

Transitioning from PARNUTS to Food for Specific Groups – The Key Issues

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EHPM

- European federation of National Associations of **Health Product Manufacturers**
- Established 1975, 14 members, from 14 Member States
- 1,750 Manufacturers and distributors of food supplements
- 100,000 jobs, turnover of €13 billion, 98% SMEs

EHPM Vision

In a modern health maintenance system, there is a legitimate place for physiologically active health enhancing products

National health systems reduce costs by preventing diseases thanks to the consumption of food supplements

Food supplements deserve an appropriate legal environment to deliver well-informed access for consumers to **safe** and **efficient** products

EHPM will back and help to build any feasible legislation project which offers coherence and legal security for serious & responsible operators



Overview

Directive 2009/39/EC on foodstuff intended for particular nutritional uses (PARNUTS)

- As this was a Directive not a regulation, there was a certain amount of flexibility in how it was implemented into national law
- This led to differences in the categories of products that fell under the scope of the Directive in different Member States
- To ensure a more uniform approach the Commission launched a proposal for regulation that led to the adoption in 2013 of Regulation (EC) No 609/2013 on foods for specific groups (FSG)

Overview

- FSG Regulation covers:
 - Food intended for infants and young children (FIFYC)
 - Food for special medical purposes (FSMPs)
 - Food for total diet replacement (FTDR)
- For each category of food covered specific implementing rules with compositional and labelling requirement have been developed

Food for Special Medical Purposes

- Rules for this category were established through Commission Regulation (EU) 2016/128 which sets:
 - Specific compositional and information requirements for food for special medical purposes
- These rules apply from 22 February 2019
- FSMPs are divided into three categories through Article 2(1) of Commission Delegated Regulation (EU) 2016/128

3 Categories of FSMPs

- (a) **Nutritionally complete food** with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;
- (b) **Nutritionally complete food** with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;
- (c) **Nutritionally incomplete food** with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

Nutritionally Incomplete Definition?

European Food Safety Authority (EFSA):

“nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment. The foods referred to in points (a) and (b) may also be used as a partial replacement or as a supplement to the patient's diet.”

Nutritionally Incomplete Definition?

Specialised Nutrition Europe (SNE):

“Nutritionally incomplete foods which are not suitable to be used as the sole source of nourishment. The “nutritionally incomplete FSMP” are products that cannot be used for total diet replacement for the patient but provide specialised nutritional support– for example FSMP for use in inherited metabolic disorders. They are an essential part of the toolkit used by Healthcare Professionals to tailor dietary management to address individual patient needs”

Nutritionally Incomplete Food

- Rules apply from 22 February 2019
- Stocks placed on the market before that date can be sold until stocks are exhausted
- It could be argued that many products traditionally sold in Hungary as PARNUTS fall into this category, such as:
 - Joint Product (glucosamine, chondroitin-sulphate, MSM)
 - Probiotics (bacteria, yeast)
 - Eye Products: lutein, zeaxanthin, (beta-carotene), zinc, A-vitamin, E-vitamin
- FSG seems likely to lead to these products being classified as food supplements or their status becoming unclear

Nutritionally Incomplete

- Joint, probiotic and eye products currently consider FSMPs in according with existing Hungarian law worth roughly 1/3 of current Hungarian food supplement market if considered as part of that market
- Clarity needed on the category into which these products fall from 22 February 2019 onwards
- Changing the status of these products to food supplements from FSMPS without transition period will have huge consequences due to VAT treatment
- VAT rate increase from 5% to 27% will make products more expensive for consumers & could kill market

Key Conclusions

- Transitioning from flexibility of Directive to rigidity of a regulation could have massive negative impact
- Pre-existing Hungarian system is unique in EU so transition to FSG from PARNUTS in Hungary is more challenging
- Current system makes certain important products more affordable for consumers and sensible transitional arrangements are needed.
- Flexible interpretation of nutritionally incomplete category can offer a solution as can applying low VAT rates for affected product categories

Key Conclusions

- Potential VAT rate of 27% for joint, probiotic, and eye health products is quite punitive in comparison to VAT rates applied for food supplements other countries – see examples:
 - Ireland (0%)
 - France (5.5%)
 - Sweden (12%)
 - Finland (14%)
 - Slovakia (20%)

Key Conclusions

- Other substances are not harmonised at EU level for food supplements so the status of the ingredients affected is a national not EU competence
- Should Hungary wish to continue its history of providing specific status for joint, probiotic and eye health products either through their VAT treatment (in the food supplement category) or a specific status, there is no impediment to do so