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Gillian Martin MSP
Convener, Health, Social Care and Sport Committee
Scottish Parliament
Edinburgh
EH99 1SP

5th November 2022

Dear Gillian,

Re: Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2022

Thank you for your letter of 24th November 2022 regarding the notification of the above Regulations. I am also grateful that you have commenced the process of your usual scrutiny of the instrument following the notification.

I would now like to turn to the specific questions raised in your letter about the SI and respond as follows:

- **What types of "food supplements" will the substances be permitted for use for?**
  - The substances will be permitted for use in the manufacture of all types of food supplements as defined in Section 2(1) of the Food Supplements (Scotland) Regulations 2003 (and equivalent legislation in England, Wales and Northern Ireland). This legislation sets the requirements for food supplements, including a prohibition on sale relating to composition of food supplements. The amendments being made do not include restrictions on use of nicotinamide riboside chloride as a form of niacin, or magnesium citrate malate as a form of magnesium in food supplements. Rather, the changes are to allow the addition of these forms of the nutrients as permitted substances for use as alternative forms in the manufacture of food supplements. Please note there are no maximum and minimum levels set in the UK or the EU for the amount of vitamins and minerals added to food supplements.

- **Why has it been determined to approve these substances for use at this time?**
  - These changes have been proposed at this time to ensure alignment with the EU as these changes are already in place there, and with Northern Ireland given the Northern Ireland protocol. As set out in Part D of the

provisional Nutrition Related Labelling, Composition and Standards (NLCS) framework (Operational Elements), the NLCS policy group acts as a discussion forum, providing an efficient process to keep pace with development elsewhere (for example, in the EU). As regards future EU legislative changes (including technical amendments and authorisations), UK authorities cannot assume mutual recognition will be in place and must therefore consider the way forward for each individual territory (GB nation) and the UK as a whole. Following extensive discussions between the four nations as part of the NLCS framework, it was agreed that these changes were necessary and needed to be made at this time.

- On the 9th March 2021 the European Commission amended Annex II of Directive 2002/46/EC to allow magnesium citrate malate to be added as a form of magnesium chloride and nicotinamide riboside chloride as a form of niacin used in the manufacture of food supplements. In the aftermath of this legislative change in the EU, the NLCS policy group, having considered the amendments, and following the risk assessment and risk management processes set out in the NLCS framework (including scientific assessment), requested and received GB ministerial consent to authorise nicotinamide riboside chloride as a form of niacin and magnesium citrate malate as a form of magnesium which can be used in food supplements.

- **Are these substances approved for use at EU level for the same purposes?**
  - Yes. This was done in March 2021. Commission Regulation (EU) 2021/418 of 9 March 2021 amended Directive 2002/46/EC to allow magnesium citrate malate to be added as a form of magnesium chloride and nicotinamide riboside chloride as a form of niacin used in the manufacture of food supplements.

- **What scientific assessments have been made to underpin the decision to approve these substances? Do the purposes for which it is proposed to approve the use of these substances cohere with the findings of the European Food Safety Authority?**
  - Yes the changes proposed are aligned with the changes which have been made at an EU level.
  - Following a request for a food safety risk assessment from the NLCS policy group, the Food Standards Agency (FSA) reconfirmed there was no safety concerns with adding nicotinamide riboside chloride or magnesium citrate malate as permitted forms of niacin and magnesium used in food supplements.– details are in the attached consultation document.

- In addition, please **could you clarify:**

- **Do all three of the provisions listed above extend to Scotland, or are some of these the ones referred to as 'England only changes' for which a separate SSI will be made for Scotland?**
  - Yes. The amendments to the GB legislation and retained EU Law in this SI do extend to Scotland.
  - In addition, the SI also makes some England only changes for which include an amendment to the Processed Cereal-based Foods and Baby Foods for

Infants and Young Children (England) Regulations 2003, to authorise the use of calcium-L-methylfolate, ferrous bisglycinate and zinc chloride in the manufacture of processed cereal-based foods and baby foods in England.

- These changes mentioned immediately above are subject to a Scottish SI - The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Amendment Regulations 2022, and was signed by the Minister for Health and Sports on the 21st of November and laid in the Scottish Parliament on the 23rd of November 2022. It is due to come into force on the 18th of January 2023. Separate legislation will make equivalent changes in Wales.

- **In relation to the definitions of pesticide residues, does the change to the definition of 'pesticide residue' affect the scope of the definition or the meaningful standard in relation to permitted levels of pesticide residue?**
  - The change in the definition will affect the scope of the definition for pesticide residue since it standardises the definition across Articles 2(2) of Regulation (EC) No 1107/2009, and Article 3(2) of the Regulation (EC) No 396/2005 by moving beyond the harmful effects on plants to expanding on the potential sources, to include veterinary and biocides. This does not change the maximum residue level set for IFFOF or iFSMPs. The details of the change are in the attached consultation document (please see page 9 of the consultation document).

- **The notification notes that the change to the pesticide residue definition would "ensure they remain aligned with the requirements of the EU and therefore NI helping to avoid divergence across the UK". Does this mean that the EU has also changed the definition for use in relation to infant formula and follow-on formula and for food for special medical purposes to satisfy the nutritional requirements of infants and young children?"**
  - Yes. This is already applicable at EU level in the detailed definition provided within the Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

I would also like to take this opportunity to inform you that the Department of Health and Social Care has reconsidered the need to update the Annex of Regulation 609/2013 to include Calcium L Methylfolate to the list of vitamins and minerals which may be added to processed cereal-based foods and baby foods. The change was proposed in anticipation of future developments in EU legislation in this area. However, progress has been delayed at EU level and therefore the amendment to Regulation 609/2013 is not needed at present.

I hope this response allows the Committee to continue its consideration of the notification.

MAREE TODD