Guidelines

on Risk Management

of the

Hazardous Substances Committee

concerning Decisions

with Far-Reaching Consequences

as of: **18 November 1998**

Index

1. Summary

Against the backdrop of the international development of demands on risk management in the area of substances, the Hazardous Substances Committee was asked to check its own risk management procedures.

In the spring of 1994, the Project Group “Risk Acceptance” (PG RA) was formed in order to assume this task.

The PG RA agreed at an early stage to limit the aspects of risk acceptance to identifying and determining appropriate measures which help to reach acceptable risks (risk management).

The inquiry of the PG RA came to the following conclusions:
The basics of the risk management procedures the Hazardous Substances Committee had used so far were confirmed. By way of determining individual procedural steps and establishing principles of procedure as well as due to the formation and the particular composition of the Project Group “Risk Management” (PG RM) and the introduction of a decision-making method, the framework conditions given in the EU and the current international knowledge on risk management were taken into account and were made applicable for the Hazardous Substances Committee, thus improving the chances of acceptability, consistency and transparency when it comes to decisions with far-reaching consequences. These guidelines serve as a reference for all of the Hazardous Substances Committee’s work in this field. The experience gained in the application of these guidelines should be used to develop them further (*cf. chapter 3.3.5.2*).

2. Introduction

2.1 International development of the demands on risk management

Only recently, the term risk management has been applied more frequently in Germany, at least in the context of substances. It refers to a process at whose end a measure is produced to eliminate or reduce a risk. A more detailed definition of the term will be given later (*3.1.1*). The general definition of the term, however, already indicates that the Hazardous Substances Committee has always been active in risk management.

Triggered by a decision of the Supreme Court in the United States on the occupational exposure limit value for benzene in 1980[1], the demands on risk management have risen significantly in the United States at first, and by now also in the EU. Expectations exist in terms of a more specific analysis of the effectiveness of protective measures, a more detailed consideration of socio-economic effects of protective measures as well as a more differentiated setting off of risk reduction on the one hand against the socio-economic effects on the other.

The EU Regulation on existing substances[2], in connection with the Technical Guidance Document on Development of Risk Reduction Strategies (TGD)[3], is the first instance in which the EU incorporated these higher demands in a regulation on substances, including the provision to take an analysis of the economic and social advantages and disadvantages into account when considering restrictive or prohibitive measures (Article 10 (3)).

It has already been agreed upon in DG XI of the EU Commission that these higher demands on risk management should be applied accordingly to new substances.

Apart from DG XI, DG III, which is responsible for the Restriction Directive[4], intends to follow the same path in order to move away from the ad-hoc procedures which have often proved to be rather unsystematic and inconsistent.

If this “refined” risk management is applied constructively, decision-making can be expected to improve to the benefit of <u>all</u> parties involved.

In order to avoid misunderstandings, it should be emphasised at this point already that the above mentioned higher demands on risk management refer to supranational or national decisions and not, at least not directly, to the very practical risk management in companies.

2.2 Up-dating of the risk management procedures in the Hazardous Substances Committee - Action of the Project Group “Risk Acceptance”

Against the backdrop explained above, the Hazardous Substances Committee saw the need to examine and, if necessary, adjust its current risk management procedures. To this end, the Project Group “Risk Acceptance” (PG RA) was formed which started its work in the spring of 1994. Since higher demands on risk management usually go hand in hand with an increased use of resources, it was determined at the very outset to focus exclusively on decisions that have far-reaching consequences. These kinds of decisions have to be made in particular when there is a great conflict of interests between risk reduction and socio-economic consequences, i.e. when both relatively high risks and significant economic and social consequences are at hand. In terms of measures, this basically translates into prohibitions, restrictions and in some instances limit values.

The PG RA started its work by compiling a glossary on the range of problems involved in “risks arising from substances at the workplace” (*cf. Annex I*). Apart from terms mainly used in natural sciences, such as hazardous property of a substance, exposure, risk, the glossary also contains terms such as risk perception and risk acceptance, which show the variety of factors influencing decisions. Its first purpose was to clarify the terms and to form a common understanding of risk management within the group. In that same sense, the glossary is also important for the Hazardous Substances Committee as a whole. Since the glossary was compiled before the discussions on the actual guidelines began, not all of the relevant terms coined or used later are included in the glossary. This, however, does not make a difference in terms of its above mentioned function.

