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What's on the menu – a review of notified 'Foods for Special Medical Purposes' products on the Irish market

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Foods for Special Medical Purposes (FSMPs) are food products specially formulated for patients with particular diseases, conditions or disorders and are defined under Regulation (EU) 609/2013⁽¹⁾. Commission Delegated Regulation (EU) 2016/128 sets out the specific labelling and compositional requirements for these products including the requirement to notify the Food Safety Authority of Ireland (FSAI) when placing these products on the Irish market⁽²⁾. In December 2018, the FSAI launched a new online system to receive notification of FSMPs. The aims of this study are to⁽¹⁾ explore the range of FSMPs notified to the FSAI since December 2018 and⁽²⁾ gain insight into the variability of such products.

Data was extracted from the FSAI Notifications System using MySQL8.0 and exported to Microsoft Excel. Product data collected included product name and manufacturer, FSMP classification, product intention and compositional information. FSMPs were categorised by product intention e.g. Disease Related Malnutrition, Phenylketonuria. The same approach was used to categorise the reasons for re-notification of FSMPs. The frequency distribution for categorical variables was explored and numerical summaries (e.g., mean kcal/100g) were calculated.

There were 475 FSMPs notified between December 2018 and December 2020: They were categorised as 'nutritionally complete with standard nutrient formulation' (n153), 'nutritionally complete with nutrient adapted formulation' (n59), and 'nutritionally incomplete with standard or nutrient-adapted formulation' (n263), as per the Delegated Regulation⁽²⁾. In terms of their use, n82 products are for infants (0–12 months), n435 products are intended for individuals over the age of 1 year and n42 products can be used by all age groups. All FSMP products were notified by n17 food businesses. FSMPs were organised into n16 categories based on the intended patient cohort. The largest category is FSMPs for disease related malnutrition (n212). In terms of nutritional composition, the average energy content for this category of FSMPs is 241 kcal/100 g (range 40–508kcal/100g). Of the total notifications received, n373 were re-notifications of FSMPs to inform the FSAI of product changes e.g. recipe or label change. The majority were re-notified with changes made in line with recent legislative updates (n299). Other reasons included product reformulation (n22) and changes in manufacturing address (n9).

This study gives an insight into the wide range of FSMP products notified to the FSAI. Products developed for disease related malnutrition made up nearly 50% of all FSMPs notified. Examination of FSMPs as a product group is important to the FSAI for official control purposes and to support information requests from EU Member States. Further analysis of this data will involve assessment of product compliance in line with relevant legislation with a view to protecting consumers and for developing supports to assist food businesses to comply.

References

1. 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 [Available at: https://www.fsai.ie/uploadedFiles/Reg609_2013.pdf].
2. Delegated Regulation (EU) 2016/128 regarding the specific compositional and information requirements for food for special medical purposes [Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0128&from=GA>].