either submit the relevant information under the individual sections of the SDS itself (notably sections 7 and 8), or he may choose to place the requirements for safe handling in an exposure scenario annexed to his SDS.

Question 1.5: What information must be contained in the exposure scenario (ES) in the annex to the safety data sheet?

Answer: An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment (including the description of risk management measures and operational conditions. This means that the annex to the safety data sheet contains additional information e.g. on maximum concentrations in mixtures.

The following table shows the format of an ES as recommended in the ECHA guidance on information requirements (Part G).

Examples of exposure scenarios are given in the "Guidance for Downstream Users“[4].

Table 2: Exposure Scenario Format

ES section	Contents
1	Short title for exposure scenario
2	Description of processes/activities covered in the exposure scenario
Operational Conditions	
3	Duration and frequency of use
4.1	Physical form
4.2	Product specification
4.3	Maximum amount used per time or per activity
5	Other operational conditions determining exposure
Risk management measures for the different target groups	
6.1	Occupational measures
	Consumer-related measures
6.2	Environment-related measures
7	Waste-related measures
Prediction of exposure and evaluation of uses by downstream users	
8	Worker exposure
	Environmental exposure
	Consumer exposure
	Derived control values
	Models for exposure prediction
9	Adjustments of exposure predictions (Guidance on how the downstream user can evaluate whether he works within the conditions set in the exposure scenario.)

Answer 1.6: What is the respective meaning of the terms "use" and "identified use"?

Answer: Both terms are defined in Article 3 of the REACH Regulation (the definitions can also be found in Annex 1 to this catalogue.)

Regardless of whether a substance is subject to registration or not, the uses of the substance/mixture have to be listed under section 1.2 of the SDS as far as they are known to the persons preparing the SDS.

Where there are many possible uses, the safety data sheet does not have to indicate all uses, but only those that are relevant to the recipient of the safety data sheet. This shall include a brief description of what the substance or mixture actually does.

[4] see http://echa.europa.eu/documents/10162/17226/du_en.pdf.

There is no prescribed system for the description of uses and identified uses. However, it would be possible in both cases to resort to the descriptor system developed as an option for the description of identified uses in the framework of REACH; it is advised to work with this system. More information about this descriptor system can be found in the ECHA Guidance on Information Requirements[5].

Where an extended SDS (eSDS) is supplied (see Question 1.1), section 1.2 must contain information on all the identified uses relevant to the recipient of the eSDS. Such information must be consistent with the information set out in the annexed exposures scenarios.

2 Information in the (extended) safety data sheet relevant for OSH: Risk assessment and derivation of protection measures

The safety data sheet (SDS) invariably provides information necessary for carrying out risk assessments and for establishing protection measures. The extended safety data sheet (eSDS) includes, in an annex, further information in the form of exposure scenarios (ES).

When a user is supplied with an eSDS, i.e. an SDS to which an exposure scenario is attached, he has to assess whether his conditions of use are covered by that scenario. The details of such an assessment are described in the ECHA Guidance for Downstream Users[6]. Where the operational conditions are not covered by an ES, the downstream user may have to meet additional requirements under the REACH Regulation. In any case, the employer (downstream user) should take the risk management measures indicated in the SDS and ES into account in his risk assessment.

The following information provided in the ES is relevant in this context:

- title of the ES: the title may indicate areas of use (e.g. use in industry), product categories (e.g. coatings) and type of use (e.g spraying);
- conditions of use: e.g. type and duration of use of the substance, open or closed processes, quantities used, surroundings in which the substance is used (room size, temperature), large-scale/small-scale application;
- risk management measures: e.g. technical ventilation, extraction.

[5] http://echa.europa.eu/documents/10162/17224/information_requirements_part_d_en.pdf and http://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf

[6] see also ECHA Guidance for Downstream Users: Chapter 5 (see FN 4)

Question 2.1: What information can be found in the SDS and/or the eSDS that is necessary for complying with the obligations under the Hazardous Substances Ordinance?

Answer: The SDS and the ES provide information that are helpful for carrying out a risk assessment according to the Hazardous Substances Ordinance, notably for:

- establishing the protection measures
- checking the effectiveness of the protection measures.

In sections 7 "handling and storage" and 8 "exposure controls/personal protection", the SDS describes protection measures as risk management measures. OELs and DNELs may be found under section 8.1 "control parameters" as parameters for assessing the effectiveness of protection measures regarding air at the workplace.

Moreover, exposure scenarios are set out in an Annex to the eSDS. Section 6 ("Risk management measures – occupational measures") supplies further information, for instance on the anticipated effectiveness of the protection measures. This information has to be taken into account when developing or reviewing protection measures in connection with a risk assessment.

When the conditions of use set out in the ES are respected and when the risk management measures described there are applied, the REACH Regulation allows the assumption that all the measures are in place that are needed to ensure that the risks to human health, safety and the environment are adequately controlled[7].

In how far any additional requirements have to be fulfilled in context of risk assessments is discussed under Question 2.5.

Question 2.2: How can it be checked whether one's own use is covered by an exposure scenario?

Answer: Based on the information under SDS section 1.2 "Relevant identified uses of the substance or mixture and uses advised against" and the information given in the exposure scenario the user has to check whether his own use is covered and whether he can use the risk management measures from the SDS or the exposure scenario (ES) for his activities.