The practical example “Use of ceramic fibre products for the reduction of high temperatures in industrial furnaces” (*cf. Annex II*) served as a test to the PG RA to meet in a concrete case and as far as possible the higher demands for analysing the effectiveness of protective measures, considering socio-economic effects of protective measures and setting off the reduction of risks against their effects. In the context of this example, the project group also made use of mediation in order to test to which extent this method of negotiating can bring about optimum decisions.

The subsequent abstraction of the experience gained in a specific case created the basis for drafting the guidelines (*Chapter 3 and 4*).

The documentation on this practical example is included in Annex II and serves to illustrate how the Hazardous Substances Committee applied the guidelines, which are necessarily a rather compact document.

It should be clearly noted that the “resulting decision” on ceramic fibres reflected in the documentation does not and cannot pre-empt the decision that might potentially be taken at a later stage by the Hazardous Substances Committee. This is due to reasons of formality as well as to the fact that owing to circumstances, a great amount of assumptions had to be used to fill data gaps during the trial phase.

An important deficit consists in the current lack of a method established at national or international level to estimate the socio-economic effects of substance-related protective measures. For the time being, the Hazardous Substances Committee will have to make do with pragmatic approaches and “learning by doing”.

Certain provisions of the guidelines are designed to keep the use of additional resources, in relation to current decision-making practice, as limited as possible. Besides, the quality of the resulting decisions should justify the additional use of resources.

3. Steps to be taken in the procedure

3.1 Preliminary remarks

3.1.1 Definition of the term risk management

The definition of risk management in the glossary (*Annex I, Item 14*) mainly breaks down the management process.

The Presidential/Congressional Commission on Risk Assessment and Risk Management of the United States selected the following definition[5]:

> *Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations.*

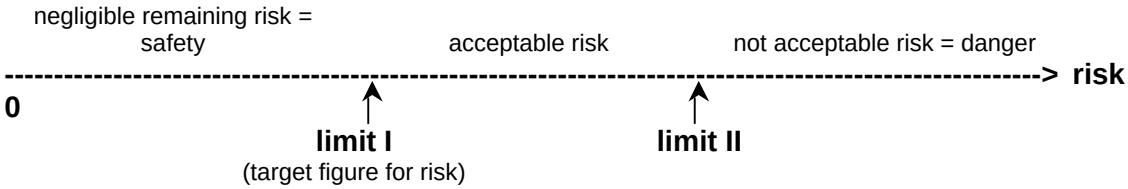
In 1994, the Presidential/Congressional Commission had assumed the task of analysing the risk management of American authorities having to decide over questions relating to substances in order to table proposals for harmonisation. The final report was submitted in 1997.

Phrase 1 of the American definition matches our definition in terms of its underlying logic, whereas phrase 2 points to the complexity of decision-making and shows that all of the numerous aspects mentioned influence the decision. Most of these aspects are listed under the term risk perception in the glossary as well (*Annex I, Item 11*).

3.1.2 Target figures for risks

For the sake of clarity and in order to simplify priority-setting for the processing of cases, it is desirable to determine definite target figures for risks with the purpose of delimiting finite but - in the general opinion - negligible remaining risks.

The PG RA agreed on the following general scheme:



The detailed discussion on potential target figures for risks (limit I) concluded that these figures - in terms of the probability of an actual incidence - should not only be related to the kind of effect the risk has but rather, under a given kind of effect, e.g. carcinogenic, to a variety of other risk-related factors as well, such as size and composition of the exposed group, reliability of the statement made on the risk existing for human beings, the relation between the dose and the incidence in the area of potential exposure at the workplace, if applicable also to the latent period, the course of the illness, chances of recovery, if predictable. The PG RA made several attempts but did not manage to set actual numerical target figures.

While limit I can be understood as being health policy related, limit II is the result of a decision of the Hazardous Substances Committee in a concrete individual case after having considered all relevant points (e.g. health policy, economic and socio-cultural aspects; *Annex I, Item 9*).

It might be possible to derive target figures at a later stage on the basis of experience gained during the practical implementation of risk management.

For the time being, priorities will still have to be defined pragmatically.

