



Placing products

on the European single market and market surveillance

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Surveillance of placing products submitted to one (or more) directive(s) based on Article 95 of the EC Treaty on the European Community market by the authorities is significant for both consumers and manufacturers. The aim is a standardized high safety-level for the users. For the manufacturers it is important that the authorities take care that the legal regulations are observed and thus distortion of free competition is avoided. In this article the market surveillance in the Federal Republic of Germany, for example, will be considered with regard to relevant regulations, organizational measures and practical experiences.

Compulsatory duties of the manufacturer

Manufacturers, authorized representatives and importers may only place products in the market submitted to one (or more) directive(s) based on Article 95 of the EC-Treaty (among others the directive 94/9/EC [1]) for sale in the European Union when the following prerequisites are fulfilled:

- › every product is in compliance with the essential safety requirements of the relevant directive(s)
- › if required, every product has to be marked with the CE-mark,
- › every product has been subjected to a conformity assessment procedure,
- › requirements of all applicable directives are observed and fulfilled.

Further information may be gained from the ›Guide to the implementation of directives based on the New Approach and the Global Approach (Blue Guide)«, [2]

Legal basis

All directives obligate the member states to take care that only products are distributed within the community that are in compliance with the directives. For this a market surveillance is required. Legal basis for the surveillance of manufacturers and distributors in the Federal Republic of Germany is the law ›Gesetz über technische Arbeitsmittel und Verbraucherschutz – Geräte- und Produktsicherheitsgesetz-GPSG [3]‹ (Act on Technical Work Equipment and Consumer Protection – Equipment and Product Safety Regulation) dated 6th January 2004. This law is applicable for placing products the first time to the market for distribution (selling to others) and exhibition of products within a business venture. Aim of this law is to make sure:

- › that only such products are distributed and shall be acquired by users that are in compliance with the relevant legal provisions. There by it is to ensure that the user or consumer of this product does not have to make modifications later to be allowed to use the product.
- › that life and health of users or third parties is protected. This is achieved with the following regulations:
- › quality and design of the product has to be state of the art. So devices using out-of-date technology shall not be sold.
- › the manufacturer supplies manuals for use and operation with all necessary instructions for the safe use of the product.

Regarding to particular products the member states are allowed to adopt additional national provisions which are intended for the protection of the workers or environment. In the Federal Republic of Germany, these are e.g. certain inspection acc. to the ›Betrieb-

ssicherheitsverordnung (BetrSichV) (German industrial health and safety regulation) or this may be regulations for the protection of the environment according to the Bundes-Immissionsschutzgesetz (BImSchG), which the employer respectively the user of an installation, has to consider appropriately when ordering.

The safety-related requirements on the products are laid down in numerous individual directives of the EU. For explosion-protection this is directive 94/9/EC (›ATEX 95‹) [1]. This directive had to be transposed unaltered into national legislation so that no trade barriers may arise. In the Federal Republic of Germany, this is normally realized by regulations acc. to § 3 para.1 GPSG. With the regulation ›11. Verordnung zum Geräte- und Produktsicherheitsgesetz-Explosionsschutzverordnung‹ (German regulation on explosion-protection for equipment and protective systems) e.g. the directive 94/9/EC has been transposed into national legislation.

Interpretation of the directive is discussed with the parties involved in a working group of commission ›Enterprise and Industry‹. Decisions are made by the so-called ›Standing Committee‹, where only government representatives have a right to vote. Results are published on the commission's home page in the Internet. For application of directive 94/9/EC, a guideline has been developed [4], into which the current decisions of the Standing Committee are entered.

Tasks and powers of the surveillance authorities

To be able to audit if the manufacturer or distributor fulfills his obligations, the representatives of the surveillance authorities may enter rooms or premises where:

- › products are manufactured,
- › products are stored for sale or
- › products are exhibited for sale.

On the premises or in the rooms, the representatives of the authorities may inspect the products and may test them. The products may also be put into service. If that is not sufficient for evaluation, products may also be taken away as samples. The manufacturer or distributor is obliged to provide any information for the authority that is required to assess a product. Furthermore, he has to render any assistance for the examination and evaluation of the product. If, despite all due care, it is not possible for a representative of an authority to assess a product conclusively, a manufacturer or distributor may be committed to have an expert's assessment made on the product at his own expense.

If a product does not comply with the provision of the applicable directive(s), the authorities may for example:

- › prohibit placing the product on the market
- › order that a warning in the language of the member state (in German) is applied,
- › order a withdrawal from the market or also a call-back by the manufacturer,
- › initiate a safe destruction of the product or
- › officially warn the public.

In regard to competence to give directions, however, the authority has to check and to pay attention to the commensurability of the means.

