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

14 November 2022

Dear Gillian,

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

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to proposals by the Scottish Ministers to consent to the making of UK secondary legislation affecting devolved areas arising from EU Exit.

That protocol, as agreed between the Scottish Government and the previous Parliament, accompanied the letter from the then Cabinet Secretary for Government Business and Constitutional Relations, Michael Russell MSP, to the Conveners of the Finance & Constitution and Delegated Powers and Law Reform Committees on 4 November 2020 and replaced the previous protocol that was put in place in 2018.

I attach a Type 1 notification which sets out the details of the SI which the UK Government propose to make in December 2022 and the reasons why I am content that Scottish devolved matters are to be included in this SI. Please note, we are yet to have sight of the final draft SI and it is not available in the public domain at this stage.

The purpose of the SI is to make provisions for minor technical amendments to units and forms of nutrients in various pieces of nutrition legislation, in order to ensure uniform and coherent interpretation of the regulations; as well as alignment with the EU of which Northern Ireland remains a part. These changes will help to safeguard the public by providing consistency and clarity for manufacturers, enforcement officers and the public, while avoiding GB divergence from NI with regards to the NI protocol. In the main, subject to the proposed legislation being approved, we will align across the UK.

The Department for Health and Social Care (DHSC) is the lead UK department for this draft negative SI which is due to be laid for scrutiny in the UK Parliament on 14th December 2022. It would be helpful if a decision could be given in advance of the

proposed laying date. However, the proposals remain under review and I will, in accordance with the protocol, advise you when the final SI is laid and advise you as to whether this is in keeping with the terms of this notification.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

I look forward to hearing from you at your earliest convenience.

A handwritten signature in black ink, appearing to read 'Maree Todd'. The signature is written in a cursive, flowing style with some loops and flourishes.

MAREE TODD

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI

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

A brief explanation of law that the proposals amend

1. Following extensive discussions and collaboration between the UK Government and the Devolved Administrations (DAs) of Scotland, Wales and Northern Ireland, the Department of Health and Social Care (DHSC) intends to lay a single Statutory Instrument (SI) to effect some minor technical changes to Nutrition legislation, which would be applicable GB wide (Scotland, Wales and England). The changes are proposed to the following nutrition amendment SI and retained EU regulations:
 - i. The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/651) as amended,
 - ii. Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009,
 - iii. Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding,
 - iv. Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes,

Summary of proposed amendments

2. This proposed legislation sets out provisions to make a series of minor technical amendments to the above nutrition regulations in the form of a GBSI, which would include:
 - a) updating the unit of measurement used for copper in food supplements;
 - b) updating the unit of measurement used for zinc in food supplements;
 - c) updating the forms of niacin which are permitted for use in the manufacture of food supplements to include nicotinamide riboside chloride;

- d) updating the forms of magnesium which are permitted for use in the manufacture of food supplements to include magnesium citrate malate;
- e) updating the forms of folate that are permitted for use in the manufacture of infant formula and follow-on formula (IFFOF) to include calcium L-methylfolate;
- f) standardising the definition of pesticide residues used in the regulations on IFFOF; and
- g) standardising the definition of pesticide residues used in the regulations on food for special medical purposes developed to satisfy the nutritional requirements of infants and young children (iFSMPs).

Details of the provisions that Scottish Ministers are being asked to consent to.

3. The proposed GBSI makes provisions for minor technical changes to the following Nutrition legislations: the Nutrition (Amendment etc.) (EU Exit) Regulations 2019; Commission Delegated Regulation (EU) 2016/127; Commission Delegated Regulation (EU) 2016/128; and parts of Regulation (EU) No 609/2013,

Summary of the proposals

4. Updating the unit of measurement used for copper in food supplements from microgram (μg) to milligram (mg) will ensure the labels are aligned with the unit of measure of copper on other food labels and divergence with Northern Ireland (NI) is avoided given the NI protocol. (The EU implemented the same change to the unit of measurement for copper in food supplements in March 2021; applicable from September 2022); Updating the units of measure for zinc in the labelling of food supplements is being made to rectify a drafting error in schedule 1 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/651), and to provide greater clarity for manufacturers, enforcement officers and the public.
5. Amending the Annex of Regulation (EU) No 609/2013 to include 'calcium-L-methylfolate' as a permitted form of folate used in food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. This particular change triggers a Type 1 Notification, since it is a new policy.
6. Aligning the definition of pesticide residue in IFFOF and iFSMPs, currently defined by using the terminology of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, to a more detailed definition, helps provide clarity and certainty on the definition used in the legislation.

