EXPLANATORY MEMORANDUM TO

THE NUTRITION (AMENDMENT ETC.) (EU EXIT) (AMENDMENT) REGULATIONS 2026

2026 No. 412

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Sharon Hodgson MP, Parliamentary Under-Secretary of State for Public Health and Prevention at the DHSC confirms that this Explanatory Memorandum meets the required standard.

2.2 Claire Pringle, Deputy Director for Healthy Weight and Nutrition at the DHSC confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Emma Jeffcock at the DHSC can be contacted by email at the following address with any queries regarding the instrument: nutritionlegislation@dhsc.gov.uk. Alternatively, the department can be contacted by telephone: 0300 790 4007.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends The Nutrition (Amendment) (EU Exit) Regulations 2019 ("the 2019 Regulations") to make a minor technical amendment on food supplements.

4.2 A DHSC Minister has authorised magnesium L-threonate monohydrate, a form of the mineral magnesium, as a novel food for use in food supplements 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.

4.3 This instrument permits this form of magnesium for use in the manufacture of food supplements by adding it to the list of permitted forms in Schedule 2 to the 2019 Regulations. Without this instrument, this form of magnesium cannot lawfully be used in food supplements in England despite having been authorised as a novel food.

4.4 In order for a food supplement to be lawfully sold in England, as well as being listed in Schedule 2 to the 2019 Regulations, it must also meet specified quality and safety standards known as purity criteria. These criteria ensure that substances are manufactured to an appropriate and consistent standard. As a result, a related instrument, The Food Supplements Purity Criteria (Magnesium L-threonate monohydrate) (England) Regulations 2026, was laid on 21 April 2026 and, subject to Parliamentary approval, is intended to come into force on 13 August 2026. This second instrument will establish the purity criteria for magnesium L-threonate monohydrate once it has been added in Schedule 2 of the 2019 Regulations. This sequencing is necessary as purity criteria can only apply to a substance once it is listed as a permitted form.

4.5 These related instruments will enable the lawful use and the lawful sale of food supplements containing magnesium L-threonate monohydrate in England.

4.6 The amendment does not require manufacturers to sell the substance but provides them with the optional basis to do so.

Where does the legislation extend to, and apply?

4.7 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.8 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England only.

5. Policy Context

What is being done and why?

5.1 This instrument will permit the use of a novel form of magnesium, magnesium L-threonate monohydrate, in the manufacture of food supplements. The policy objective is to give practical effect in England to the safety authorisation for this substance, thereby enabling manufacturers to use it on an optional basis, widening choice of permitted sources of magnesium and supporting innovation. The change initially affects only the applicant who requested this authorisation and who benefits first from a 5-year exclusive use period. During this period, only the applicant may place magnesium L-threonate monohydrate on the market unless another business obtains authorisation based on its own data or with the applicant's permission.

5.2 An application to authorise magnesium L-threonate monohydrate as a novel food for use in food supplements was assessed by the Food Standards Agency (FSA) through the regulated products process. Following that assessment, a positive opinion[1] concluded that the substance is safe under the proposed conditions of use for food supplements. Authorisation under assimilated Regulation (EU) 2015/2283 was given by Ministerial Determination and came into force on 5 March 2026.

5.3 In order for magnesium L-threonate monohydrate to be lawfully used as a permitted form of magnesium in food supplements in England, it must be added to the list of substances, by the addition of an entry for magnesium L-threonate monohydrate to Schedule 2 to the 2019 Regulations. This instrument will add magnesium L-threonate monohydrate to the list in Schedule 2 to the 2019 Regulations.

5.4 Foods supplements containing magnesium L-threonate monohydrate may only be sold once the relevant purity criteria are also specified. Those criteria will be established in a separate instrument laid on 21 April 2026 and, subject to Parliamentary approval, due to come into force on 13 August 2026. These instruments together will permit both the use of the substance and lawful sale of food supplements containing it, providing manufacturers with greater choice whilst maintaining appropriate safety and quality standards.

What was the previous policy, how is this different?

5.5 The existing legal framework permits only those vitamins and minerals that are listed in Schedule 1 to the 2019 Regulations, and only in the forms listed in Schedule 2 to the 2019 Regulations, to be used in food supplements. Magnesium is already a

[1] Safety Assessment: Magnesium L-threonate as a novel food for use in food supplements | Food Standards Agency https://www.food.gov.uk/research/research-projects/safety-assessment-magnesium-l-threonate-as-a-novel-food-for-use-in-food-supplements

permitted mineral listed in Schedule 1; however, magnesium L-threonate monohydrate was not listed in Schedule 2 as a permitted form of that mineral and therefore cannot be used in food supplements.

5.6 This amendment permits magnesium L-threonate monohydrate to be used in the manufacture of food supplements as a form of the mineral, along with the other existing forms of magnesium listed in the 2019 Regulations.

6. Legislative and Legal Context

How has the law changed?

