POLICY NOTE

THE FOOD SUPPLEMENTS (MAGNESIUM L-THREONATE MONOHYDRATE) (SCOTLAND) REGULATIONS 2026

SSI 2026/XXX

The Scottish Ministers make the following Regulations in exercise of the powers conferred by regulations 2(2) and 3 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019. The instrument is subject to affirmative procedure.

Summary Box

The purpose of this instrument (SSI) is to allow the mineral substance Magnesium L-threonate monohydrate, a novel food concurrently authorised in Scotland by the Scottish Ministers under Regulation (EU) 2015/2283, to be used in the manufacture of food supplements.

This SSI also sets the purity criteria for this mineral substance.

Policy Objectives

An application was received by Food Standards Scotland (FSS) and the Food Standards Agency (FSA) seeking the authorisation under Regulation (EU) 2015/2283 of the mineral substance Magnesium L-threonate monohydrate as a novel food. The application is for Magnesium L-threonate monohydrate, a novel form of the mineral Magnesium, to be used in the manufacture of food supplements for adults aged 18 years and older.

The mineral substance Magnesium L-threonate monohydrate has been subject to the regulated products safety assessment process by FSS and the FSA, as required by Regulation (EU) 2015/2283. In March 2024, a positive opinion on Magnesium L-threonate monohydrate was published on the FSA's website, https://www.food.gov.uk/research/research-projects/safety-assessment-magnesium-l-threonate-as-a-novel-food-for-use-in-food-supplements.

The Food Supplements (Scotland) Regulations 2003 (the "2003 Regulations") sets out labelling and compositional requirements for food supplements. The 2003 Regulations stipulate that only vitamins and minerals listed in schedule 1, and in the form specified in schedule 2, of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (the "2019 Regulations") and which also meet purity criteria for the substance in question, can be used in the manufacture of food supplements.

Therefore, in order for Magnesium L-threonate monohydrate to be used in the manufacture of food supplements, an amendment to schedule 2 of the 2019 Regulations must be made to add an entry for this mineral substance, and purity criteria of the substance must be set, both by this SSI.

This is in addition to an authorisation of the novel food under Regulation (EU) 2015/2283, which is by way of a Ministerial Determination.

UN Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024 Compatibility

The Scottish Ministers have made the following statement regarding children's rights.

In accordance with section 23(2) of the United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Act 2024, the Scottish Ministers certify that, in their view, the Food Supplements (Magnesium L-threonate monohydrate) (Scotland) Regulations 2026 are compatible with the UNCRC requirements, as defined by section 1(2) of the Act.

EU Alignment Consideration

Magnesium L-threonate monohydrate has been approved as a novel food in the EU and Directive 2002/46 has been amended to allow for its use in food supplements across member states.

The terms of the GB and EU safety assessments which underpin the novel food authorisations differ. The EU risk assessment included information on microbiological data, however this is not included in the GB assessment as the view in GB is that this is deemed unnecessary because the product is synthetic in nature. The EU have also not included heavy metals in their assessment, whereas GB has included this detail in their assessments. These minor differences do not amount to any material difference in terms of the safety assessments nor do they raise any safety concerns. The EU has not set purity criteria for this substance. Magnesium L-threonate monohydrate is currently produced in such a way that it will meet the legislative specifications required by both the GB and EU markets. As such, these Regulations will not have any material impact upon the Scottish Government's policy to maintain alignment with the EU.

Consultation

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002.
On the 8th January 2025, Food Standards Scotland launched an 8-week consultation which closed on the 5th March. During the consultation, no concerns were raised in regard to adding Magnesium L-threonate as a form of magnesium for use in the manufacture of food supplements.

A full list of those consulted and who agreed to the release of this information is attached to the consultation report published on the Food Standards Scotland Citizen Space Website, https://consult.foodstandards.gov.scot/regulatory-policy/regulatory-policy-tranche4-wave1-miscellaneous/

Impact Assessments

A Child's Rights and Wellbeing Impact Assessment (CRWIA) has been undertaken to consider the impact of these Regulations on children's rights and welfare. The CRWIA for these Regulations concluded that the impacts upon children's rights is neutral. A copy of the completed CRWIA accompanies this policy note.

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.

Financial Effects
The Minister for Public Health and Women's Health confirms that no BRIA is necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Food Standards Scotland

January 2026