



Malnutrition and disease related malnutrition - A review of Food for Special Medical Purposes notified to the Food Safety Authority of Ireland

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Malnutrition refers to undernutrition due to restricted dietary intake or starvation, while disease related malnutrition (DRM) refers to malnutrition caused by acute or chronic disease. When primary treatment options such as dietary fortification and micronutrient supplementation are insufficient, Food for Special Medical Purposes (FSMPs) are used⁽¹⁾. FSMPs are food products specially formulated for the dietary management of certain diseases and disorders⁽²⁾. FSMPs placed on the Irish market must be notified to the Food Safety Authority of Ireland (FSAI) via the FSAI Food Notification System. In 2021, the FSAI conducted a review of FSMPs notified between 2018 and 2020, which reported that FSMPs for DRM made up 44.6% of total notified FSMPs⁽³⁾.

Therefore, the aims of this study were to: 1) compare recent trends in FSMP notifications with previous trends identified between December 2018 – December 2020 (2018–2020) and 2) investigate patterns of FSMPs for the treatment of malnutrition and DRM notified to the FSAI between January 2021 – January 2023 (2021–2023).

Data were extracted from the FSAI Food Notification System and analysed using SPSS Version 28. Product data collected included product name and manufacturer, product category, intended age groups and notifying countries.

When comparing the previous report (2018–2020) (n = 475) to present (2021–2023) (n = 362), total notified FSMPs decreased by 23.8%. A reduction in the number of FSMPs for DRM was also observed (2021–2023) (n = 162) compared with those notified between 2018–2020 (n = 212). There was an increase of n = 1 country notifying FSMPs in 2021–2023 compared to n = 3 in 2018–2020. The additional country is considered a 'third country' as it is outside of the EU.

When FSMP notification patterns were investigated for 2021–2023, n = 6 FSMPs notified were for malnutrition. The highest notified category of FSMPs for DRM and malnutrition in this timepoint were those which were 'Nutritionally complete with standard nutrient formulation' (n = 89), followed by those that were 'Nutritionally incomplete food' (n = 74) and lastly, those that were 'Nutritionally complete with nutrient adapted formulation' (n = 5). When intended age was analysed, FSMPs for use by individuals > 1 year were most frequently notified (n = 168), while n = 1 was for FSMPs intended for infants 0–12 months or by both age groups. FSMPs were notified by n = 8 food businesses.

There was a decrease in the number of FSMPs notified to the FSAI between the two timepoints, including a reduction in notified FSMPs for DRM. This reduction may be due to the changes required to comply with Commission delegated Regulation (EU) 2016/128 which came into force in February 2020 and 2021 for FSMPs for infants. Although, fewer FSMPs were notified from 2021–2023, FSMPs for DRM remained the largest category. Reporting these trends is useful towards the FSAI's risk-based approach to monitoring compliance in FSMPs.

References

1. National Institute for Health and Care Excellence (NICE) (2017) *Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition* [Available at: <https://www.nice.org.uk/guidance/cg32>].
2. Regulation (EU) No 609/2013. [Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013R0609>].
3. McMonagle L *et al.* (2021) *Proc Nutr Soc* 80 (OCE5), E189.