3.2 Overview over the steps of the procedure and general principles

Whenever these guidelines are applied, in general the steps listed below are to be taken in the following order:

- creating a Project Group “Risk Management” (PG RM)
- starting with the description of a risk
- identifying the options for action and their potential for risk reduction
- assessing the socio-economic impact of the selected options for action
- making a decision in the PG RM and submitting recommendations to the General Committee

The amount of work invested in each individual step should be guided by the question whether a greater amount of data is expected to influence the decision which is to be made. If this is not the case, the fact-finding process should be aborted for the time being. It may turn out later in the course of the procedure, however, that further data are required. It has to be possible then in the sense of an iterative process to re-enter the procedure at an appropriate point and to go through (parts of) it again.

Accordingly, the procedure and results of every individual step have to be documented in a transparent and logical way.

In order to avoid unreasonable delays through the collection of data or even the abortion of the procedure due to lack of data, it is ensured that the Hazardous Substances Committee can still make a decision by using the instrument of the “best plausible estimate”, which fills the gap of lacking data.

The Hazardous Substances Committee assumes that if its decisions should conflict with the interests pursued in the objectives set for other areas of protection (environmental or consumer protection), the relevant departments will identify and clear up these conflicts or transfer tasks back to the Hazardous Substances Committee, giving appropriate instructions.

3.3 Individual steps of the procedure

3.3.1 Creating a Project Group “Risk Management” (PG RM)

The PG RM prepares recommendations for the decision to be made by the General Committee, e.g. in the form of several options for action, by gathering data and evaluating comparisons of facts (*cf. 3.3.5*).

For this purpose, the project group should be composed of permanent members (the “inner circle” of the group) and be complemented by experts who are appointed on a case-by-case basis (the “outer circle” of the group). The PG RM should be headed by a neutral chairperson. For the “inner circle”, a parity among representatives from different fields is of special importance, as is the relevant expertise within the Hazardous Substances Committee, offered by the Sub-Committee on Toxicology (Sub-Committee “Tox”) and the Sub-Committees I, III, IV and V (*cf. 3.3.2, 3.3.3*). In addition, the project group should be provided with economic know-how on a permanent basis. The number of permanent members should be kept small so as to ensure that the group is functional and able to make decisions. The members forming the “outer circle”, whose number should also be limited, should be employees and employers affected in a positive or negative sense by the problem at hand and the options for solution currently discussed.

The decision to involve the Project Group “Risk Management” and thus to apply the guidelines is made by the General Committee. As was presented in chapter 2.2, the group will be involved in particular when relatively high health-related risks for employees are to be countered by measures which might have significant economic and social effects. A typical instance for involving the group will be when bans and restrictions in the context of the EU regulation on existing substances are being considered. It is assumed that the PG RM will be able to deal with 1 to 2 problems of this nature per year.

Once the problem has been delegated and entrusted to the project group, the outer circle is to be formed, i.e. the institutions concerned are asked to appoint experts. The preparatory work of the Sub-Committees “Tox”, I, III, IV and V and of the members of the outer circle should also be commissioned at the beginning. The pooling of facts requires documents on which a decision can readily be taken and which will be subject to queries by the PG RM - i.e. questions for better comprehension or technical questions which have come up or have received a special significance in the decision-making process. Besides, the project group will base its work on the current state of knowledge within the bodies of the Hazardous Substances Committee mentioned above and therefore will not conduct expert hearings on questions belonging to the fields of responsibility of these bodies.

3.3.2 Risk description

The health-related risk for an employee handling a dangerous substance depends on the exposure at the workplace and the profile of action of the substance. A risk description thus combines exposure and action-related facts. If possible, the type, the degree of severity and the incidence of the damage to health which is to be expected should be estimated.

Since chemicals are handled under all kinds of different conditions in all sorts of different areas, different activities will lead to different exposure profiles. Key parameters for the description of the exposure are the level of occupational safety and health in the company, a rough picture of the field of activity and the safety equipment, the presumed way of exposure (inhalative and dermal), the number of employees exposed to the substance, the average and peak exposures and the duration of the exposures.

The action profile of a substance is not only determined by the qualitative description of the potential toxicological properties of a substance; an essential parameter of the action profile is the intensity of the action or the relation between the dose and the action of the substance in question, which can be described using data collected from experiments or occupational medicine for the area of exposure observed. Facts which could be used for a quantitative toxicological assessment of relatively low exposures at the workplace are hardly available; data gaps resulting hereof have to be bridged by means of assumptions and models. Knowledge about the individual mechanism of action of a substance can substantially contribute to the description of the relation between dose and action.