Even when one's own use is not explicitly mentioned in the ES, it may basically be covered by the ES. In any case, the user has to check whether his conditions of use are identical or comparable with the operational

conditions indicated in the ES (see Question 2.4). In case of doubt, in-depth compliance checks have to be made along the lines of the European REACH guidance for downstream users. In the end these checks may show compliance with the operational conditions indicating that one's own use is covered be the ES.

The interface between "own use" and "description of use in the SDS / short title for the ES" may produce numerous constellations. For three such constellations the following table indicates possiblities of checking whether one's own use is covered and whether the substance may be used under REACH.

In how far any additional requirements have to be fulfilled in context of risk assessments is discussed under Question 2.5.

Table 3: Checking one's own use

	Example 1	**Example 2**	**Example 3**
„Use of the substance/mixture“ **„Short title“ for exposure scenario**	Building and construction work (SU19)[8] Coatings and paints, thinners, paint removers (PC9a) Roller application or brushing (PROC10)	Application of solvents	Leather lubricants for industrial use Recommended restrictions on use (subsection 1.2 SDS): not for industrial use
Your practice	Manual coating of metal parts with brush or roller	Manual surface cleaning of metal parts	Leather lubrication in a shoemaker's workshop
Consequences	Your own use is **covered** by the identified use.	Your own use is **not clearly covered** by the identified use.	Your own use is **not covered** by the identified use.
Action	Risk assessment and establishment/review of protection measures taking ES into account Ensuring compliance with identified conditions of use	Consideration whether the own conditions of use are covered by the SDS. If so, risk assessment and establishment/review of protection measures can be carried out taking ES into account. If not, the supplier has to be contacted or an own chemical safety report has to be prepared, which may be based on the risk assessment.	Risk assessment and establishment of protection measures cannot be based on the SDS. REACH may entail additional requirements (see also BAuA REACH Info 5).

[7] See Art. 37 (6) of the REACH Regulation
[8] The descriptors indicated here are taken from the descriptor system set out in the ECHA Guidance on Information Requirements, Chapter 12: Use Descriptor System: http://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf

Question 2.3: Is it permitted to use a substance or mixture in a way that the supplier advises against in the eSDS?

Answer: Yes, even if the supplier advises against a use in section 1.2 of the eSDS, it is in principle permitted. In this case, the risk assessment and the establishment of protective measures cannot be carried out solely on the basis of the SDS.
Under the Hazardous Substances Ordinance, there is an obligation to carry out a risk assessment or – if the substance is already being used in the corresponding way – to review and, if necessary, update the existing risk assessment. For further details, please refer to the information in item 4.
Under the REACH Regulation, the specifications set out in Article 47 (4) must be observed. For further information in this regard, please refer to question 4.3.
Furthermore, it must also be checked whether the use is subject to legal environmental obligations; this catalogue does not, however, examine these in further detail.

Question 2.4: How can it be checked whether the operational conditions of the exposure scenario are fulfilled?

Answer: In the exposure scenario the operational conditions are described by a range of factors that determine exposure (e.g. amounts used, concentration, temperature, frequency). The respective risk management measures are also set out. The case is simple when all parameters of the described exposure scenario are identical with one's own conditions of use.

If some of your operating conditions differ from those in the exposure scenario, you can nevertheless operate within the conditions of the exposure scenario. Individual differing conditions may be compensated by changing other parameters. The possibility of changing individual paramenters is defined as "scaling" and described in the guidance on REACH (Guidance on Information Requirements and Chemical Safety Assessment Part G “Extending the SDS”, Appendix G-1[9]). With the last item of the exposure scenario the person responsible for placing the substance on the market provides assists the user in evaluating whether he works within the boundaries of the ES by including references to the tools or methods he himself used for the preparation of the exposure scenario. In this context the user may take into account whether any advice on risk management measures is included. (Guidance on Information Requirements and Chemical Safety Assessment Part D “Exposure Scenario Building” D8.2 “Advice to DU to check whether he works within the boundaries set by the ES”) [10].

[9] http://echa.europa.eu/documents/10162/17224/information_requirements_part_d_en.pdf
[10] See FN 5 Link 1.

Question 2.5: Do the protection measures described in the eSDS and/or the ES render one's own risk assessment superfluous?

Answer: No, but the exposure scenario provides valuable information for the risk assessment and for the identification of health and safety measures.

Under certain circumstances the ES may be directly used for certain parts of the risk assessment: According to section 6 (7) of the Hazardous Substances Ordinance the ES may be used as a risk assessment supplied with the product if it meets the requirements set out in Annex 2 to technical rule TRGS 400. Annex 2 of the technical rule TRGS 400 is a checklist for judging whether the quality of the information in the safety data sheet meets the required standard for a risk assessment supplied with the product.

This checklist is reproduced in Annex 2 to this document; and additional column SDS/ES has been added to connect it directly to the safety data sheet. At least items 1 and 2 (a) to (e) of the table attached in Annex 2 must be answered with "yes" for the risk assessment supplied with the product to be used according to item 5.2 of technical rule TRGS 400. For any other items which may have been answered with "no" the employer must independently gather information and take it into account when laying down the protection measures.

Question 2.6: Is the duty to obtain information according to section 6 of the Hazardous Substances Ordinance fully covered by the supplier's duty to communicate information under the REACH Regulation?

