Federal Institute
for Materials Research
and Testing, Berlin

Presidential Board

Safety in technology and chemistry
Tasks and role of
BAM Federal Institute for Materials Research and Testing

With amendment notes. Status: December 2011

Berlin, May 6, 2002 (English version of July 18, 2003)

Amendment notes

This strategy paper of the BAM Federal Institute for Materials Research and Testing is the unaltered version of 6 May 2002 in terms of content. It is in some aspects no longer up to date, both internal to BAM, and in a number of then current developments outside BAM. The basic statements will remain valid as previously. As long as no updated content version is available, the following instructions should establish linkage to BAM's current structures and goals.

I. "Safety in technology and chemistry" has provided a sharper profile to BAM's guideline.

II. The five project areas were replaced with the following key areas:

- Analytical chemistry
- Safe handling of dangerous materials and dangerous goods
- Safe and environmentally compatible use of materials
- Safe operation of technical systems and processes
- Damage mechanisms and damage analysis.

The guideline governs these key areas. The strategy paper is therefore valid throughout the whole of BAM and its title has been adjusted accordingly.

III. Since the term "technical and public safety" has frequently been queried outside BAM, it has been replaced with "technical safety". BAM is concerned with issues of technical safety only insofar as they fall within the specialist areas of competence and involve risks requiring government provisions and government action in terms of type and extent.

IV. The changes in the Decree on BAM of 31 May 2011 do not change the content of this strategy paper.

1. Purpose

BAM is legally responsible for the development of safety and reliability in chemical and materials technologies. This is BAM's guideline. BAM's activities, however, are divided among five main project areas:

- Analytical chemistry
- Technical and public safety
- Environmental compatibility
- Materials technologies
- Technical and scientific service functions

In its main project area "Technical and public safety" BAM has an outstanding position in the Federal Republic of Germany. This is based on

1. the impartiality of a state agency.
2. the legal responsibilities in different fields,
3. the role as coordinator of the German accreditation and conformity assessment activities assigned to it by the economy and the ministries,
4. the acknowledged technical competence resulting from the cooperation over many years between the areas of activity “advice and information”, “testing, analysis, approvals”, and “research and development”,
5. the wide technical range of the projects within the field of technical and public safety,
6. the experimental facilities, for example the world class laboratory test facilities and the open air test site at Horstwalde, and last but not least
7. the inclusion into the multidisciplinarily organized institution BAM.

As a result of the conception and strategy talks 1999 and 2001, the presidency of BAM decided on a further strengthening of this main project area, which was confirmed by the target agreement 2002 until 2004 between the Federal Ministry of Economics and Technology (BMWi) and BAM. Therefore it is necessary to describe a joint scope of activities as the focus for all departments of BAM.

2. What is technical and public safety?

The citizens right to life and to physical integrity is established in Article 2 of the Constitution of the Federal Republic of Germany, amended by the commitment by property in Article 14 (its use should also serve the public good) and by the protection of the natural living conditions for future generations in Article 20a.

This means that the state has a responsibility for keeping its citizens safe from risks resulting from scientific and engineering research and development and particularly from the application of the resulting products and technological methods (e.g. technical products, processes, plants and systems). It is described as technical and public safety and embraces a wide field meaning that occupational safety and certain aspects of the environmental protection are included as well as consumer protection and product safety (protection from products which

may be hazardous), plant safety and the safety of transport:

Providing technical and public safety in permanently changing technical and industrial surroundings should today be considered just as important as the concern of the state for the internal and external security.

The required governmental measures depend primarily on the inherent risks from the related technical products, processes, plants and systems including their consequences. They range from providing legal framework conditions via surveillance to direct public action.

3. Safety, risk and risk limitation in the legal/technical context

In the technical/scientific context a risk is described as a probability, taking into account the expected frequency of occurrence of an event resulting in damage and also the extent of damage in the case of occurrence. In order to describe the term chance, which is complementary to risk, damage should by substituted by benefit.

Safety is a situation where the risk defined through the probability of occurrence and the extent of damage is not higher than the highest acceptable risk - the risk limit. In the field of technical regulations the state is obliged to set the limit of the acceptable risk, being responsible both for the society as a whole and for each individual. The measure for the risk limit, however, cannot only be determined on the basis of the safety needs of objects enjoying legal protection, e.g. human beings and environment; a careful consideration – in social consensus - of the risks of technologies and their utility and necessity is indispensable.