Risk descriptions are an essential basis for decisions in risk management. The portrayal of exposure situations, of the action profile of a substance and of the health-related risks at the workplace determined from these risk components must be such as to give the risk managers, who are often unacquainted with this particular field, a more or less accurate impression of the risk situation which is to be evaluated. First, it has to be clear on which basis the risk description was established. Did average exposures and employees with an average sensitivity serve as a basis? Or does the risk in question apply to a particularly sensitive employee under extreme exposures which hardly ever occur? The risk manager has to be informed about the quality and the validity of a risk description. Are key points based on facts or on model assumptions? Was significant extrapolation (from rats to human beings, from oral to inhalative, from high to low areas of exposure) necessary in order to state the risk for a concrete workplace? Do the persons describing the risk basically agree on a concrete risk description or do they hold controversial opinions?

For the sake of consistent risk management decisions, the risks in question need to be presented in a transparent and comprehensible manner.

The risk description, serving as a starting point for the subsequent risk management, characterises the current way of handling a substance and includes at least the exposure-intensive activities along the active life of a substance.

As can be gathered from the previous passages, Sub-Committee V and Sub-Committee “Tox” have to do the preparatory technical work. Three options are conceivable for actually producing a risk description. Sub-Committee V and Sub-Committee “Tox” could form a working group for this purpose; the project group itself could assume the task and enter deeply into the problem at hand this way; as a third possibility, the case could be commissioned to an external body. For this option, adequate terms and accurate results regarding the subject matter have to be ensured. Apart from that, the selection of an option should depend on the individual workload involved.

For cases concerning the EU regulation on existing substances, the evaluation office of the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin - BAuA) will produce the risk description, always taking into consideration any statements which may have been made by the BUA (committee for the assessment of existing substances according to the EC Regulation on existing substances) and other EU member states.

3.3.3 Identifying the options for action and their potential for risk reduction

If in a first assessment of the PG RM, the risk presented in the risk description is assumed to be too high in comparison with other substance-related risks at the workplace, Sub-Committee I has to elaborate options for action. This work consists in checking which provisions already exist, how they are implemented and if they are complied with, unless this information is already included in the risk description (in the part on the exposure).

Against the backdrop of the current situation, Sub-Committee I will then identify technical and organisational options for action which are specifically related to the particular activity. These options will be developed on the basis of the regulatory principles, the hierarchy of measures under the Hazardous Substances Ordinance as well as the state of the art, the practicability in companies and a first assessment of Sub-Committee I on the reasonableness of potential actions. If it is difficult to give a rough estimate of the costs of an action or to assess its reasonableness, Sub-Committee I should continue to work with the action concerned rather than abandon it. A more detailed assessment will then take place during the decision-making process of PG RM.

When Sub-Committee I has selected options for action for closer consideration, Sub-Committee V estimates together with Sub-Committee I the reduction of the exposure both for scenarios in which personal protective equipment is worn as for those in which this is not the case, always assuming that the options selected are fully implemented and complied with.

PG RM assesses the risk reductions resulting from the exposure reductions according to the procedure described under 3.3.5. If and at what time restrictions or bans should be considered on top of technical or organisational options for action, has to be determined on a case-by-case basis. Should this be necessary, PG RM commissions Sub-Committee IV to check the availability of substitutes and replacement solutions as well as their functional equivalence. The Technical Guidance Document on the EU regulation on existing substances highlights in this context that restrictions can trigger the development of alternatives and that it is important to take into account the dynamic nature of this kind of situation in which technical progress and the development of the market can happen particularly quickly[3]. Thus, Sub-Committee IV also has to anticipate and duly consider predictable or probable developments.

Apart from reducing or eliminating the risk caused by the hazardous substance which is to be substituted, it is important for decision-making to learn about potential new risks caused by the substitute. Thus, substitutes which are to be considered more closely generally prompt Sub-Committee “Tox” and Sub-Committee V to carry out the same estimates on the exposure and the impact as in the case of the original hazardous substance. The Technical Guidance

Document mentioned above, however, recommends a step-by-step approach; no more efforts should be deployed than absolutely necessary in order to demonstrate probable risks. One should start with information which is available. The Technical Guidance Document recommends to generate data or to go as far as to assess the substance according to the EU regulation on existing substances only after thorough consideration, as these processes consume a the great amount of time and funds. It is not an exception that e.g. substitutes are expected to have the same critical effects as the hazardous substance they are to replace, but toxicologically seen, there is reason to believe that the effect will be less strong. According to the philosophy of the Technical Guidance Document, one should enter the decision-making process with this information.