Answer: No. The employer continues to be required to consider in particular substitution possibilities. He must also identify hazardous substances in articles to which workers may be exposed e.g. during processing.

According to REACH the employer receives information on selected substances in articles. However, this applies only to those substances that have been selected as candidates for inclusion in an authorisation procedure[1]. The information must be passed on automatically, a specific format is not required.

Moreover, the employer must identify the risks from substances that are produced only when using other substances. Whether more information on such substances will be available under REACH remains to be seen.

Basically the exposure scenario and hence the eSDS have to provide information covering the entire life-cycle of a substance and outline possible degradation, transformation, or reaction processes. In how far this includes information on the properties of any resulting sustances and the

corresponding risk management measures has not yet been settled conclusively.

Question 2.7: Does the exposure scenario in the eSDS suffice as documentation of the risk assessment according to section 6 (8) of the Hazardous Substances Ordinance?

Answer: Not fully. The exposure scenario can be a "risk assessment supplied with the product"; see also Question 2.5 and Annex 2. However, as a rule it has to be more specific in terms of the operating conditions. It is also supposed to include information concerning reviews of the effectiveness of protection measures, e.g. review schedules, and responsibilites.

Question 2.8: Is the obligation to take the technical rules into account (section 7 (2) of the Hazardous Substances Ordinance) complied with when the risk management measures described in the eSDS have been implemented?

Answer: No. The employer has to check whether the risk management measures specified in the eSDS are consistent with the technical rules announced by the German Ministry of Labour and Social Affairs (BMAS) or show that they are equivalent. Here, the prioritisation of the protective measures according to the Hazardous Substances Ordinance must also be observed. The REACH Regulation also includes specifications for this in the guidelines[11].

Question 2.9: Is the obligation to reduce the risks for employees to a minimum or to abolish them (section 7 (4) of the Hazardous Substances Ordinance) complied with when the risk management measures described in the eSDS have been fully implemented?

Answer: Only in part. The eSDS informs about

- the provision of suitable work equipment and adequate maintenance procedures,
- limits to the duration and extent of exposure, and
- suitable work processes.

As far as the other requirements of section 7 (4) of the Hazardous Substances Ordinance are concerned, the employer has check in how far his operational conditions require further measures to be taken.

[11] Guidance on information requirements and chemical safety assessment, Part D: Exposure Scenario Building; p. 32 and p. 60 and Guidance on information requirements and chemical safety assessment, Chapter R.13: Risk management measures and operational conditions; p. 9 and p. 23; (http://echa.europa.eu/documents/10162/17224/information_requirements_r13_en.pdf).

Question 2.10: Does the employer have to check the possibility of substitution according to section 6 (1) of the Hazardous Substances Ordinance, or is such a check included in the registration by the person responsible for placing the substance on the market?

Answer: Registration does not include an analysis of substitution possibilities. This means that the employer has to analyse the possibilities of substitution as provided for in section 6 (1)(2)(4) of the Hazardous Substances Ordinance.

Question 2.11: Does the safety data sheet contain all the necessary information for the selection and use of personal protective equipment (PPE)?

Answer: No. The SDS must only include the information on the suitability of PPE for substance and product-specific risks as requested in section 8, e.g. on the type of material and the maximum time of use. Information on cleaning, maintenance and storage of the PPE and problems for employees have to be obtained from the PPE supplier, from the technical rules and from the accident insurance funds.

In general, the prioritisation of the protective measures according to section 7 (4) of the Hazardous Substances Ordinance must be taken into consideration before PPE is used.

Question 2.12: Is an exposure assessment to check the achievement of OELs obligatory when the risk management measures described in the eSDS have been implemented?

Answer: Yes. The effectiveness of technical precautionary measures also depends on the environmental conditions and the current technical state, e.g. of an extraction system. If necessary, the exposure has to be determined (through measurements or similar assessment procedures) to check the effectiveness of the precautionary measures. At any rate, compliance with OELs is imperative (see also Question 3.1). Exposure shall be determined along the lines of technical rule TRGS 402.

Question 2.13: When the risk management measures described in the eSDS have been implemented, can it then be assumed that the DNEL is achieved?

Answer: Not automatically. According to REACH the risk management measures guarantee compliance with the DNEL established by the person responsible for placing the substance on the market. However, this is no release from the obligation to conduct checks of the effectiveness of such measures as required by the Hazardous Substances Ordinance.

Question 2.14: Can the DNEL be used as a benchmark for the effectiveness checks according to section 7 (9) of the Hazardous Substances Ordinance?

Answer: Yes. But this does not automatically imply that measurements have to be conducted. The DNEL may be used to check the effectiveness of the protection measures by benchmarking against the determined level of exposure. Technical rule TRGS 402 describes suitable methods for exposure determination.

Question 2.15: Are all DNELs for the hazardous ingredients always stated in section 8 of the SDS for a mixture?

Answer: Not necessarily. According to Annex II of the REACH Regulation, the SDS need only state the DNELs that have been used as a standard for derived risk management measures in associated exposure scenarios.

If the employer requires the DNEL of a constituent for their risk assessment and realises that the constituent is registered because subsection 3.2 contains a registration number, they should request the inhalative DNEL for workers from the manufacturer or supplier of the mixture in accordance with section 6 (2) of the Hazardous Substances Ordinance.

