EXPLANATORY MEMORANDUM TO

THE FOOD SUPPLEMENTS PURITY CRITERIA (MAGNESIUM L-THREONATE MONOHYDRATE) (ENGLAND) REGULATIONS 2026

2026 No. [XXXX]

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 sets quality and safety standards (purity criteria) for a form of a mineral for use in food supplements.

4.2 DHSC 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. In order for an authorised form of a vitamin or mineral to be lawfully used and sold in food supplements, the substance must be listed in Schedule 2 to The Nutrition (Amendment) (EU Exit) Regulations 2019 ("the 2019 Regulations") and the purity criteria must also be specified in legislation.

4.3 This instrument gives effect to the requirement to set quality and safety standards (purity criteria) in legislation by establishing the purity criteria for magnesium L-threonate monohydrate in this regulation. The criteria ensures that the form of the mineral used in food supplements meets appropriate quality and safety standards. Without this instrument, this form of magnesium cannot lawfully be sold in food supplements in England.

4.4 This instrument is related to the Nutrition (Amendment etc.) (EU Exit) (Amendment) Regulations 2026 (SI 2026/412), which will add magnesium L-threonate monohydrate to the list of permitted forms of magnesium in Schedule 2 to the 2019 Regulations. SI 2026/412 makes provision for this form of magnesium to be lawfully used in food supplements in England and is intended to come into force on 12 August 2026. Once

added to Schedule 2, it is intended that this instrument will come into effect on 13 August 2026 to establish the purity criteria for magnesium L-threonate monohydrate. 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 sets the purity criteria for magnesium L-threonate monohydrate, a novel form of the mineral magnesium, for use in food supplements in England. The policy objective is to give practical effect to the safety authorisation of this substance as a novel food for use in food supplements by ensuring that, where it is used, it meets appropriate quality and safety standards. Specifying purity criteria enables the authorised substance to be lawfully sold in food supplements.

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 Purity criteria specify the required composition and quality of a substance and ensure that it is manufactured and marketed to a consistent and safe standard. In the case of magnesium L-threonate monohydrate, these criteria reflect the specification considered as part of the FSA's safety assessment and provide a clear legal basis for enforcement.

5.4 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 in Schedule 2 to the 2019 Regulations, which is the purpose of a separate statutory instrument (No. 412). Foods supplements containing magnesium L-threonate monohydrate may only be sold if the substance is listed in Schedule 2 to the 2019 Regulations and the relevant purity criteria for this substance is also set in legislation. This instrument fulfils the requirement to set the relevant purity criteria in legislation. The two statutory instruments together permit both the lawful use of magnesium L-threonate monohydrate in the manufacture of food supplements and lawful sale of

[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

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 permitted vitamins and minerals listed in Schedule 1 to the 2019 Regulations to be used in food supplements. Magnesium was already a permitted mineral listed in Schedule 1 to the 2019 Regulations; however, magnesium L-threonate monohydrate was not listed in Schedule 2 to the 2019 Regulations as a permitted form. Therefore, magnesium L-threonate monohydrate could not be used legally in food supplements in England. This instrument establishes purity criteria for magnesium L-threonate monohydrate which together with the addition of magnesium L-threonate as a mineral substance to the list of authorised substances in Schedule 2 to the 2019 Regulations, permits its lawful use and sale in food supplements in England.

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 a form listed in Schedule 2 to the 2019 Regulations, and with relevant purity criteria, to be lawfully used and sold in food supplements in England.

6.2 The Schedule to this instrument sets the purity criteria for magnesium L-threonate monohydrate for the purposes of regulation 5 of the 2003 Regulations (see paragraph 5.3 for further information on purity criteria).

6.3 Regulation 2(3) of the 2019 Regulations provides the power to set purity criteria for a vitamin or mineral substance listed in Schedule 2 to the 2019 Regulations, and regulation 6(3) requires this to be done by an instrument subject to the affirmative procedure. This instrument uses those powers.

Why was this approach taken to change the law?

6.4 Regulation 5(2) of the 2003 Regulations provides two ways for a substance to meet the relevant purity criteria. These are using: (a) purity criteria specified in legislation, or (b), where no such criteria are specified, generally acceptable purity criteria recommended by international bodies.

6.5 In the case of magnesium L-threonate monohydrate, purity criteria was not in legislation nor was international purity criteria established. Therefore, the approach was to set purity criteria in legislation through regulations made by the Secretary of State, informed by the FSA's safety assessment. This approach provides regulatory clarity for businesses, a consistent and transparent basis for enforcement authorities, and ensures that the applicable specification is clearly identifiable in law and is aligned with the conditions underpinning the novel food authorisation.

6.6 The 2019 Regulations, as they apply in England, set out different procedures for different types of amendments. Adding a permitted vitamin or mineral substance to the list of authorised substance in Schedule 2 to the 2019 Regulations requires an instrument which is subject to the negative procedure (regulation 2(2) and 6(2)). In contrast, regulation 2(3) and regulation 6(3) require purity criteria for a substance listed in Schedule 2 to be set in a separate instrument which is subject to the affirmative procedure. It is anticipated that the negative SI will come into force shortly before this instrument (see paragraph 4.3). 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.

6.7 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 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

8.1 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.[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

[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

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. DHSC 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.

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 The Parliamentary Under-Secretary of State for Public Health and Prevention has made the following statement regarding Human Rights:

"In my view the provisions of The Food Supplements Purity Criteria (Magnesium L-threonate monohydrate) (England) Regulations 2026 are compatible with the Convention rights."

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").