3.3.4 Estimating the socio-economic effects of the selected options for action

The term “social effects” mainly refers to the protection of jobs, social security, motivation and the working atmosphere.

Economic effects include the aspects relating to the company, sector and national economy. Parties concerned are producers, users and the respective employers, both in terms of the hazardous substance and in terms of the substitute. The costs and the economic benefit for all parties concerned have to be taken into consideration.

Effects are an important aspect for decision-making. However, the use of resources involved generally permits an assessment of the effects only in the case of restrictions and bans, and in individual cases also for actions whose consequences will be particularly strong.

PG RM assesses the socio-economic effects. The required data will be provided by industry via the members of the “outer circle” of the project group.

Currently, there is a national and international deficit in established methods to estimate socio-economic effects of substance-related protective measures. It would be a priority to determine a system or a framework within which these estimates would be carried out. Apart from the above mentioned aspects and parties concerned it would have to be determined for example if the effects are to be estimated for a specific point in time (and if so, which one), or if the estimate is to be made on a dynamic basis. In order to assess the follow-up costs of an action, a comparison with a model company of the sector concerned would have to be carried out.

In this context, the case used in Annex II of the guidelines is an example for the weaknesses of the estimate which was made on the follow-up costs. However, a comparison of the costs from the point of view of the sector proves to be helpful both in scenario 1 and 2 (*Annex II, page 31 ff.*). It was also demonstrated, though, that particular uncertainties came up when conducting the assessment under an economic aspect, which may distort the results.

In the current situation, the only option is to proceed pragmatically in order to learn from a specific example. It will also be interesting to see how other countries deal and cope with this problem and which importance the EU will attach to estimating socio-economic effects in the future.

The following principles should be applied in the Hazardous Substances Committee for estimating social and economic effects:

- the data made available by industry should be understandable and verifiable, but at least plausible;
- the Hazardous Substances Committee has the right to demand additional data from industry which is required for decision-making;
- estimating the effects starts with a qualitative assessment, for example following the spirit of TRGS (Technical Rules on Substances) 440, Annex III, and applying them to companies of a specific sector, progressive quantification is only carried out if necessary;
- the estimate will be aborted when a consensus is reached or when a more detailed assessment would not be relevant for the decision;
- methodological deficits and elements of uncertainty in forecasts have to be indicated.

3.3.5 Decision-making in the PG RM and recommendations to the General Committee

3.3.5.1 The structure of the decision-making process

At this stage, the task of the inner circle of the PG RM is to arrive at well-founded recommendations that are passed on to the Hazardous Substances Committee concerning the action which is to be taken - this process is referred to as decision-making here.

After the previous steps have been taken, the information which is relevant for decision-making will normally be available in the form of the risk description, the options for action selected, including the risk reductions related to them and their social and economic effects.

During the decision-making process further data may be required, which would lead to a repetition of part of the previous step *(cf. 3.2)*.

For the sake of well-balanced decisions and a targeted discussion, it is highly recommendable to structure the discussion. For this purpose, the current situation as well as one or more scenarios (according to the selected options for action) are juxtaposed to decision-making aspects in a matrix (Table 1). Such aspects are risks to one's health and life, number of cases, costs, benefits, effects on the size of the staff, implementation guarantee, competitive advantages through innovation, availability of substitutes and replacement solutions *(cf. Annex II, p. 39)*. In some cases it might be necessary to break down individual aspects further (e.g. costs); or decision-making aspects might be dropped (e.g. the availability of substitutes if restrictions/bans are out of question), whereas other aspects might be added.

The decision-making aspect "implementation guarantee" requires further explanation. This is a term stemming from quality management. It means guaranteeing that an action will be put into practice and thus includes the practicability of a measure as well as permanent compliance with it, as it is called in international documents. The implementation guarantee is influenced by monetary factors (operating costs, external costs) and non-monetary factors (appeals, voluntary agreements, incentive systems, motivation/business management, possibilities of supervision). The decision-making aspect "implementation guarantee" is relevant, because during the process of identifying options for action and estimating the risk reductions related to them, it was merely assumed that full implementation of the measures were guaranteed, but this assumption does not always correspond to reality *(also cf. Annex II, p. 41)*.