In general, the risk limit cannot be determined quantitatively. Normally it is described indirectly through technical safety specifications. Such a description or definition of the risk limit implies that the risks related to certain technical products, processes, plants and systems are sufficiently known or at least qualitatively describable. Therefore, the description and assessment of technical risks do belong to the duties of the state as well - a task for which the state makes use of the impartiality and technical expertise of its technical/scientific state institutes.

Legal systems usually determine the required safety by legal requirements in laws and regulations, be it through specifying the safety level to be met (generally acknowledged rules of engineering, current state of engineering, current state of safety engineering, current state of science and technologies), or be it by means of detailed safety provisions. This usually happens for practical purposes by technical and administrative rules set on a level below the laws, like accident prevention rules, technical rules, standards etc. which are set up with the participation of all parties concerned, particularly the economy.

In any case for determining the risk limit the following principles apply:

I. Absolute safety in the sense of zero risk (risk prohibition) cannot be required by the legislators nor is it stipulated.[1]

II. Different technical products, processes, plants and procedures should, if possible, not present any different risks for the objects enjoying legal protection (risk equivalence).

[1] Editorial amendment, December 2011

III. The measure for the highest acceptable risk is not only determined by the need for legal protection of the objects considered, but also by the possibility of meeting social requirements (chance), where in general a careful consideration under social aspects is needed (risk adequacy; risk and chance control).

Dealing with risks which are not sufficiently known or controllable presents a particular problem. Difficulties also arise if there are strongly different opinions with respect to the risk assessment. In these cases the required precaution is mainly a political decision which may even include a complete ban of a technical product or a process.

The description and assessment of technical risks belong to the national duties as well, due to their difficulties to determine and communicate them and to their effect on the society. Also the risk assessment in the deregulated areas need public control by suitable structures.

4. Activities of BAM related to technical and public safety

BAM contributes with its scope of activities (advice and information - testing, analysis, approvals - research and development) in all fields of expertise to ensure and develop the technical and public safety. Particularly affected are the fields which are regulated by law as the explosives and weapons law, the hazardous substances and the dangerous goods law, the equipment safety law, the immission control law, the atomic law, and the building law.

In particular for handling and transport of hazardous substances and dangerous goods, BAM is very well equipped with legal competences (conformity assessment[2], approvals, classification etc.).

Questions concerning the technical and public safety arise as well in other fields of expertise, e.g. analytical chemistry, non-destructive testing, and materials engineering or protection. In these fields it is BAM's task, to identify these problems early, to evaluate them, and to take care of them in the regulation process.

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[2] The "modular concept" of the European Union provides a risk-orientated system of testing, quality assurance and conformity assessment. It should ensure the safety of products and services. It is binding in all states of the European internal market and is adopted in all signatory states. The entire system of the conformity assessment should ensure that innovation and safety are not contradictory. In so far as the tasks of technical and public safety are closely linked to the technical and scientific service

functions of BAM. BAM is using its above mentioned advantageous structure for these tasks.

4.1 Advice and information

The central task in the area of advice and information is advising the Federal Government according to § 4 of the Statute of October 13, 1995 concerning the Federal Institute for Materials Research and Testing (called Statute below). This happens mainly by directly supporting the Federal Ministries responsible for the different legal areas or through participation in the related advisory or regulatory committees.

The basic principles about the risk limit above are taken into account.

§ 1 of the Statute, according to which BAM is required to promote the German economy by doing the assigned tasks, is to be understood in this context in such a way that

- a high safety level is to be maintained or achieved in the Federal Republic of Germany,
- economical aspects should be considered before the background of the necessary safety level,
- apart from its ethical importance hazard prevention is of high economic and microeconomic benefit.

§ 1 of the Statute further obliges BAM that solutions for safety related matters which are found, proposed and pursued by BAM should be economically acceptable. Restrictions should not go beyond what is necessary to achieve the respective objective (principle of proportionality).

Other authorities, standard organizations, associations, companies etc. are advised according to the same principles.

With the development and expansion of the European internal market and with globalization, the reduction of risks also means monitoring the behavior of partner countries, the products and services of which get to the German market. Conformity assessment and quality assurance therefore present an indispensable advisory task in the context of technical and public safety.

4.2 Research and development

Research and development in the field of technical and public safety contribute to

- more and deeper safety-related knowledge,
- maintaining and improving safety levels,
- securing internal expertise.

In that respect innovations on products, processes, plants and systems should be accompanied by safety-related precautionary research.

