

Sterile Barrier Association (SBA) feedback on the interim assessment of the Impact Assessment study conducted by Eunomia for the European Commission

Executive Summary

The SBA strongly supports global efforts to minimise the negative environmental impact caused by packaging, and in particular the European Commission's goal to review and update the Directive 94/62/EC on Packaging and Packaging Waste.

SBA members are already committed to the use of the least possible amount of packaging to reduce the carbon footprint of the industry's supply chain without compromising product safety and quality. Furthermore, the SBA has no objection to the introduction of reinforced rules with respect to secondary or tertiary packaging. However primary packaging in the form of Sterile medical packaging or Sterile Barrier Systems (SBS) packaging plays a critical role in protecting the patient by maintaining the safety, sterility, and performance of the medical device. It is our position for the reasons described in the paper below, that Sterile Barrier Systems (SBS) packaging needs special consideration and should be exempt from the proposed legislation in the following ways:

1. where the necessary technical composition of the material means recyclability of SBS materials is not possible
2. where in order to comply with medical safety and quality legislation it is not possible to include recycled content in the manufacture of SBS packaging.

Recyclability

Recyclability of SBS packaging is currently constrained due to a number of considerations detailed below:

1. **Conflicts with other legislation:** SBS packaging is part of the CE approval and so governed by specific sectorial regulations that guarantee the safety and performance of medical devices, namely the Regulation (EU) 2017/745 on medical devices (MDR), Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (IVDR), and specific medical packaging standards such as EN ISO 11607-1/2: 2020. It is crucial to **ensure that new packaging requirements to be introduced are not in conflict with these regulations** nor with other legislation such as Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation), Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation), etc.
2. **Disposal:** The medical technology sector faces challenging complexities for recycled plastic disposal due to contamination of materials by resistant bio-contaminants, reagents, and other chemical substances. The selection of packaging waste for recycling must be accurate due to potential reactions between recyclable plastic ingredients and other substances, as this may lead to chemical hazards. In some cases, the packaging may contain or have been exposed to bio-hazardous waste during a healthcare procedure and may still have to be treated as hazardous waste

in compliance with relevant legislation. It would then have to be incinerated and cannot enter the recycling stream. The sectorial legislation requires the avoidance of Substances of Very High Concern (SVHCs), including carcinogenic, mutagenic, or toxic to reproduction (CMR) and endocrine-disrupting (ED) substances, to minimize the risk to the patient.

3. **Harmonisation:** the sector needs a harmonised assessment basis for classifying the recyclability of packaging materials and defining manufacturing & design criteria for various packaging materials (e.g., print amount, print colours, adhesives, etc.).
4. **Limited alternatives:** The medical technologies sector has different levels of packaging material, and our industry should not be penalised where setting goals on recyclability cannot be met because alternative suitable solutions are unavailable. More precisely for Sterile Barrier Systems packaging, we believe an exemption should apply where there are specific demands or requirements which make their use necessary, and in particular, where they have to meet legislative, product technical and patient safety requirements.

Recycled Content

Recycled content currently available for use is unable to fully satisfy the technical and legislative requirements placed on the industry. The key constraints placed upon manufacturers are detailed below:

1. **Technical capability:** All packaging materials must be 'fit for purpose'. Primary packaging for sterile medical devices or sterile barrier packaging systems are classified as the packaging that enables and maintains the sterilisation or protection (including from light and humidity) of the medical device or in-vitro diagnostic device to the point of use and allows for aseptic presentation to minimise the risk of infection to the patient. This can involve more than one layer of packaging e.g., double entry packaging to support aseptic presentation.
2. **Regulatory constraints:** According to the MDR: *Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.* This will apply to the devices and its packaging. Without consistency of material quality and/or composition, it is not possible to comply with these requirements.
3. **Material composition:** Patient safety is paramount, and it is essential to consider the implications of mandating the use of recyclable plastics in both laboratory environments and for direct use on or by patients, when it is difficult to regulate and standardise the type of plastic being utilised within the product. The potential variation in the recycled plastic employed could lead to inconsistencies, e.g., within sensitive diagnostic test processes, and strict regulatory requirements with unforeseen and damaging consequences.
4. **Product contamination (e.g., impurities, unintended substances, or biohazardous residues):** the inability to guarantee contamination free content in post-consumer recycled materials with no or

very limited traceability, will lead to a higher risk of contamination of the product, both biological and chemical and a conflict with the applicable regulations.

5. **Traceability:** Traceability is a fundamental requirement for medical and in-vitro devices in the MDR and IVDR supported by various standards. EN ISO 11607-1: 2020, the standard for medical packaging, *requires that the source, history and traceability of all materials, especially recycled materials, shall be known and controlled to ensure that the preformed sterile barrier system and/or sterile barrier system will consistently meet the requirements ...* (subclause 5.1.5). It is noted in the standard: *with current commercial technologies, it is unlikely that anything other than virgin manufacturing waste will be used in recycled materials, due to insufficient controls to allow the safe use of other recycled material in sterile barrier systems.* It was confirmed in the workshops that traceability will not be possible for recycled content. Hence, it will not be possible to confirm quality, or safety of that product, making it impossible for manufacturers to comply.
6. **Packaging functionality:** Sterile barrier packaging systems are essential to fight healthcare associated infections. The sector has no objection to the use of recycled materials for secondary or tertiary medical packaging because there are no similar concerns about biological and chemical contamination. Primary plastic packaging represents only a very small percentage of overall plastics packaging waste. A recent BCC Research Market Data Report,¹ shows that healthcare packaging is 7.2% of overall plastics packaging volume in the EU based on 2019 data and this does not delineate between primary, secondary, and tertiary plastics packaging. Primary packaging is expected to be approximately 25% of the (7.2%) overall mix, with secondary and tertiary packaging accounting for the remaining volume of plastics.

At present, most of the recycled content available for use is unable to satisfy the specific requirements above-mentioned. **Thus, the SBA recommends that until there is sufficient chemically recycled material, which has been duly tested, proven to be safe, compliant with the sector constraints, and equivalent to the use of 100% virgin content, an exemption should be granted for Sterile Barrier Systems used for medical technologies.** This should apply to all types of packaging necessary to support aseptic presentation at the point of use to minimize the risk of infection to the patient (e.g., double barrier entry systems).

The SBA welcomes the opportunity to participate in these discussions and consultations and can provide more detail on these points, as necessary.

¹ BCC Research Market Data Report PLS113A “Global Plastic Packaging Market”
<https://www.bccresearch.com/market-research/plastics/plastic-packaging-market.html>



About the SBA

The Sterile Barrier Association (SBA) is the European trade association for companies who produce Sterile Barrier Systems (SBS) and associated equipment and accessories for the healthcare industry.

It was formed in 1992 to help develop technical and safety standards, for sterile barrier packaging which were then adopted throughout the industry. It has consistently supported the introduction of patient safety, quality, and environmental standards, with many current members being actively involved in ISO/CEN workgroups.

All members must be a manufacturer of sterilisation products or provide relevant services and provide these products and services to the European Healthcare Industry.

The SBA is a not-for-profit organisation whose mission is: To be the recognised expert association in the healthcare industry, promoting the use of and providing education on the most suitable single use sterile barrier systems to ensure patient safety.

Patrick Sparkes
Director General

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