Table 1: **Basis for risk assessment** *(also cf. Annex II, p. 39)*

decision-making aspects	current situation	scenario 1	scenario 2
risks			
absolute number of cases			
costs			
benefits			
effect on the size of the staff			
implementation guarantee			
competitive advantage through innovation			
availability of a substitute			

After completion, an assessment of Table 1 is made using the assessment categories risk acceptability, appropriateness, distributive justice, idea of precaution and functional equivalence. We are talking about assessment categories rather than assessment criteria because the items mentioned do not constitute a yardstick which is to be applied by the person conducting the assessment but are to be seen as categories supporting the thought process.

In this context, the term “risk acceptability” only refers to the comparison between the risk which is to be assessed and other comparable risks (comparability regarding the parameters which determine the reaction of human beings to risks, such as voluntary/involuntary actions). It does not refer to the acceptability of a management decision, which is affected not only by the risk but also by all other factors influencing a decision, e.g. costs.

“Appropriateness” signifies attaining the objectives efficiently, “distributive justice” encompasses the idea of fairness, “functional equivalence” of the scenarios, which is particularly relevant with regard to substitutes, is self-explanatory, the “idea of precaution” means taking the uncertainties within the assumptions into account during the decision-making process. In order to come to an overall picture of the certainty of assumptions, they can be listed per scenario and assessed individually, ranging from very certain ++ to very uncertain -- *(also cf. Annex II, p. 42 ff.)*.

One by one, the assessment categories mentioned will then be applied to the matrix (Table 1) in a discursive process. Not every completed field of the matrix is relevant for any assessment category. “Risk acceptability”, for example, only refers to the risk-related fields in the matrix and the hypothetical comparison with other substance-related risks for employees.

The results from the process of applying the assessment categories can be collected in a second table by checking the assessment categories against the scenarios and ranking the scenarios for every category; e.g. in the case of 3 scenarios: 1 to 3, while 1 stands for the highest and 3 for the lowest ranking.

Table 2: **Overall assessment in the decision-making process**

assessment category	current situation	scenario 1	scenario 2	comments
risk acceptability for employees	e.g. 3	e.g. 2	e.g. 1	
appropriateness				
distributive justice				
idea of precaution				
functional equivalence				

Every assessment line of Table 2 can be complemented by additional comments from the discussion.

After taking a general view on Table 2 with its individual rankings per line and the comments that were added, the group conducts an overall assessment by ranking the scenarios in their entirety. This ranking of the options for action then constitutes the recommendation of the PG RM to the General Committee *(cf. Annex II, p. 42 ff.)*.

Documentation will be attached to the recommendation which presents in an understandable manner the individual steps that were taken as well as their results and an explanation of those results, starting with the risk description and, if applicable, including any alternatives.

If no decision can be made after having gone through the procedure described, every group within the PG RM has the right to propose an attempt for decision-making based on the monetarisation of human health/human life. This procedure requires the explicit consent of all other groups.

The idea of monetarisation is to facilitate the comparability of risk reductions on the one hand and economic costs on the other hand by expressing the life and the health of employees in monetary terms. Such monetary sums are established e.g. by the method “willingness to pay”. These methods are subject to highly controversial discussions. Thus, if the PG RM decides to apply them in individual cases, the demand for transparency is particularly strong *(cf. chapter 4)*[8].

3.3.5.2 The mediation procedure

It is in the nature of the decision-making process described above that facts have to be considered which are not comparable at all or only to a very limited extent and to which individual groups of society may attach different importance.

In order to overcome the difficulties related to this situation, we recommend a structured discussion between the persons concerned or their representatives. Whether this discussion will be successful is mainly determined by the way in which this discussion is held. In the example “ceramic fibres”, the PG RA applied the mediation procedure to everyone’s satisfaction. We suggest to make use of this mediation procedure in the future and to have scientists support the first actual cases with their expertise.

