



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Consumer goods  
Cosmetics and Medical Devices

Brussels, 24th November 2008  
M/433 EN

**Standardisation mandate addressed to CEN and CENELEC within the framework of Directive 2007/47/EC, amending Directive 93/42/EEC relating to Medical Devices, concerning graphical symbols for use in the labelling of medical devices containing phthalates**

**GENERAL**

This mandate relates to Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 on medical devices, amending Directive 93/42/EEC.

According to Annex I, section 7.5 of Directive 93/42/EEC, as amended by Directive 2007/47/EC, some categories of medical devices containing phthalates which are classified as CMR of category 1 or 2 in accordance with Annex I to the "Dangerous Substances" Directive 67/548/EEC, must be labelled as devices containing phthalates.

To achieve the above-mentioned objective, the standards shall specify graphical symbols for use in the labelling of medical devices containing phthalates. This is to warn and protect human beings from hazardous effects, which may be caused by exposure to phthalates. The standards are intended to become Harmonised Standards giving a presumption of conformity to Directive 93/42/EEC.

**I BACKGROUND**

For a number of years there has been ongoing research in the field of plasticizers, to tentatively evaluate their safety/toxicity to the patients, in particular specific groups possibly at risk, taking into account the level of exposure under specific conditions of use.

According to Recital 27 of Directive 2007/47/EC, the Commission should give a mandate to CEN and/or CENELEC to specify a suitable specific label for phthalate-containing devices within 12 months after entry into force of this Directive.

On the 6<sup>th</sup> of February 2008, the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) adopted, after public consultation, the Opinion on the safety of

medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.

This mandate takes into account the requirements of Directive 2007/47/EC concerning the labelling of devices containing phthalates.

## **II MOTIVATION AND NEEDS**

Directive 2007/47/EC requires the Commission to issue a mandate to CEN and CENELEC to specify a suitable specific label for phthalate-containing devices. The Directive (Recital 28) also stated that many Member States have established recommendations with the aim of reducing or limiting the use of medical devices containing critical phthalates on children, pregnant and nursing women and other patients at risk. To enable medical professionals to avoid such risks, devices which possibly release phthalates to the body of the patient should be labelled accordingly.

## **III DESCRIPTION OF THE MANDATED WORK**

CEN and CENELEC are requested to consider the requirements for labelling of some categories of medical devices containing defined categories of phthalates and to draw up a standard containing the specific labelling requirements or to revise existing standards with a view to incorporate the specific labelling requirements.

At least the following elements should be taken into account:

- The existing standards concerning graphical symbols for use in the labelling of medical devices,
- The international standardisation and current technical practice in this sector. CEN and CENELEC must co-operate with ISO/IEC and avoid duplication of work.

## **IV EXECUTION OF THE MANDATE**

The Commission hereby entrusts to CEN and CENELEC the described mandate.

In order to ensure transparency in the work to be carried out, CEN and CENELEC will provide the following information within three months of the acceptance of the mandate:

- A programme indicating which standards will be covered by the mandate and the target dates for public enquiry and for adoption;
- An indication of the features to be modified and/or supplemented.

As a matter of urgency CEN and CENELEC shall complete the mandated work by 31 October 2009. This is to comply with the requirements of Directive 2007/47/EC.

Acceptance by CEN of this mandate starts the standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998 (OJ N° L 204/37 of 21 July 1998).

## **V BODIES TO BE ASSOCIATED**

As appropriate, CEN and CENELEC will invite the representative organisations of consumers' interests (ANEC), environmental protection (ECOS), workers (ETUI-REHS) and small and medium-size enterprises (NORMAPME) to take part in the standardisation work.