Explanatory Memorandum to The Food Supplements (Magnesium L-threonate monohydrate) (Wales) Regulations 2026

This Explanatory Memorandum has been prepared by the Department for Health, Social Care and Early Years and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Food Supplements (Magnesium L-threonate monohydrate) (Wales) Regulations 2026. I am satisfied that the benefits justify the likely costs.

Sarah Murphy MS
Minister for Mental Health and Wellbeing

13 January 2026

1. Description

The Food Supplements (Magnesium L-threonate monohydrate) (Wales) Regulations 2026:

- updates the list of substances at Schedule 2 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 ("2019 regulations") to add magnesium L-threonate monohydrate, for the purposes of regulation 5(1)(b)(i) of the Food Supplements (Wales) Regulations 2003 ("2003 regulations");
- sets purity criteria for magnesium L-threonate monohydrate for the purposes of paragraphs (1)(b)(ii) and (2)(a) of regulation 5 of the 2003 regulations.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

None.

3. Legislative Background

The 2003 regulations implemented the provisions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Part 2 of the 2019 regulations, and Schedules 1 and 2, contain provisions and powers in relation to food supplements.

Regulation 5 of the 2003 Regulations prohibits the sale of food supplements in Wales containing a vitamin or mineral unless:

- the vitamin or mineral is listed in Schedule 1 of the 2019 regulations (magnesium is listed as a mineral in Schedule 1);
- the vitamin or mineral is in a form which: (i) is listed in Schedule 2 of the 2019 regulations; and (ii) meets purity criteria as defined in regulation 5.

This instrument follows the Senedd approval procedure and is made using the powers under regulations 2(2), 3 and 5(1) of 2019 regulations. These powers came about as part of our exit from the EU. They enable Welsh Ministers to carry out the functions in relation to food supplements that were previously undertaken by the Commission and the European Parliament under Directive 2002/46/EC.

4. Purpose and intended effect of the legislation

The Welsh Ministers have authorised magnesium L-threonate monohydrate as a novel food under the provisions of assimilated law, namely Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods. Information about the authorisation is available on the list of novel food

authorisations maintained by the Food Standards Agency ("FSA") (Foss House, Kings Pool, 1-2 Peasholme Green, York YO1 7PR) in accordance with Article 3B of Regulation (EU) 2015/2283.

These Regulations:

- permit magnesium L-threonate to be a form of magnesium for use in the manufacture of food supplements;
- set purity criteria for magnesium L-threonate.

The regulations are taken forward in parallel with the novel food authorisation for the substance which will come into force on the same date as these regulations come into force.

5. **Consultation**

Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety was considered. Article 9 requires open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

The FSA launched a 9-week public consultation on the market authorisation of 10 regulated food and feed products (including magnesium L-threonate) on 18 December 2024. While it was open to the public, the consultation was in particular aimed at all food and feed businesses, including local authorities and other stakeholders with an interest in food and feed safety. Food Standards Scotland launched a parallel consultation.

On 18 December 2024, as part of their consultation, the FSA published the draft Risk Management Recommendation for the substance. The risk management recommendations outlined the safety of the substance at the proposed conditions of use. On 16 October 2025 the FSA responded to the consultation.

REGULATORY IMPACT ASSESSMENT

The proposal is likely to have a neutral effect on businesses operating within the Welsh market. This regulatory change is business facilitative and does not place any obligations on businesses to change their business model or the products they sell. We have therefore not identified any financial impacts.

6. Options

Option 1: Business as usual/do nothing.
The Welsh Ministers have authorised this substance as a novel food. This instrument is required to enable the substance to be sold as a food supplement in Wales without breaching regulation 5 of the 2003 regulations. We therefore consider this option to be high risk.

The FSA concluded that the novel food is safe under the proposed conditions of use and does not pose a safety risk to human health. The anticipated intake levels and the proposed use was not considered to be nutritionally disadvantageous. A similar authorisation has been approved for the EU market.

Option 2: update the list of substances at Schedule 2 of the 2019 regulations to add magnesium L-threonate monohydrate for the purposes of regulation 5(1)(b)(i) of the 2003 regulations and set its purity criteria for the purposes of regulation 5(1)(b)(ii) of those regulations.

There are no feasible alternative options.

We consider this is the best option to ensure that the novel food supplement complies with all aspects of regulation 5 of the 2003 Regulations.

Making the legislation would enable magnesium L-threonate to be a permitted form of magnesium which may be used in the manufacture of food supplements and set out the purity criteria for the substance. This instrument will allow the substance's use in Wales and will ensure our policy on the substance is aligned with the EU where the supplement has already been authorised for the food supplements market, based on similar purity criteria.

7. Costs and benefits

Option 1 – Business as usual/do nothing
This is the baseline option and as such there are no additional costs or benefit associated with this option.

As explained above, this is not the preferred option as it would mean the novel food authorised by ministers could not be sold as a supplement without breaching regulation 5 of the 2003 regulations.

Option 2 – update the list of substances at Schedule 2 of the 2019 regulations to add magnesium L-threonate monohydrate, for the purposes of regulation 5(1)(b)(i) of the 2003 regulations and set its purity criteria for the purposes of regulation 5(1)(b)(ii) of those regulations.

The proposed change is not expected to result in any significant additional costs for Welsh Government or regulators outside of their usual work in relation to authorised novel foods and food supplements.

The regulations are not expected to impose any additional costs on businesses operating in Wales or the wider UK. The business who applied to the FSA for this authorisation will retain exclusive rights to sell the product on the food supplement market in Wales for five years after it is authorised so initially only this business will be directly impacted. In the longer term, enabling the use of magnesium L-threonate will also provide other food businesses with another form of magnesium for use in food supplements but its use will be optional. It is anticipated producers will only use magnesium L-threonate if they perceive there to be product or price benefit for their business.

The authorisation has the potential to encourage greater market competition, supporting growth and innovation in the food supplements sector. Consumers will also benefit from the option of this food supplement.

The use of magnesium L-threonate has already been approved as a novel food in the EU along with the use of the substance in food supplements. The substance has been approved as a novel food in Scotland, and they have laid regulations in a similar form to the regulations described in this option. This option ensures Welsh businesses are not placed at a potential disadvantage to producers elsewhere.

The FSA[1] has undertaken an assessment of Magnesium L-threonate and concluded it is safe under the proposed conditions of use and does not pose a safety risk to human health.

8. Competition assessment

The competition filter test (below) has been completed. The regulations are not expected to have a detrimental impact on competition in Wales or the competitiveness of Welsh businesses.

[1] Safety Assessment: Magnesium L-threonate as a novel food for use in food supplements

The competition filter test	
Question	**Answer yes or no**
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

9. Post implementation review

A post-implementation review of the Welsh Statutory Instrument will take place in 2029, three years post-implementation.