The mediation process requires a moderator who pushes forward the decision-making process as a catalyst without constituting a party himself. All parties agree on common rules; the moderator supervises the compliance with them. These rules include the equality of different rationalities, interests and values, the obligation to provide evidence for statements of facts, the right to question and check statements of others as well as the rules of common sense. Voting modes are consensus, tolerated consensus (some participants do not agree with other participants in all points but tolerate an approval) or majority decisions. The success of the mediation depends on the preparedness of the parties involved to cooperate and seek an agreement, based on the understanding that a sound decision requires taking into account the interests of all participants in an appropriate manner. From this point of view, a consensus ranks higher than a majority decision[6 7].

4. Transparency

For reasons of practicability, decisions on action of the Hazardous Substances Committee and its bodies can only be made via the representatives of the individual groups of society. They make decisions to the best of their knowledge and belief as to which solutions they judge to be acceptable. The assumed acceptability thus does not necessarily have to be identical to the actual acceptance by the persons directly concerned. This is why the persons concerned should be informed and involved in an appropriate form early on. This could be done through suitable publications or hearings, for example. This point is particularly relevant in the case of far-reaching decisions strongly influenced by values. Publishing the results and the explanation of the results, including the conceivable alternatives, in an understandable form, e.g. in the Bundesarbeitsblatt (Federal Employment Bulletin), will give the persons concerned the possibility to intervene and to suggest corrections.

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Annex I

to the Guidelines on Risk Management of the Hazardous Substances Committee

Glossary on the Problems Involved in

"Risks arising from Substances at the Workplace"

as of: May 1996

Glossary on the Problems Involved in *"Risks Arising from Substances at the Workplace"*

1. Damage to health

Damage to health can be defined as a state which differs from the normal state of health and may range to a state of illness.

Health is defined as the absence of illness here and also a state of optimum physical, mental and social well-being[12].

The term illness is primarily seen from a medical and clinical point of view and is defined as an objectively perceivable, irregular, abnormal physical or mental state which requires curative treatment of the person and/or leads to a reduction of the earning capacity, even up to a complete loss of the working capacity[13].

This is a very broad definition. Providing a more precise decision-oriented definition is considered to be impossible.

2. Hazardous property of a substance

Capacity inherent in a substance to cause damage to health under certain conditions. This includes in particular the hazardous properties of a substance described through hazardous characteristics (Chemicals Act).

3. Harmful effect

Impact of a substance on an organism in a way which causes damage to health.

Remark
Since the scope of this glossary is limited to health risks at the workplace, this definition does not cover damage to the environment for the time being.

4. Exposure

Nature (inhalative, dermal) and degree (amount, duration, frequency) of the exposure at the workplace, considering the size and the composition of the exposed group.

Remark
The different composition of a group of exposed persons concerning the number of persons, age, sex, state of health etc. is an important aspect in estimating the exposure. In concrete cases, however, it is often difficult to make reliable statements in this respect.

5. Relation between dose (exposure) and incidence

Quantitative relation between the dose (or exposure) and the incidence and/or the severity of harmful effects.

6. Risk

Expected nature, degree of severity and incidence of damage to health in a given exposure situation.

7. Risk Description

Statement on the occurrence of a damage to health related to a concrete case under the relevant exposure conditions, including an assessment of the reliability of all data used.

Remark
The reliability of data in terms of the effect, the exposure and thus the risk can be categorised, for example (assessable, partly assessable, not assessable). The reliability is classified according to these categories on the basis of expert judgements on the data concerned.

Uncertainties in estimating the exposure and effect directly detract from the reliability of the statement. The character of the risk description may thus become increasingly qualitative and may eventually only allow for a distinction whether or not a damage to health is considered possible under the given exposure conditions. In such cases, the term *‘risk’* is often replaced by the less specific term *‘endangerment’*.

8. Estimating risks

Procedure which eventually leads to a qualitative or quantitative description of a risk.

Remark
Estimating risks is a process which is composed of different steps, the most important of which being:

- definition of the exposure situation which is to be assessed,
- projection into the relation between the exposure and the incidence which will serve as a basis,
- determination of the frequency of the occurrence of a damage linked to the exposure situation under a given nature and severity of the damage,
- identification of the reliability of the data.

9. Danger

unacceptable risk (pre-DIN 31 000)

Remark
The term danger used here is not only to be understood in its meaning under police law (“danger is looming”).

The differentiation between an acceptable risk and a danger is based on a dynamic limit set by society which is established considering all relevant aspects (e.g. health-related, economic and socio-cultural aspects).

In an area not defined as a danger, risks are accepted or found to be acceptable, which however is not to be put on a level with *‘safety’*.