In the area of technical and public safety, BAM carries out research and development on its own initiative and partly at its own expense. Important fields are

- description and assessment of risks,
- determination of safety-relevant properties of substances, products and systems,
- development and optimization of protective measures,
- development of testing and investigating methods, including non-destructive methods and sensors,

- exploitation of safety-related data and knowledge.

Research and development done by BAM in this area may have the nature of basic research to some extent.

An active patent policy, as required for other areas of BAM, should be applied in the area of technical and public safety only with considerable restrictions. In this field, in particular the statutory tasks must have priority before any exploitation interests.

4.3 Testing, analysis, approvals

These are different activities, usually paid by the applicant, including those of a statutory nature (administrative acts) and expert opinions for external parties. As far as these activities include some form of evaluation about the acceptability of a risk, the same principles as described in section 4.1 are applied.

This area, apart from research and development, contributes considerably to securing BAM's expertise providing the institute with practical information about current problems and developments in the economy in an efficient way. To a reasonable extent and taking into account the subsidiarity principle, safety testing supports this as well.

On the basis of § 5 of the Statute, BAM in particular, as impartial and competent agency, offers its direct services if this is required for maintaining and increasing the safety level (particularly in legally regulated areas) and if other suitable bodies are not available.

5. Current developments and consequences for BAM

BAM's role as testing and approval authority for different areas of the technical and public safety has changed considerably during the last ten years. Keywords are:

- European internal market, particularly New and Global Approach in the field of technical harmonization and standardization (Directives according to article 95 of the EC Treaty)
- European Directives according to article 137 of the EC Treaty concerning workers' health and safety and according to article 175 on plant safety and environmental protection (minimum provisions)
- European agreements as well as Directives according to article 71 of the EC Treaty on the transport of dangerous goods and respective international regulations (in particular UN Recommendations)
- UN Earth Summit on Environment and Development (UNCED) 1992 in Rio de Janeiro with Chapter 19 of the Agenda 21 on environmentally sound management of toxic (dangerous) chemicals
- Development of the world trade and the globalization in general, e.g. in the framework of the TBT Agreement
- Final report of the "Lean State" Advisory Council and deregulation/privatization as well as the concept of "activating state".

Altogether these developments mean that national regulations (material as well as organizational requirements and legal structures) are increasingly influenced or even replaced by European and international regulations. This means in detail:

- Material - also safety-related - product requirements are changing to reduce non-tariff barriers to trade.

- Competition aspects are increasingly taken into account in legal developments.
- Other legal systems will influence national procedures and structures, e. g. concerning
  - the distribution of roles between state and economy (public versus private responsibility),
  - the rating of organizational requirements and measures (e.g. management systems) versus technical measures or material requirements,
  - (product) liability and quality assurance, and
  - the importance and use of quantitative risk analysis.
- National approval authorities more and more loose their exclusive position and are in competition with other Notified Bodies (normally accreditated) in performing the European conformity assessment, once the existing national legal provisions are superseded by European law by implementing a Directive according to the New Approach.
- National authorities, however, also maintain their importance in the international context, when innovative solutions with a short product half life are pursued, which in particular enables the quicker market access of small and medium enterprises (SME).
- Modified structures must ensure the existing safety level, for any changes the equivalency of efficiency must be proven.

6. Conclusions

In the area of technical and public safety the following tasks arise for BAM as a whole from the above:

1. **BAM - in its function as a national chemical and materials technological institute and on the basis of its tasks in the area of technical and public safety by advice and information, by research and development as well as by testing, analysis, approvals - contributes to maintain and ensure a high safety level and, if necessary, increase it for the protection of human beings, environment and properties.**

2. **BAM takes an active part in the actual developments in the area of technical and public safety including the support on conformity assessment systems, in particular by contributing to national, European or international committees, taking into account economic and competition aspects. BAM helps to solve respective goal conflicts by means of technical contributions and to determine accordingly.**

3. **In particular BAM makes its technical expertise available for determining and describing risks of technical products, processes, plants and systems and thus contributes to socially and legally appropriate decisions.**

4. **BAM immediately takes charge of legal responsibilities in the scope of formally assigned competences, while extent and function are determined by social, administrative and technical requirements. BAM takes economic effectivity and efficiency into account as well.**

5. **BAM accompanies and supports the European and worldwide harmonization of product, quality and safety standards as well as conformity assessment, with the aim to contribute to improve the framework conditions for the economy and to ensure technical and public safety as well as to stabilise and sustain its related role in the network of European and international research, testing and approving institutions in the context of this aim.**