Organization of market surveillance

The enforcement of the German Equipment and Product Safety Regulation is delegated to the individual Federal States. The law demands effective surveillance of the distribution of products. This can only be achieved by a coordination of the different authorities among each other. That is why a ›working committee market surveillance‹ has been established.

Members of this committee are:

- › the Supreme State Authorities that are responsible for equipment and product safety (in most cases these are ministries)
- › the representatives of the directives, appointed by the Federal Council of Germany,
- › Federal Ministry for Labor and Social Affairs
- › ›Bundesanstalt für Arbeitsschutz und Arbeitssicherheit‹ (Federal Institute for occupational health and safety and occupational medicine) and
- › Zentralstelle der Länder für Sicherheitstechnik‹ (centre for safety engineering of the states).

The ›working committee market surveillance‹ prepared a guidelines ›Leitlinie zum Geräte- und Produktsicherheitsgesetz‹ [5] that answer the most important questions and thus are meant to help provide a standardized enforcement of the law. The guidelines may be downloaded from the Internet.

The surveillance authorities use the ›Handlungsanleitung für die Marktüberwachung in Deutschland‹ (operational instructions for market surveillance in Germany) [6] as instructions for a standardized approach to their tasks. →

The central tasks of the working committee market supervision are:

Arrangement of dividing of tasks between the states

Other member states report more and more products that are not in compliance with the respective provisions of the community. It is the task of the member states to check if the same or similar products are on the market in Germany. Here a division of tasks between the different German Federal States has been agreed upon so that each individual state would not have to look in an uncoordinated effort for these products.

Nationwide coordination of planning and measures

Inspections and required surveillance are arranged and coordinated so that, as far as possible, a nationwide control in the Federal Republic may be achieved and so distortion of free competition is avoided. In 2006 a campaign for market surveillance in the field of 11th GPSGV has been realized, besides other procedures. During this campaign, into which several Federal States have been involved, small and middle-sized companies that manufacture products or that import them into the European Economic Area should be given assistance especially in regard to comply to their legal obligations, and it should be controlled, if the regulations are observed. One emphasis of surveillance also in the field of directive 94/9/EC will furthermore be the observation of flow of goods e.g. during large trade fairs.

Support with communication

For this purpose internet-supported database ICSMS has been installed into which all examined products are entered. The database contains the following information:

- › general information on the authority that reported the product
- › information for identification of the product
- › information on the manufacturer or distributor
- › information on the relevant directives and other regulations
- › information on the verification of the conformity
- › information on scope of testing of the inspected product
- › test results and classification of defects
- › information on accidents and other incidents
- › information on the measures the authorities have taken.

Under <http://www.ICSMS.org> every citizen may get information about results and tests from the public part and e.g. information on the authorities locally responsible.

Cooperation with external bodies

Reasonable market surveillance also requires communication with manufacturers and associations. Here the problems of the manufacturers and also that of distributors are discussed. Therefore authorities will increasingly approach associations to discuss the problem areas with them in future.

Europe-wide cooperation with the enforcement authorities via the directive representatives

The directive representatives that have been appointed by the Federal Council of Germany are specialist civil servants from surveillance who, amongst other things, also have the task to ensure coordination on an EU-level with other member states from the field of enforcement. The representatives of the European market surveillance authorities meet regularly to discuss questions of enforcement practice (Administrative Cooperation Committee [ATEX-ADCO]). Amongst others this is reasonable and required to avoid distortion of free competition due to different requirements for market access.

The tasks of the directive representatives are:

- › contact persons for the Federal States for questions concerning the directives
- › upon request support for the states with local execution of market surveillance
- › contact persons for industry, associations, etc. for questions concerning the directives
- › contact persons for the European Council and the Commission for questions of enforcement
- › transmitting of reports on defective products to the appropriate administrative authorities outside the Federal Republic of Germany
- › acceptance and transmitting of reports of European authorities to the appropriate local administrations in Germany



According to the new approach, a contact person has been appointed for each directive in the individual EU-member states to make quick exchange possible between the highest authorities for market surveillance in regard to circulation of faulty technical products (see <http://lasi.osha.de/docs/lv36.pdf>). The directive representative for directive 94/9/EC is at the moment the author of this article, Dipl. Ing. Ursula Aich, Regierungspräsidium Darmstadt, Abteilung Arbeitsschutz und Umwelt, Wiesbaden, Simone-Veil-Str. 5, 65197 Wiesbaden.

Complete enforcement of Directive 94/9/EC is in the interest of users of installations with hazardous areas and also of the manufacturers. While the first ones are mainly interested in the supply of safe products, manufacturers put special emphasis on the prevention of distortion of free competition. All parties involved are also interested in stopping violations of the directives quickly and efficiently.

Practical experiences

During the inspection at the Achema 2006, 109 stands (70 domestic exhibitors and 39 foreign ones) were visited to check how provisions of directive 94/9/EC are kept. Results and findings of this inspection are shown here.