Safety is attained if the remaining risks are considered negligible. For these decisions, another health-related limit is needed. This three-way splitting of the scale of risk is based on the experience gained in the risk management of hazardous substances. A suggestion was made to take these experiences into account when revising the pre-DIN 31 004.

10. Prospect

Expected nature, extent and frequency of occurrence of a benefit arising from a substance or its use under the given parameters.

Remark
Apart from rational aspects such as maintaining an industrial location or safeguarding or improving jobs, the term *'benefit'* also includes emotional components, e.g. a gain in prestige and job satisfaction. A particular individual benefit might quite possibly be juxtaposed by a different collective benefit.

The term *'prospect'* additionally includes an element of probability: The actual occurrence of a particular benefit can be described statistically through its expected frequency of occurrence, but it cannot be unequivocally predicted. In this respect, the expression *'prospect'* constitutes the adequate counterpart of the term *'risk'*.

11. Risk perception

Process of subjectively taking in, processing and assessing risks. This process is influenced voluntarily or involuntarily through numerous factors, such as technical and scientific understanding of risks, experience of life, value systems, interests or cultural background.

Remark
The risk perception of scientific experts is strongly (but not solely) affected by the scientific and technical risk definition. One tends to forget, however, that experts have to resort to extrapolations in order to estimate risks. Data gaps have to be bridged through assumptions, which may be influenced by personal judgements (e.g. scope of experience, interests, personal philosophy). This is why the objective correctness of an identified risk is often overestimated, e.g. through believing in "hard" facts.

Studies have shown[7] that the risk perception of scientific experts can be subject to a strong "affiliation bias" (e.g. in the case of toxicologists depending upon whether they work in the chemicals industry or in academic or administrative institutions).

Scientific experts also tend to underestimate e.g. risks with a higher probability but causing less damage[7].

The risk perception of non-experts is primarily intuitive. Studies[7] have shown that it is by no means arbitrary but rather follows certain patterns. The following factors, for example, have proven to play a role here:

- whether the risk was taken on voluntarily,
- whether the beneficiary is identical with the person exposed to the risk,
- whether the source of the risk is perceived as natural or as artificial,
- whether there is a time-related connection between the exposure and the occurrence of a damage.

The risk perception of non-experts has also shown to be more “comprehensive” than the one of scientific experts (e.g. concern about shifting social and political structures or power structures in connection with the risk-burdened activities in a community, apart from the concern about the risks as such)[7].

In the case of risk perception at the workplace it is assumed that the employees as referred to in the above mentioned study do not come under the category of scientific experts but rather under the one of (well-informed) non-experts.

12. Communication on risks

Communication of the persons concerned and involved on the following issues:

- the scientific and technical presentation and justification of a risk,
- the different risk perceptions,
- acceptable options and solutions.

The objective of this sort of communication is to contribute to the viability of decisions which are to be made by means of a transparent and cooperative communication process.

13. Risk acceptance *and risk acceptability*

a) risk acceptance: preparedness of an individual to take on a risk

b) risk acceptability: judgement of a legitimate body on the tolerability of risks on the basis of given qualitative or quantitative criteria

Remark

Ideas on the reasonableness of individual risks often differ enormously between different groups of people, depending on their experience and interests. The acceptance of a certain risk may be the result of the communication on the risk which took place among all persons concerned. It might be helpful to resort to “comparable” civil risks of life in order to come to a decision, but this does not result in justifications for other civil risks. In order to accept risks, the persons concerned have to see a prospect juxtaposing a risk. A difficulty involved here is that prospects and risks may be distributed unevenly among different groups of society.

14. Risk management

Searching and identifying adequate actions in order to achieve acceptable risks.

Remark

The process of risk management ideally includes

- identifying different conceivable solutions,
- estimating the risk reductions corresponding to the solutions,
- estimating the risks newly arising through the solutions,
- estimating the costs and social implications of the different solutions and choosing the ideal solution.

Only in a rather small number of cases is this standard actually attained in full.

15. Risk assessment

Process in which a decision on the acceptability of a risk is made or prepared on the basis of a risk description and considering social, economic, occupational safety and health related and other aspects.

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Annex II

to the Guidelines on Risk Management of the Hazardous Substances Committee

Practical example "Use of ceramic fibre products"

This annex was not translated