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Specialised Nutrition Europe[1] (SNE) Position on the proposed EU Regulation on Packaging and Packaging Waste

In a nutshell

Specialised Nutrition Europe (SNE) supports FoodDrinkEurope's position 'A circular economy for food and drink packaging'[2] and welcomes the objectives of the Commission's proposal[3]. However, some important adaptations are required to **make the proposal's environmental objectives compatible with the specific use and the especially strict safety requirements for foods for vulnerable groups**. Unfortunately, current recycling technologies do not yet enable an adequate supply of high grade recycled plastics and they are not specifically designed to reach consistency of quality among batches for the packaging of foods intended for infants and young children, as well as foods for special medical purposes (FSMP)[4]. SNE therefore recommends **treating foods for vulnerable groups the same way as medicines and medical devices** – which are exempted from the proposal's requirements for recyclability (until 2034 – Art. 6) and for minimum recycled content (indefinitely, Art. 7).

Any foods intended for infants and young children and foods for special medical purposes (FSMP) should also be exempted from the proposal's provisions on re-use and refill (Art. 26) and on deposit and return schemes (Art. 44). Furthermore, especially for Foods for Special Medical Purposes (FSMP), the use of digital labels (e. g. QR code) should be allowed (Art. 11). SNE also recommends promoting the future availability of recycled plastics suitable for foods intended for infants and young children and foods for special medical purposes.

- ## Recyclable packaging (Art. 6)

In order to protect the high quality and safety of foods for vulnerable groups, a lot of effort is being put into preventing the migration of substances into the food. This could be done by applying functional barriers in multi-layer materials, as envisaged by the regulation on plastic materials intended to come into contact with food[5]. While these multi-layer systems help to protect the product and enhance its shelf life (thereby reducing food waste), they might have detrimental effects on the recyclability of the packaging material. To simultaneously enhance recyclability and integrate recycled content, more time is needed to find technical solutions that do not compromise the quality and safety of the products for vulnerable groups.

Furthermore, there are many different types of packaging used for specialised foods, including flexible packaging, suitable for the intended use and target population for the product. The possibility to recycle at scale food contact materials suitable for foods for vulnerable groups depends on anticipated technological advances and on the development and implementation of recycling, collection, and other infrastructure in the EU Member States. Current infrastructure in Europe is not able to ensure recyclability at scale for all packaging materials suitable for packaging foods for vulnerable groups. For similar reasons, the Commission's proposal exempts packaging of medicines and medical devices from the provisions of Art. 6 until 31 December 2034.

➢ To treat FSMP and all foods intended for infants and young children the same as medicines and medical devices, these two product groups would need to be added to the list of exempted products (medicines and medical devices) in the proposal's Art. 6.10.

[1] EU Transparency Register Number: 33498019160-40
[2] A circular economy for food and drink packaging, November 2022 - LINK
[3] COM (2022) 677 final: Proposal for a Regulation (…) on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC - LINK
[4] See annex for explanations about these two product categories
[5] Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food –Art. 13 & 14

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- **Minimum recycled content in plastic packaging (Art. 7)**

SNE supports the European Parliament's call to "increase recycled content, phase out hazardous and harmful substances, and promote re-use without compromising food safety and hygiene standards"[6]. Foods intended for infants and young children and foods for special medical purposes (FSMP) require specific food contact materials beyond 'food grade'. Current recycling streams do not yet enable an adequate supply of recycled plastics with consistently high quality that would guarantee compliance with applicable regulations and be suitable for use in foods intended for infants and young children, as well as in FSMP.

Foods intended for infants and young children are subject to very strict EU regulatory requirements for composition and safety. The specific requirements for this product category stipulated in the food contact materials regulation[7] can be more than seven times stricter than for general foods (see annex to this position paper), and the same regulation prohibits the softener Bisphenol A in food contact material for this product category. At the same time, several studies indicate that recycled plastics can have traces of contaminants and additive degradation products not found in virgin plastics[8], in particular those specifically formulated for specialised nutrition products.

