

POSITION PAPER

Ref. 03/2012/02



Packaging and Packaging Waste Directive (94/62/EC) 1994 amended by Directive 2004/12/EC – Essential Requirements

The Packaging and Packaging Waste Directive (subsequently referred to as the Directive) Annex II specifies the following requirements:

1. *Requirements specific to the manufacturing and composition of packaging - Packaging shall be so manufactured that the packaging volume and weight be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product and for the consumer.*

- Packaging shall be designed, produced and commercialized in such a way as to permit its reuse or recovery, including recycling, and to minimize its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of.

- Packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimized with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled.

Article 11

In addition to these requirements, Article 11 of the Directive states:

the sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100ppm by weight.

Responsibility for Compliance

Responsibility for ensuring compliance with the above requirements ultimately lies with the individual or organisation responsible for placing the finished product on the market.

SBA Position

The SBA is a trade association representing manufacturers of single use sterile barrier systems (SBS). These systems are used by medical device manufacturers as an integral part of or accessory to a sterilised medical device.

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A sterile barrier system is defined in EN ISO 11607 (Packaging for terminally sterilised medical devices) as “the minimum packaging configuration that provides a microbial barrier and allows aseptic presentation of the product unit at the point of use”. This is distinct from protective packaging which is defined as the “packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use”.

Sterile Barrier systems are considered to be ‘accessories’ to medical devices as defined under the Medical Device Directive (93/42/EC) and for the purposes of the Directive, accessories are treated as medical devices in the requirement to comply with the essential requirements as set out in Annex 1 of the Directive. These requirements take precedence over the requirements of the PPW Directive in the design and use of SBS.

However, the SBA **accepts** the principles of the Packaging and Packaging Waste Directive and therefore, the following statements are offered:

SBA statements

- 1) Only the medical device manufacturer can decide what is the minimum weight and volume required of the sterile barrier system to maintain safety, hygiene and compatibility with the packed product and acceptance by the consumer and to ensure compliance with the requirements of the Medical Device Directive (93/42/EC). SBA members will, however, be happy to work with them to make a suitable choice of material.
- 2) **Where there is risk of contamination of the SBS with blood, body fluids and tissue products, the SBS should be disposed of as contaminated waste.** The SBA advocates clean combustion with energy recovery as the current best environmental option for disposal of materials that show a net calorific gain. Materials show a net calorific gain if they are composed of more than 50% of organic material.

Where there is no risk of contamination the Directive advocates a number of alternative approaches to the recovery and recycling of packaging materials. The decision as to which one to choose will depend on the materials and the waste streams/facilities available to the user.

- 3) Article 6 of the Directive requires Member States to encourage the use of materials obtained from recycled packaging waste for the manufacture of packaging and other products. SBA members comply with the material requirements of the European standards that support the Medical Device Directive (93/42/EC) amended by Directive 2007/47/EC in that reclaimed materials will only be used in sterile barrier systems where the source, history and traceability of the materials are known and controlled to ensure that the finished product consistently meets the requirements of the standards.

Sterile Barrier Association, Pennygate House, St Weonards, Herefordshire, HR2 8PT, UK

Tel 01981 580 190 <mailto:director.general@sterilebarrier.org> Website: www.sterilebarrier.org

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Registered Office 4. King Sq., Bridgwater, Somerset TA6 3YF

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- 4) SBA members can provide information, based on an “upstream approach” and calculation, to verify that no noxious or hazardous materials, as defined in Annex 1 of Directive 67/548/EC (Dangerous Substances Directive) and its amendments as dangerous to the environment (assigned the symbol N), are intentionally used in or added to their sterile barrier systems or their components above the levels considered in the Directive.

- 5) SBA members can provide information, based on an “upstream approach” and calculation, to confirm that the sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium present in their sterile barrier systems does not exceed 100ppm by weight.