Question 2.16: Are the necessary control measures for fire and explosion hazards complied with by implementing the measures described in the eSDS?

Answer: No. Section 11 of the Hazardous Substances Ordinance, in particular, requires additional checks to identify risks arising for instance from potentially explosive atmospheres, from the presence of ignition sources or from storage together with other hazardous substances. For further information in this regard, please refer to the technical rules TRGS 720, 721, 722 and 800.

3 The relation between DNEL/DMEL and the benchmarks from the Hazardous Substances Ordinance

To assess the risks to human health the REACH Regulation requires the registrant to determine "derived no-effect levels" (DNELs) when preparing the chemical safety report. For this purpose, DNELs are determined for all relevant routes of exposure (inhalative, dermal or oral). These values are communicated to the employer in the safety data sheet. For the person responsible for placing the substance on the market the DNELs serve as benchmarks for the derivation of risk management measures. Within the framework of this catalogue of questions, particular consideration is made of

DNELs for the inhalation route, since the OEL, as an essential benchmark under the Hazardous Substance Ordinance, only relates to this route.

The risk characterisation[12] in the context of the chemical safety report is targeted at a comparison of human exposures with the established DNELs. When DNELs are achieved, human health is not at risk and no further protection measures are needed.

For carcinogenic and mutagenic substances without a threshold value, a value called DMEL (derived minimal effect level) can be determined. In contrast to the DNEL, the DMEL is not defined in the REACH Regulation; rather, it is a value introduced in the guidance[13], which is not legally binding. Unlike with a DNEL, it is not possible to rule out the occurrence of harmful effects on health at an air concentration matching the DMEL.

Relation between the DNEL and OEL

Question 3.1: What legally binding value do OELs and a DNELs each have for an employer?

Answer: Occupational exposure limits (OELs) are the workplace limits that are legally binding on employers in Germany. According to item 5.3.2 (3) of technical rule TRGS 402, inhalative DNELs act as guidance to assess whether the protection measures taken are adequate in those cases where no OEL is available.

Question 3.2: What steps have to be taken when the OEL differs from the DNEL or when there is no OEL at all?

Answer: Where the OEL is stricter than the DNEL, the employer has to comply with the OEL. Where the DNEL is sticter than the OEL, the OEL has to be reviewed by the Committee on Hazardous Substances (AGS). In these cases employers are advised to contact the Committee on Hazardous Substances[14]. If there is no OEL for a particular substance but a DNEL, the DNEL should serve as yardstick that can be taken into account when assessing the risk or checking effectiveness.

[12] Annex I (6) of the REACH Regulation
[13] Guidance on information requirements and chemical safety assessment; Chapter R.8: Characterisation of dose [concentration]-response for human health, (http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf)
[14] Committee on Hazardous Substances (AGS), Secretariat; Federal Institute for Occupational Safety and Health (BAuA).

Using DMELs

Question 3.3: What does the DMEL mean?

Answer: A DMEL indicates the air concentration of a substance at which it is assumed that only a very small probability exists of developing cancer. The level of this probability must be known in order to be able to apply a DMEL.

However, no binding level for the cancer risk to which the DMEL is supposed to relate has yet been specified. The corresponding guidance only reports risk values from various countries. It remains up to the manufacturer or importer to decide which risk value to use as a basis for the DMEL.[10]

If no information is provided in the eSDS on the level of the risk linked to the DMEL, the employer must request the corresponding information from the manufacturer or importer in order to learn what level of protection is achieved with the risk management measures described in the eSDS.

Question 3.4: What legally binding value does a DMEL have for the employer?

Answer: A DMEL is not legally binding for the employer. It can be used for the risk assessment in connection with the underlying risk and the associated risk management measures (see questions 3.6 and 3.7).

Question 3.5: Does German hazardous-substances legislation include values comparable to the DMEL?

Answer: A concept is described in Announcement on Hazardous Substances 910[15] (Announcement 910) that includes values that are comparable to the DMEL. The application of this concept is regulated in technical rule TRGS 400.

The acceptable concentrations laid down in Announcement 910 correspond, at present, to a risk of 4:10,000. From 2018 at the latest it is planned to reduce the value to 4:100,000. Within the framework of the concept set out in Announcement 910, it should be taken into account that accordingly graduated measures are assigned to the exposure ranges.

[15] Announcement on Hazardous Substances 910: Risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances; http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/Announcement-910.pdf

Question 3.6: How can the DMEL, together with the associated risk figure, be used in the risk assessment?

Answer: For substances that are listed in Announcement 910, only the values published in the Announcement – and not the DMEL – should be used.

For substances not included in Announcement 910, the risk-based concept in the German hazardous-substances legislation for carcinogenic substances can be used. Here, the risk figure on which the DMEL is based is compared with the two risk figures according to the risk concept.

This can be used to derive the additional measures that are necessary for the corresponding risk area within the framework of the graduated measures concept. This includes in particular the further minimisation of exposure, unless the associated risk is below the acceptable risk.

If the risk figure on which the DMEL is based is not known, the DMEL cannot be used for the risk assessment.

Question 3.7: Are the risk management measures set out in the SDS, which are supposed to guarantee compliance with a DMEL, sufficient?