The setting of mandatory recycled plastic targets in food packaging would be extremely challenging for manufacturers of foods intended for infants and young children and FSMP in the short term. The Commission has rightly noted the safety requirements and limited availability not just for medicines and medical devices, but also for foods intended for infants and young children (see annex for substantiation). Therefore, it would be logical to exempt these product groups, along with medicines and medical devices, for which exemptions are foreseen in the proposal. In fact, an indefinite exemption for FSMP from provisions on minimum recycled content is already included in existing law on single use plastics[9].

➢ To treat FSMP and foods intended for infants and young children the same as medicines and medical devices,
  - the FSMP exemption would need to apply not only to single use plastic beverage bottles (as is the case with the existing exemption), but also to the other packaging types listed in art. 7, namely: contact sensitive packaging made from PET, contact sensitive packaging made from plastic materials other than PET, and 'packaging other than those referred to in points (a), (b) and (c).
  - Foods intended for infants and young children would need to be added to the exemptions for all packaging types listed above.

- **Use of a QR code and other digital data carriers to fulfil the labelling requirements (Art. 11)**

Art. 11 introduces labelling requirements and formats related to consumer sorting, reusable packaging, recycled content and compostability. Accommodating this additional information on packaging for Food for Special Medical Purposes (FSMP) would be very challenging, given the frequent use of multilingual labels.

The supply of FSMP products, particularly for rare diseases, relies on the use of multilingual packaging, as the target population is often too limited to justify separate labelling for each country. FSMP products are often also exported outside the EU. The packs often do not have enough space to present numerous variations of sorting information for numerous markets, and in addition, this information could be confusing. FSMPs are intended for a limited number of patients, who are mostly using these products repeatedly over a prolonged period. Once they have accessed the sorting information, they can be expected to become familiar with it, without the need to have the information directly on every pack. Also, managing repeated labelling changes creates a significant challenge for label and stock management, increasing risk for patients. Provisions of packaging information and sorting via digital means (QR code or website) is sufficient to support users of FSMP to understand how to sort/recycle and dispose of packaging.

[6] European Parliament resolution of 10 February 2021 on the new circular economy action plan - LINK
[7] Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food - LINK
[8] Geueke et al. 2018 Food packaging in the circular economy: Overview of chemical safety aspects for commonly used materials. Journal of Cleaner Production;
Gerassimidou et al. 2022 Unpacking the complexity of the PET drink bottles value chain: A chemicals perspective;
Muncke et al. 2020 Impacts of food contact chemicals on human health: a consensus statement
[9] See annex for substantiation.

- **Re-use and refill targets (Art. 26)**

  In line with the principles of the proposal's explanatory memorandum, foods intended for infants and young children and FSMP should be exempted from the obligation of art. 26, given the sensitive users and the potential risks that the reuse of these packaging materials could pose from a food safety and hygiene perspective.

  Specialised nutrition products are developed to meet various uses, adapted for specific populations, and have specific requirements in terms of hygiene/safety and use. Foods for special medical purposes are particularly specialised foods and may require the use of specific administration/delivery systems. They are used under medical supervision both in hospitals and also at home. They are very nutrient dense and are at high risk of hygiene issues unless manufactured, packaged and used appropriately. They are intended for vulnerable patient populations.

  Similarly, foods intended for infants and young children have specific hygiene requirements, and specific packaging is used to ensure the required level of hygiene (sterility, conservation under protective atmosphere). The design of the products/packaging is adapted to their use and takes into account a number of criteria relating to the fragile populations for which they are intended, sterility requirements, compatibility of use of the products in specific establishments, ease of use as well as maintenance of the nutrient content.

