

No. 1016

Act on the conformity of certain technical devices to relevant requirements

Issued in Helsinki on 26 November 2004

Section 1 – *Objective*

The objective of this Act is to ensure that machinery, work equipment, personal protective equipment or other technical devices (*technical device*) meet the relevant requirements and do not cause a risk of accident or harm to health when used as intended by the manufacturer. The aim of this Act is also to ensure that technical devices, when appropriately designed, manufactured and equipped, may without hindrance be placed on the market or provided for use.

Section 2 – *Scope of application*

- (1) This Act is applied to manufacturers, importers, sellers and other persons who place technical devices, predominantly intended for use at work, on the market or provide them for use.
- (2) Separate provisions shall be issued regarding employer obligations as to the acquisition, safe use and inspection of technical devices.

Section 3 – *The relation of this Act to other legislation*

If any other act contains provisions, different from this Act, on the placing on the market and provision for use of technical devices, those shall be applied instead of this Act.

Section 4 – *Manufacturer's general duty of care*

- (1) The manufacturer shall design and manufacture a technical device with its structures, equipment and other properties so that the device is fitted for its function and, when used in the intended way, it does not cause a risk of accident or harm to health. If the risk of accident or harm to health cannot be eliminated adequately enough in any other way, appropriate protective measures shall be used in the manufacture. Effective warnings of the risks and harmful effects shall be given. Personal protective equipment must be effective against the dangers from which it is to provide protection.
- (2) Further provisions on the following points shall be issued by government decree:
 - (1) health and safety requirements related to the design and construction of machinery, as well as controls, the prevention of mechanical and other hazards, the protection characteristics of guards and safety devices;
 - (2) requirements related to the design and construction of personal protective equipment and the innocuousness and protective characteristics of personal protective equipment; and
 - (3) health and safety requirements related to the design and construction of technical devices other than those mentioned in subparagraphs 1 and 2.

Section 5 – *Indication of conformity*

- (1) The manufacturer shall, in a manner required on the basis of the characteristics of the technical device,:
 - (1) prove in a reliable way that a technical device conforms to the relevant requirements; dangerous technical devices and personal protective equipment, other than simple one designed to protect from minor hazards, must be type-examined or its conformity must be certified by an expert body;
 - (2) draw up technical documentation for indication and control of conformity;
 - (3) draw up appropriate operating instructions and other instructions to be provided with the device; and
 - (4) label the technical device with a marking of conformity and, in case the device otherwise is not clearly identifiable, with a necessary marking of identification.
- (2) Further provisions shall be issued by government decree on technical devices which shall undergo type-examination or other certification of conformity, and on the related procedure, as well as on the content of instructions provided with the device and on the labelling of the device.

Section 6 – *Consideration of a dangerous substance*

If a dangerous substance is permanently incorporated in a technical device, the manufacturer shall provide the device with the name of the substance and with a necessary marking to indicate the dangerousness of the substance in use and in case of accident. Appropriate operating and safety instructions for the substance shall be provided with the device.

Section 7 – *Obligations for importers to the European Economic Area*

If the manufacturer has not fulfilled the obligation laid down in sections 4 to 6, the obligation falls on such other person who in his or her own name for the first time places a technical device on the market or provides it for use in the European Economic Area.

Section 8 – *Presumption of conformity*

- (1) A technical device is considered to meet the relevant requirements if the manufacturer has duly declared its conformity and affixed a mark of conformity to the device, or it has been proved in some other manner that the device conforms to the requirements laid down in section 5.
- (2) If the enforcing authority proves that a technical device does not conform to the relevant requirements or that it is dangerous in use, the availability of the device on the market may be impeded or restricted, as separately provided by statute.

Section 9 – *Obligations for persons supplying technical devices further*

A person who supplies further a technical device placed on the market shall ensure that the device conforms to safety requirements in the same manner as it did when it was placed on the market. In addition, it shall be ensured that appropriate instructions in the Finnish and Swedish languages accompany the device.

Section 10 – *Technical devices in use*

- (1) The provisions in sections 8 and 9 also concern, where appropriate, the sale, leasing and other supply of technical devices in use.
- (2) If a technical device is altered contrary to its intended purpose or in a manner otherwise essentially affecting safety, it will be treated as a new device and sections 4 and 5 will be applied to it.

Section 11 – *Exhibition*

A technical device may be exhibited even if it does not conform to the requirements of this Act, provided that it is indicated by a clear marking that the device does not conform to the relevant requirements and it must not be supplied or put into service until it has been brought to conformity. It shall also be ensured that a device on display does not cause any risks.

Section 12 – *Enforcement*

- (1) This Act shall be enforced by occupational safety and health authorities in accordance with the Act on the Supervision of Occupational Safety and Health and Appeal in Matters Concerning Occupational Safety and Health (131/1973).
- (2) Provisions on the conformity and surveillance of technical devices which are intended for private consumption or predominantly used by private consumers are laid down in the Act on the Safety of Consumer Products and Services (75/2004).

Section 13 – *Penal provision*

- (1) A manufacturer or supplier who intentionally or through carelessness fails to fulfil obligations provided by this Act shall be sentenced to a fine for *violation of the safety of devices*, unless a more severe punishment for the act is prescribed in some other legal provision.
- (2) Punishment for a crime against occupational safety and health is provided in section 47(1) of the Penal Code (39/1889).

Section 14 – *Entry into force*

- (1) This Act enters into force on 1 January 2005.
- (2) This Act repeals section 68(3) of the Act on Occupational Safety and Health (738/2002) of 23 August 2002.