Answer: The employer can expect this to be the case if the DMEL is less than or equal to the acceptable concentration in Announcement 910.

For substances not listed in Announcement 910, the risk connected with the stated DMEL must be determined. If the risk is less than or equal to the acceptable risk, the measures stated in the exposure scenario are sufficient. In both cases, the employer must check whether measures that are necessary even below the acceptable concentration based on the graduated measures concept set out in Announcement 910 should be taken in addition to the risk management measures. Furthermore, the prioritisation of the protective measures according to the Hazardous Substances Ordinance must be observed.

4 Risk management measures according to the safety data sheet vs. protection measures according to the risk assessment

Both the REACH Regulation and the Hazardous Substances Ordinance require downstream users and employers to take risk management measures or protection measures respectively. This chapter indicates how the obligations from the two legal areas can be reconciled.

It should be noted that the requirements of the REACH Regulation also touch on other legal areas such as consumer protection, and notably environmental protection. The present catalogue of questions covers only occupational health and safety issues.

Requirements under the REACH Regulation:

Once the downstream user is satisfied that his uses are covered by the identified uses in the safety data sheet or exposure scenario for the substance in question, he has to comply with the risk management measures outlined there or with the established DNELs. If his uses are not covered, he is obliged to check whether he has to prepare a chemical safety report for the uses that are outside the conditions described in the exposure scenario (Article 37 (4)).

If the downstream user who uses a substance or mixture calls into question the appropriateness of the risk management measures described in the safety data sheet for an identified use, he has to pass on that information to the next actor up the supply chain. (Article 34).

Requirements under the Hazardous Substances Ordinance:

The requirement of the Hazardous Substances Ordinance to conduct a risk assessment including an effectiveness check of the protection measures taken implies an obligation on the part of an employer, on adopting the risk management measures from the safety data sheet, to assess their appropriateness and to check their effectiveness. In doing so he must compare the conditions that formed the basis for the defined measures with the conditions of his intended use.

Question 4.1: Must an existing risk assessment be reviewed after receiving an eSDS?

Answer: The risk assessment has to be updated whenever new information so requires. New information supplied in the context of an eSDS may constitute, in particular, DNELs and risk management measures (see Item 2). The risk assessment needs not to be updated when the risk management measures are consistent with the measures currently taken.

Question 4.2: What does the employer have to do if the risk management measures according to the eSDS do not conform to the protection measures according to the existing risk assessment?

Answer: In this case the risk assessment has to be reviewed with a view to deciding whether the current protection measures can be maintained or whether they have to be adapted.

Depending on the situation, different aspects have to be taken into account in the review.

Case 1: An OEL or process and substance-specific criteria are in place for the substance used

Current protection measures can be maintained in principle if they ensure compliance with the OEL or the process and substance-specific criteria.

If the eSDS specifies a DNEL below the OEL or the exposure levels achieved through the process and substance-specific criteria, the Committee on Hazardous Substances should be informed for the purpose of reviewing the situation.

Case 2: There are no OELs and no process and substance-specific criteria for the substance used and the substance is not a category 1A or 1B carcinogen

The first step should be to check the effectiveness of the protection measures applied so far. If these measures guarantee compliance with the DNEL, there is no need to adjust them. In this case a note should be added to the documentation of the risk assessment stating that the effectiveness was checked (according to technical rule TRGS 402) by using the DNEL as a benchmark.

If the protection measures do not guarantee compliance with the DNEL, the risk assessment has to be updated. In doing so, the employer should be guided by the risk management measures specified in the eSDS so as to achieve compliance with the DNEL. In this case a note must be added to the documentation of the risk assessment stating that the effectiveness was checked (according to technical rule TRGS 402) by using the DNEL as a benchmark.

Case 3: There is neither a process and substance-specific criterion nor an OEL for the substance used and it is a category 1A or 1B carcinogen

If a DMEL is stated for the substance in the eSDS, the effectiveness of the protection measures so far applied (including the measures according to Announcement 910) should be checked.

For substances listed in Announcement 910 and whose acceptable concentration is not met, the previous measures can be maintained (see Question 3.6).

If no DMEL is stated in the eSDS, the protective measures so far applied under the Hazardous Substances Ordinance must generally be maintained.

In the process, the rule on the minimisation of risk according to the Hazardous Substances Ordinance must always be observed.

Question 4.3: Is it permitted to implement protection measures that deviate from the risk management measures described in the eSDS?

Answer: Yes. This is possible both in the context of the Hazardous Substances Ordinance and in the context of REACH. The effectiveness and prioritisation of such measures has to be checked and documented in connection with the risk assessment.

When protection measures for the use of a substance on its own or in a mixture deviate from the risk management measures described in the exposure scenario, obligations may arise under REACH. However, the mere deviation from the exposure scenario in itself does not automatically entail an obligation under REACH to prepare a separate chemical safety report (see also Question 2.4).

For further comments reference is made to the ECHA guidance "Guidance for Downstream Users"[2] and to REACH Info 5 of the Federal Institute for Occupational Safety and Health (BAuA) (Rights and Obligations of Downstream Users under REACH)[16].

If an effectiveness check carried out according to the Hazardous Substances Ordinance reveals that the risk management measures specified in the eSDS do not suffice or are not necessary to ensure the achievement of the DNEL, the downstream user is obliged[17] to (informally) inform the supplier of this. The employer must then take the measures specified in their risk assessment with regard to handling.