  Moreover, refill is not a possibility for foods for specific groups, which are legally required to be prepacked: As recognized in recital 65 of the proposed regulation, "*Refill should be considered as a specific waste prevention measure that counts towards and* ***is necessary for meeting of the re-use and refill targets***". Refill is further defined in art. 3.28: "*refill means an operation by which* ***an end user fills its own container****, which fulfils the packaging function, with a product or several products offered by the final distributor in the context of a commercial transaction*". As such, the newly introduced concept of 'refill' is mutually exclusive with the established concept of 'prepacked foods'[10], and all food for specific groups (which includes inter alia foods intended for infants and young children and FSMP) can only be placed on the market as prepacked food[11]. Hence, the sector cannot rely on "refill" to meet the proposed targets.

- **Deposit and return systems (Article 44)**

  Article 44 of the proposal introduces an obligation for Member States to set up, by 2029, deposit and return systems for single use plastic beverage bottles and single use metal beverage containers with the capacity of up to three litres. Exemptions are provided for certain milk products in Art. 44.2b, but not for foods intended for infants and young children and FSMPs, which are subject to stricter hygiene and safety constraints compared to most consumable products in bottles.

  As liquid foods intended for infants and young children and FSMPs may be presented in containers that could be considered as "beverage bottles" (despite the fact that these product categories are not beverages), it is important that these requirements relating to beverages to not apply to these specialised food categories.

Recommendations:

- **Treat all foods intended for infants and young children and foods for special medical purposes the same way as medicines and medical devices.**
  For the reasons summarized above, the same transition periods and exemptions should also apply for foods intended for infants and young children & FSMP.

- **Promote the availability of recycled plastics suitable for foods intended for infants and young children and foods for special medical purposes.**
  Measures to increase the supply of suitable recycled plastics may include the promotion of advances in recycling technology including chemical recycling.

[10] article 2 of EU Regulation (EU) 1169/2011 on the provision of food information to consumers: *'prepacked food' means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; 'prepacked food' does not cover foods packed on the sales premises at the consumer's request or prepacked for direct sale;*

[11] Art. 4 of Regulation (EU) No 609/2013

ANNEX

Explanations about product categories

- **Foods intended for infants and young children** are specific products suitable for the needs of infants and young children from 0 to 3 years of age. This product category is defined and regulated by Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.
- **Foods for special medical purposes** - used under medical supervision - are specialised foods formulated to manage a range of diseases, disorders, and medical conditions which may require the use of specific administration systems. They are used in hospitals but also at home under medical supervision. This product category is defined and regulated by Regulation (EU) No 609/2013.

Substantiations

The Commission has rightly noted the **safety requirements** and limited availability not just for medicines and medical devices, but also **for intended foods for infants and young children**.

Substantiation:

- Recital 28 of the proposal justifies the exemptions for medicines and medical devices, referring also to the security of supply: "to avoid any risk to the security of supply and to the safety of medicines and medical devices".
- Impact assessment (Part 2, pp. 559-560) – LINK: "Plastics that come into contact with food for infants and young children are also subject to stricter requirements under 10/2011, whereby some types of common plastic food packaging would not be allowable in this application. This extends to recycled plastic, but the lack of supply of food grade recycled plastic more generally is exacerbated by these stricter requirements". (10/2011 is a reference to the 'Food Contacts Materials Regulation').

An **exemption for FSMP** from provisions on minimum recycled content is foreseen in existing law.

Substantiation:

- Directive (EU) 2019/904 of 5 June 2019 on the reduction of the impact of certain plastic products on the environment – LINK.
- ANNEX Part C b: FSMP are exempted from Article 6(1) to (4) on product requirements: *'… single-use plastic products listed in Part C of the Annex that have caps and lids made of plastic may be placed on the market only if the caps and lids remain attached to the containers… ';*
- ANNEX part F b: FSMP are exempted from the requirements of Article 9 on separate collection and Article 6(5) on product requirements (minimum recycled content).