Missing documents

At 19 stands no documents or documentations were available for the exhibited products that fall under directive 94/9/EC. Obligation according to § 4 para. 3 of the GPSG (German equipment and product safety regulation), which allows only to exhibit products that comply with the requirements of § 4 para. 1 and 2 GPSG, has often not been known or has been avoided by exhibiting ›trade fair samples‹. But these have not been marked with an appropriate label according to § 4 para. 5 of GPSG.

Avoiding directive 94/9/EC

At 17 stands we checked, the exhibitors offered products (mills, mixers, dryers, filling installations, stirring devices) without measures in regard to explosion protection; predictably these products may also be used in hazardous areas (e.g. in the food processing industry and in installations for the production of colors and paints). Upon inquiry about the application range of directive 94/9/EC, one manufacturer told us that the product (stirring devices) would be too expensive offering it according to directive 94/9/EC. Two vendors from Asia did not know the requirements in regard to explosion protection according to directive 94/9/EC at all; some de-

nied necessary explosion-protection measures for installations for the food processing industry. Further answers were that the product is also delivered for use in potentially explosive areas upon customer's request. This has often been answered by manufacturers of installations for filling and packaging industry. In the field of plant engineering, it often is the case that the customer orders a part (e.g. dryers) for which he himself draws up an explosion protection concept. In these cases questions often arise in regard to selection of the appropriate conformity assessment procedure according to directive 94/9/EG.

Question on the field of application of directive 94/9/EC

Furthermore, there were many questions on the field of application of directive 94/9/EC. These were e.g. questions on the difference between equipment and components.

Other questions have been about placing ›combined devices‹ into on the market (in the guideline of the Standing Committee on directive 94/9/EC called ›assembly‹) and the required conformity assessment procedure according to directive 94/9/EC (art. 8).

With the result from the discussions during this trade fair, it can be assumed that plants and machine manufacturers often have the opinion it would be enough to only use equipment and components that have →

an EC-type examination for assemblies. It was not known that possible additional ignition hazards have to be assessed when completely approved individual apparatus are assembled. Or it could not be found out if a manufacturer of assemblies has examined and assessed possible new potential ignition sources.

Voluntary type examinations of equipment and components

Another finding was, that due either to uncertainty or for marketing reasons, manufacturers apply for products to be tested by a 'notified body' that records the result of this examination in a 'EC-type examination certificate'. The products are then offered with an 'ATEX-approval'. Such products exhibited at the trade fair were, among others, e.g. mechanical air flow control units that are fitted into exhaust channels, the exhaust arm of an exhaust system or a cable conduit. It surely cannot be objected when a manufacturer consults a notified body. But this notified body should not, by the form of its test certificate, create the impression that it provides an approval required by law.

Marking of equipment

With electrical equipment and components, mainly the markings comply with the requirements of the directive and the applicable standards. The markings which were found of non-electrical equipment and components were often faulty:

- › no complete marking according to standard, e.g. no information on maximum surface temperature for equipment used in dust-explosive atmosphere.
- › identification number of the 'notified body' for non-electrical devices category 2 has not been indicated.
- › Assembly (combination of individual devices) have not been marked as such. The label of the assembly and the labels of the individual devices that belonged to this assembly have been one directly below the other. So it has not been recognizable which marking belonged to which part, and the marking has been contradictory and not serviceable for the user.

Concerning ventilators, solvent distillation installations, refrigerators and comparable installations, it has not been distinguished between the inside of the equipment and the external environment. It could not be seen from the marking if the explosion protection refers to the inside of the device or to the external environment or to both and which zone is classified inside or outside.

References

- [1] Directive 94/9/EC of the European Parliament and Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protecting systems intended for use in potentially explosive atmospheres, Official Journal of the European Communities, No L 100/1-29
- [2] Guide to the implementation of directives based on New Approach and Global Approach, 'Blue Guide', European Commission 2000.
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- [3] Gesetz über technische Arbeitsmittel und Verbraucherprodukte – Geräte- und Produktsicherheitsgesetz – GPSG vom 6. Januar 2004 (BGBl. I. S. 2, zuletzt geändert durch Gesetz vom 7. Juli 2005 [BGBl. S 1970])
- [4] ATEX Guidelines (Second Edition) July 2005, Guidelines on the Application of Council Directive 94/9/EC of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protecting systems intended for use in potentially explosive atmospheres, <http://ec.europa.eu/enterprise/atex/guide/index.htm>
- [5] Leitlinie zum Geräte- und Produktsicherheitsgesetz, http://lasi.osha.de/docs/Lv_46.pdf
- [6] Handlungsanleitung für die Ausführung der Marktüberwachung in Deutschland, http://lasi.osha.de/docs/Lv_36.pdf