Question 4.4: Has the prioritisation of the protective measures been taken into consideration for the risk management measures in the eSDS?

Answer: The employer cannot automatically assume this. Before adopting the risk management measures conveyed in the eSDS, they must check whether the prioritisation of the protective measures has been taken into consideration.

If the use of respiratory protection is stated as part of the risk management measures, the employer also cannot assume that the air concentration in the workplace falls below the associated DNEL or DMEL.

[16] http://www.baua.de/de/Publikationen/Broschueren/REACH-Info/REACH-Info-05.html
[17] according to Article 34 subparagraph b) of the REACH Regulation

5 Additional information under REACH

Apart from the safety data sheet, REACH requires additional information that may also be relevant for safety and health at the workplace. This includes, for instance, the information requirements under Articles 32 and 33 (1) of the REACH Regulation. These Articles refer to the supplier's duty to communicate information in cases where a safety data sheet is not required.

For these cases Article 32 states that the supplier has to provide the recipient with the following information for which no specific format is required:

- information as to whether the substance is subject to authorisation and details of any restriction of the substance,
- any other available and relevant information concerning appropriate risk management measures,
- and, in addition, the registration number, if available.

Article 33 (1) regulates the communication of information for certain substances in articles.

Question 5.1: For what kind of hazardous substances will the employer in future receive "any available and relevant information" according to Article 32 of the REACH Regulation?

Answer: The employer can, for instance, expect information on dangerous substances that are not hazardous substances within the meaning of the Chemicals Act, such as asphyxiant gases or cryogenic substances. Moreover, information needs to be supplied for substances that were not tested (and hence not classified as dangerous, if appropriate) for the sole reason that the person responsible for placing the substance on the market assumes the presence of certain operational conditions and risk management measures. The supplier/distributor has to communicate such assumptions.

Question 5.2: Which information according to Article 32 of the REACH Regulation can be used for the risk assessment, and which not?

Answer: Based on Article 32 of the REACH Regulation the employer receives information on the substance's properties that call for risk management measures. Information on substitution possibilities cannot be expected. References to substitution possibilities and authorisation requirements may also be relevant for the risk assessment.

The communication of information under Article 32 of the REACH Regulation is an implicit confirmation for the employer that the substance in question is not a substance to be classified as dangerous according to the applicable classification criteria nor a dangerous mixture within the meaning of section 3a of the Chemicals Act.

Question 5.3: What does "waiving" mean?

Answer: The REACH Regulation provides for possibilities of refraining from testing certain substance properties. In the REACH terminology this is called waiving. Under the specified conditions testing may be waived if:

- the substance is placed on the market in quantities of < 10 t/a per manufacturer or importer provided nothing indicates that it may constitute a substantial risk to human health or the environment, or
- testing is scientifically or technically not necessary or not possible, or
- exposure to this substance can be ruled out.

Question 5.4: What consequences does it have for employers when waiving is indicated in the eSDS or in information according to Article 32 of the REACH Regulation?

Answer: An indication of waiving according to Annex XI section 3 of the REACH Regulation tells the employer that certain properties of the substance were not tested because the person responsible for placing it on the market

- found only insignificant exposure for the intended uses that was clearly below the derived DNEL or PNEC, or
- demonstrated strictly controlled conditions of use as required according to the specific rules for transported isolated intermediates (i.a. contained systems), and
- demonstrated that – when incorporated in an article – the substance is not released during its life-cycle and that exposure is negligible.

In particular, waiving may concern testing for sub-acute toxicity, subchronic toxicity, reproductive toxicity and carcinogenicity, as well as numerous tests for ecotoxicity (especially long-term effects).

When the eSDS or information supplied under 32 of the REACH Regulation indicates waiving, the employer has to respect the operational conditions specified therein. The substance must not be used under different conditions.

Question 5.5: What information on articles does the employer receive?

Answer: Under Article 33 of the REACH Regulation the employer receives information on selected substances in articles. This applies only to substances of very high concern in terms of their effects to human health or the environment (Article 57). By means of a specific procedure they are identified as candidates for the authorisation procedure (Article 59) and published in a regularly updated candidate list. [1]

The supplier (including the distributor) of an article containing a candidate substance in a concentration above 0.1% must routinely inform the recipient thereof. He has to provide sufficient information to allow safe use of the article including, as a minimum, the name of that substance. There is no prescribed format for the communication of such information.

Irrespective of REACH, the employer, when conducting the risk assessment, continues to be obliged to take into account substances that may be produced or released from articles.

6 Authorisation, substitution, restriction

The authorisation requirement is a new instrument under the REACH Regulation. Substances that are subject to authorisation must not be placed on the market and used unless the use has been authorised by the Commission. Substances that may require authorisation (SVHC: substances of very high concern[18]) are at first placed on a candidate list according to Article 59 of the REACH Regulation and, after an evaluation, included in Annex XIV of the REACH Regulation (List of substances subject to authorisation). CMR substances are typical substances of very high concern.

There are two procedures for the authorisation of substances of very high concern:

- An authorisation is granted if the risk to human health or the environment is adequately controlled. This is normally the case when a threshold has been complied with.
- For substances for which it is not possible to determine a threshold and for substances with PBT or vPvB properties an authorisation may only be granted if the socio-economic benefit outweighs the risks and there are no suitable alternative substances or technologies.