Foods intended for infants and young children are subject to requirements which can be more than **seven times stricter than for general foods.**

Substantiation:

- The specific requirements for foods intended for infants and young children stipulated in the food contact materials regulation can be **more than seven times stricter** than for general foods.
- Conformity assessment of a packaging containing BHT[12] for a "normal" cereal bar and a cereal bar for infants:

	cereal bars for normal consumption	**cereal bars for infants and young children**
Packaging	PET-Foil with OPP[13]-barrier with BHT	
Weight of packed food	20 g	20 g
Surface of packaging foil per kg of food	45,6 dm^2	45.6 dm^2
Measured BHT migration	0,100 mg BHT/dm^2	0,100 mg BHT/dm^2
SML for BHT	3 mg/kg	3 mg/kg
Calculated BHT migration according to article. 17 Regulation (EU) No 10/2010	0,6 mg BHT[14]/dm^2	4,56 mg BHT[15]/dm^2
Assessment	compliant	non-compliant

[12] BHT: *approved antioxidant 2,6-di-tert-butyl-p-cresol*
[13] OPP: oriented polypropylene
[14] Application of the EU cube method according to Regulation (EU) No 10/2010 article. 17 (2) sentence 1
[15] Application according to Regulation (EU) No 10/2010 article. 17 (1)

- Conclusion: In this specific example, the packaging of the cereal bar for infants must **meet 7.6 times stricter** requirements for migration of BHT from the film than the packaging of a comparable bar for normal consumption.
- In order to achieve these stricter requirements for migration – especially when recycled content has to be used, functional barriers play an important role in the packaging of foods for vulnerable groups. At the same time, these functional barriers might have **detrimental effects on the recyclability of the packaging material.**
- Consequences: **More time is needed to develop functional barriers to migration** that are not detrimental for the recyclability of the food product and allow at the same time integration of recycled content in the packaging materials.

Additional arguments

Recycled content

The main polymer used in packaging for foods intended for infants and young children and FSMPs is polyolefin-based. However, in Europe, neither a mechanical recycling stream for polyolefins for food contact materials nor an ad-hoc process validated by EFSA[16] exist yet. Significant technical developments are still needed to be able to recycle polyolefins for food applications. On top of that, there is little knowledge on feedstock characteristics and cross-contamination which may occur during recycling. What is known is that polyolefin formulations used for food contact packaging are not always compatible with specialised nutrition requirements with regards to the additives used in the formulations. Therefore, the recycled material might contain potential compounds not compatible with requirements for specialised nutrition products (such as foods intended for infants and young children and FSMP). Knowledge about available technology and feedstock is not enough to be able to validate compatibility of recycled materials with specialised nutrition requirements (i.e. technology to remove the incompatible additives). This applies for mechanical recycling. Chemical recycling is not yet recognized for the recycling targets. Although it is expected to have great potential to separate unintended contaminants and impurities, some challenges remain with regards to the maturity of technologies, capability and traceability. In case chemical recycling is recognized, then time will be needed for technologies to be deployed at scale throughout Europe.

Recyclability

To drive recyclability by design, food business operators work towards a harmonized approach with the Design for Recycling (D4R) guidelines[17] to ensure consistency and to maximize process efficiency, reduction of material loss with multiple set-ups, plastic/material reduction, lowest possible level of CO2 emission and packaging recyclability.

A harmonized D4R approach across the Member States, as well as fit-for purpose infrastructure, are key to identifying sustainable packaging solutions. These need to be, at the same time, recyclable in practice and at scale, while avoiding a significant increase of plastic/ material and greenhouse gas emissions to pack the same amount of product.

Re-use

Re-use requires harmonised/ standardised packaging formats and a market size big enough to ensure that re-use contributes significantly to the objectives of the circular economy (or reduction of packaging waste and low carbon footprint due to short transport distances). As packaging for specialised nutrition foods serves many different needs, such a standardisation is very difficult to attain. In addition, the market for many of these specialised products is not big enough to significantly contribute to environmental goals by re-use of packaging.

[16] HDPE & PP State of play – 2020 Eunomia
[17] Design for Recycling Guidelines - RecyClass – LINK

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