6.1 The Food Supplements (England) Regulations 2003 ("the 2003 Regulations") regulate the composition, marketing and labelling of food supplements. Regulation 5 of the 2003 Regulations permits only those vitamins or minerals listed in Schedule 1 to the 2019 Regulations and in the form listed in Schedule 2 to the 2019 Regulations, to be lawfully used in the manufacture of food supplements. This instrument amends Schedule 2 to the 2019 Regulations, to add magnesium L-threonate monohydrate as a permitted form of magnesium. This enables manufacturers to use it in the manufacture of food supplements should they choose to do so. Purity criteria for the substance is established in a separate draft statutory instrument (SI) which is intended to allow food supplements containing this form of magnesium to be lawfully sold.

6.2 The amendment to Schedule 2 is made using powers in regulation 2(2) of the 2019 Regulations. By virtue of regulation 6(2) of the 2019 Regulations, the instrument is subject to the negative procedure.

Why was this approach taken to change the law?

6.3 This is the only possible approach to make the necessary changes and is a routine update to the 2019 Regulations following authorisation. As the appropriate authority, Ministers in England may amend Schedule 2 when new forms of vitamin and mineral substances are authorised for use in food supplements under the 2019 Regulations as they apply in England. Adding a permitted vitamin or mineral form to Schedule 2 can be done by an instrument subject to the negative procedure (regulation 2(2) and 6(2)). By contrast, setting purity criteria for a substance listed in Schedule 2 must be done by a separate statutory instrument (SI) subject to the affirmative procedure (regulation 2(3) and 6(3)). Accordingly, we are laying the two related instruments together so that the permitted form and its associated purity criteria can come into effect in a coordinated way, resulting in the use and sale of food supplements containing magnesium L-threonate monohydrate to be lawful.

6.4 Food law is a devolved matter. Wales and Scotland have made equivalent amendments to their Food Supplements Regulations. Northern Ireland applies the existing EU-equivalent Regulations as required by the Windsor Framework. Wales and Scotland made their equivalent changes in a single instrument under their respective powers. The policy outcome cannot be achieved without changing the law.

7. Consultation

Summary of consultation outcome and methodology

7.1 Article 9 of assimilated EU Regulation 178/2002 requires open and transparent public consultation during the preparation, evaluation and revision of food law, except where urgency does not allow it. In line with this requirement, the FSA undertook a public

consultation on the market authorisation of a number of regulated food and feed products, including magnesium L-threonate monohydrate.

7.2 The consultation[2] ran for nine weeks, from 18 December 2024 to 19 February 2025, and was open to the public. Responses informed the advice provided to the Minister by the FSA in relation to the authorisation of magnesium L-threonate monohydrate as a novel food. A link to the summary of responses can be found here[3].

7.3 The overall number of responses was low. Respondents who commented supported the authorisation of magnesium L-threonate monohydrate for use in food supplements and raised no safety concerns for intended consumers. Comments highlighted that listing the substance in legislation as a permitted form of magnesium would provide regulatory clarity and facilitate market entry. One respondent raised a point relating to differences between maximum levels permitted in the EU and proposed by the FSA, this related to regulatory divergence rather than the safety of the substance. The FSA subsequently proposed a change to the maximum level for clarity and consistency and confirmed the level remained within the parameters assessed as safe.

8. Applicable Guidance

Guidance relating to these amendments is not being issued. This is not a new regulation, it is an amendment to existing regulations. There is specific UK guidance for food supplements legislation which remains fit for purpose.[4]

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 The expected impacts of this instrument have been considered. The amendment is technical, enabling an option and does not mandate the use of magnesium L-threonate monohydrate. As a result, any costs to business are expected to be minimal. The proposal does not meet the threshold for requiring a full Impact Assessment under the Better Regulation Framework. Enforcement bodies may need to familiarise themselves with the amendment as part of routine regulatory activity.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies because this legislative addition 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.

9.3 The legislation does not impact small or micro businesses.

9.4 There is no, or no significant, impact on the public sector.

[2] https://www.food.gov.uk/news-alerts/consultations/consultation-on-market-authorisation-of-10-regulated-food-and-feed-products-december-2024

[3] Consultation on Market Authorisation of 10 Regulated Food and Feed Products December 2024: Summary of Stakeholder Responses | Food Standards Agency https://www.food.gov.uk/our-work/consultation-on-market-authorisation-of-10-regulated-food-and-feed-products-december-2024-summary-of-stakeholder-responses

[4] https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 There are no plans to monitor or review the instrument. Monitoring this legislation is not appropriate given there is no significant impact on business and particularly small businesses.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 Sharon Hodgson MP, Parliamentary Under-Secretary of State for Public Health and Prevention, has made the following statement: The impact of this measure is expected to be very low, and there are no additional factors that would make it particularly desirable to include a review clause.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative procedure and does not amend primary legislation no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 (“relevant European Union Acts”).