The authorisation requirement is different from the restriction process according to Title VIII of the REACH Regulation. The Restriction Directive 76/769/EC was carried over to the REACH Regulation as of 1 June 2009.

[18] Note: according to http://echa.europa.eu/en/candidate-list-table, the substances on the candidate list are already called "substances of very high concern".

Question 6.1: Does the existence of an authorisation under the REACH Regulation render the substitution check according to the Hazardous Substances Ordinance superfluous?

Answer: No, the authorisation of a use under the REACH Regulation does not exempt the employer from conducting a substitution check according to the Hazardous Substances Ordinance in conjunction with technical rule TRGS 600.

The findings of an authorisation procedure based on a socio-economic analysis must not be automatically adopted; they may, however, provide valuable information for the substitution check according to the Hazardous Substances Ordinance.

In cases where authorisation is granted because the risk is adequately controlled the requirement of the Hazardous Substances Ordinance to look for a less dangerous alternative is not satisfied. The analysis of alternatives must be conducted parallel to authorisation and needs to be documented.

Moreover, the REACH Regulation requires users of substances within the terms of the authorisation to notify ECHA (Article 66).

Question 6.2: Does the employer have to take additional measures according to the Hazardous Substances Ordinance for substances that are included in the candidate list?

Answer: No. The inclusion of a substance in the candidate list does not entail any additional obligations under the Hazardous Substances Ordinance. However, the user should be aware of the fact that authorisation procedures according to the REACH Regulation may start any time for a substance on the candidate list, with the effect that, at a later stage (the “sunset date”), the use of that substance may no longer be possible or may be possible only under special conditions. The placement of a substance on the candidate list does not allow conclusions as to the date of commencement of an authorisation procedure.

Question 6.3: Are uses of a substance which is listed in Annex XIV of the REACH Regulation (List of substances subject to authorisation) permissible?

Answer: This depends on the respective substance-specific date, which is specified in Annex XIV of the REACH Regulation. Up to that date uses are not restricted, but regardless thereof the substitution requirement of the Hazardous Substances Ordinance has to be met. After that date only uses that have been authorised are permissible.

Moreover, particular uses of a substance may be exempted from the authorisation requirement. Such exemptions may be subject to special conditions that have to be satisfied (see Article 58 (1)(e) of the REACH Regulation).

Question 6.4: What are the obligations of an employer in his role as a downstream user when using an authorised substance?

Answer: A downstream user may use a substance provided that his conditions of use are in accordance with the conditions of the authorisation granted. He has to notify ECHA within three months of this use (Article 66 of the REACH Regulation).

In addition, he has to ensure that the exposure is reduced to as low a level as is technically and practically possible (Article 60 (10) in conjunction with Article 56 (2) of the REACH Regulation). This overlaps with the requirements of the Hazardous Substances Ordinance.

Question 6.5: Are uses of a substance which is listed in Annex XIV of the REACH Regulation (Restrictions) permissible?

Answer: Yes, such a substance may be used as long as it complies with the conditions set out in Annex XVII of the REACH Regulation (see Article 67 (1) of the REACH Regulation). Annex XVII of the REACH Regulation reproduces Annex I of the former Restriction Directive 76/769/EC.

Compliance with the conditions of restriction under the REACH Regulation does not replace the substitution check required under the Hazardous Substances Ordinance.

Question 6.6: How does the employer receive information on authorisations and restrictions?

Answer: For substances and mixtures, information on authorisations is communicated through the safety data sheet (section 15) and the label; information on restrictions is provided under section 15 of the SDS. The safety data sheet has to be updated once an authorisation has been granted or refused or a restriction has been imposed.

For substances and mixtures for which no safety data sheet is needed the supplier has to inform the recipient of any authorisation granted or denied

and provide details of any restriction imposed[19]. There is no specific format for the information.

The Commission publishes the authorisation number and the reasons for the decision in the Official Journal of the European Union.

[19] Article 32 of the REACH Regulation

Annex 1 Abbreviations and definitions

OEL: occupational exposure limit

Announcement: Announcement on Hazardous Substances

CLP: Classification, labelling and packaging. Regulation (EC) No. 1272/2008 (CLP Regulation) contains requirements for the classification, labelling and packaging of substances and mixtures, amends and repeals Directives 67/548/EEC and 1999/45/EC, and amends Regulation (EC) No. 1907/2006 (REACH Regulation).

CMR: carcinogenic, mutagenic, reprotoxic

DMEL: Derived Minimal Effect Level

DNEL: Derived No Effect Level

ECHA: European Chemicals Agency

Import: the physical introduction into the customs territory of the Community (REACH Regulation, Article 3 (10).

eSDS: extended safety data sheet

extended safety data sheet: safety data sheet which contains one or more exposure scenarios in an annex.

Exposure scenario: an exposure scenario means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. This set of conditions includes a description of the risk management measures and the operational conditions that the manufacturer or importer applies or recommends to downstream users.

Distributor: any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance as such or in a mixture, for third parties. (REACH Regulation, Article 3 (14))

Manufacturer: any natural or legal person established within the Community who manufactures or produces a substance. (REACH Regulation, Article 3 (9))

Manufacturing: production or extraction of substances in the natural state (REACH Regulation, Article 3 (8))

Importer: any natural or legal person established within the Community who is responsible for import. (REACH Regulation, Article 3 (11))

Candidate list: List of substances for inclusion in Annex XIV (keyword: authorisation).

Downstream user: any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either or its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2 (7)(c) is regarded as a downstream user. (REACH Regulation, Article 3 (13))

PBT: persistent, bioaccumulative, toxic

PPE: personal protective equipment

Risk management measures, risk minimisation measures, control measures: The terms "risk minimisation measures" are "risk management measures" are used synonymously. „Risk management measures“ is the term used in the REACH Regulation (see for example Article 3, Definitions, subparagraph 37). This corresponds to the term "control measures" used in the context of the Hazardous Substances Ordinance.

RMM: see risk management measures

SDS: safety data sheet

Safety data sheet: an instrument for transmitting safety information on substances and mixtures, including information from the relevant chemical safety report down the supply chain to the downstream user. It is meant to provide professional users with the necessary information and advice for handling substances and mixtures so that users are able to take the necessary measures relating to the protection of human health and safety at the workplace, and protection of the environment.

TRGS: technical rules for hazardous substances

vPvB: very persistent, very bioaccumulative

VSK: process and substance-specific criteria for the risk assessment as defined in the technical rule TRGS 420

Use: any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation (REACH Regulation, Article 3 (24))

Identified use: “identified uses” are uses that are intended by an actor in the supply chain. An exposure scenario always relates to one or more identified uses of a substance or mixture[20].

Waiving: waiving of testing under specified conditions (REACH Regualtion, Annex XI)

[20] The description of an identified use may follow the structured descriptor system set out in the guidance to REACH (see FN 8).

Annex 2 TRGS 400 checklist for the applicaton of risk assessments supplied with the product according to section 7 (7) of the Hazardous Substances Ordinance, with an additional column "Section in the SDS or ES"

Items 1 and 2 (a) to (e) in the following table must all be answered with "yes" for the risk assessment supplied with the product to be used as a standardised working procedure according to item 5.2 of technical rule TRGS 400. For any other items which may have been answered with "no" the employer must himself gather information according to item 4 of that technical rule and take it into account when laying down the protection measures.

		yes	no	Remarks	Section in the SDS or ES
1	Are activities conducted in accordance with the information and stipulations given by the manu-facturer/person placing the product on the market?			If no, an independent risk assessment must be con-ducted by the employer.	SDS: 1.2 Use: Product information ES: 2 Description of activities/process(es) covered in the exposure scenario
2	Does the risk assessment supplied with the product contain information of the following points:				
	a. dangerous properties of the substances or mixtures			Is information given on the classification and labelling (R/S phrases and danger symbols) of the product and its constituents? Are indications given as to whether risks can be expected which go beyond the labelling? Item 4.2 (7) of TRGS 400 applies accordingly. If there is a lack of checks or assessments, have the dangerous properties of item 4.2 (8) been assumed for the recommendation of protection measures?	SDS: 2 Hazard identi-fication ES: 5 Product specification
	b. occupational exposure limits (OEL) and biological limit values (BLV)			Are the limit values of TRGS 900 and 903 respectively given (in the safety data sheet)? This point is not relevant for hazardous substances without OEL or BLV.	SDS: 8 Exposure controls/Personal protection
	c. information on health protection and safety from the manufacturer/person placing the product on the market			Is the safety sheet available? Are details given on the framework conditions for the safe use of the product (e.g. concrete details of personal protective equipment, ventilation)? Note: If there is a	ES: 8 Risk management measures: occupational measures

		yes	no	Remarks	Section in the SDS or ES
				need to use protective gloves and no makes are specified, the employer must find suitable ones himself.	
	d. extent, nature and duration of exposure taking account of all routes of exposure			Are inhalative exposures at the workplace and, where relevant, skin exposures described?	ES: 3.1 Duration and frequency of use ES: 8 Prediction of exposure resulting from the conditions described
	e. physicochemical effects			Are details of flash points and, where appropriate, explosion limits etc. given?	SDS: 9 Physical and chemical properties
	f. working conditions and procedures including the work equipment and the quantities of the hazardous substance			Are concrete details given of the working conditions and the process in which the product is used? Where relevant, the employer must add information e.g. on the quantity of the product used.	ES: 3.2 Maximum amount used per time or per activity ES: 3.3 Other operational conditions
	g. possibilities of substitution			Are details given of why no harmless or less dangerous products or processes can be used? If this is not the case, the employer must himself check possibilities of substitution.	To be checked by the employer
	h. effectiveness of the protection measures taken or to be taken			Is assistance provided in checking the effectiveness of the protection measures described under the information and stipulations given in the risk assessment supplied with the product (e.g. compliance with the limit values)? The effectiveness of the protection measures applied has to be checked by the employer.	ES: 6 Risk management measures: occupational measures
	i. conclusions drawn from occupational health care examinations			Normally this information is not part of the risk assessment supplied with the product, but has to be determined independently by the employer (see item 4.7 of technical rule TRGS 400).	To be checked by the employer
3	Have all operational states been taken into consideration in accordance with item 4.3 (1)?			These are not normally included in the standardised work process.	To be checked by the employer