England Only Changes- For Information

7. To note, a number of further changes applicable only in England will be made as part of this proposed legislation. Three of these amendments expand the form of substances which are permitted for use in the relevant food categories (increasing the forms of niacin and magnesium in food supplements and the forms of folate in processed cereal-based foods and baby foods and IFFOF). In particular, amendment to the Annex of the 2003 Baby Food (England) Regulation to permit the addition of calcium-L-methylfolate, ferrous biglycinate and zinc chloride to processed cereal-

based foods and baby foods. (A separate SSI is being drafted to amend the corresponding legislation in Scotland- *The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004*.)

Does the SI relate to a common framework or other scheme?

8. Yes. This proposed legislation is the outcome of several months of extensive and collaborative work of the Nutrition related Labelling Composition and Standards (NLCS) working group. This group was established under the NLCS common framework, which comprises members from all the nations of the UK- DHSC England, FSS (Scotland), FSA Wales and FSA NI.

Summary of stakeholder engagement/consultation

9. A joint 3-week public/stakeholder consultation was carried out across the UK between November and December 2021. The consultation generated responses from one local authority, three trade associations, one consumer healthcare association and one industry group representative. Out of the 6 responses received, 3 of the responses focused on legislative amendments to food supplements being made to the Schedules of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.
10. There was overall support for the technical amendments that impact on food supplements and the respondents welcomed the changes which were proposed. One response requested a longer transition period was required for the change in unit of measurement for copper. The concerns relating to the length of the transition period were considered. As food supplement products containing copper, which use micrograms (μg) as the unit of measure placed on the market or labelled prior to the end of the transition period date may continue to be marketed until the stocks run out the proposed 18-month transition period was retained. The EU implemented the same change to the unit of measurement for copper in food supplements in March 2021. An 18-month transition period was implemented suggesting this time period is sufficient for industry to make the required changes.
11. Out of the 6 responses received, 4 of the responses focused on legislative amendments covered by the four categories of food covered by Regulation (EU) No 609/2013 and the Annex of the 2003 Baby Food Regulation. A separate SSI is being drawn up to amend the corresponding legislation in Scotland- *The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004*. There was overall support for the amendment to expand the permitted forms of folate that may be used in processed cereal-based foods and baby foods and IFFOF to include calcium-L-methylfolate. Respondents also indicated that as use of these substances is not mandatory, the amendment will not negatively impact on manufacturing.
12. Through the consultation it was identified that at the end of the EU-Exit transition period a legislative error occurred, where the Annex of the 2003 Baby Food Regulation was not updated to align with the Annex of Regulation (EU) No 609/2013. The SI will therefore update the 2003 Baby Food Regulation to include ferrous biglycinate as a

permitted form of iron, zinc chloride as a permitted form of zinc (as was intended at the end of the EU-exit transition period). The Annex will also be amended to include calcium-L-methylfolate as a permitted form of folate which can be used. A separate SSI is being drawn up to amend the corresponding legislation in Scotland- *The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004*.

13. Three respondents raised similar concerns regarding amending the definition of pesticide residues used in IFFOF and iFSMP from the terminology used in Regulation (EC) No 1107/2009 to the more precise definition taken from Regulation (EC) No 396/2005. The concerns raised were considered and the Health Safety Executive and Food Standards Agency confirmed that there was no safety concern with making the change and that the change as was proposed would improve clarity and certainty over the definition for pesticide residues. This proposed SI would update both Commission Delegated Regulation (EU) 2016/127 and Commission Delegated Regulation (EU) 2016/128 ensuring they remain aligned with the requirements of the EU and therefore NI helping to avoid divergence across the UK.

A note of other impact assessments, (if available)

N/A

Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

14. The Scottish Ministers believe that the changes proposed in the Regulations are necessary so far as falling within devolved competence to secure alignment with NI in view of the NI protocol. This would provide continuation of an effective regulatory regime for Nutrition Composition matters, along with clarity for Enforcement officers and FBOs. Due to the minor nature of these amendments, and, since DHSC, in collaboration with the NLCS working group have developed the draft text for the legislation, we agree that it is in Scotland's interest to support a GB wide approach for amending the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (retained), considering also our present resource constraints.

Intended laying date (if known) of instruments likely to arise

15. The SI is subject to the negative procedure at Westminster and officials at the DHSC advise that is not due to be laid for scrutiny until 14th December 2022. We would welcome a view from the Committee once it has considered the proposal to consent to the SI under the agreed protocol.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister's proposal to consent, why not?

N/A

Information about any time dependency associated with the proposal

N/A

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

N/A

Any significant financial implications?

16. The Regulations are not expected to have any significant financial implications for food business or enforcement stakeholders in Scotland. The cost to businesses of relabelling is anticipated to be solely limited to updating the unit of measurement from micrograms to milligrams for copper and zinc. As the unit of measure for zinc is being updated to rectify a drafting error in schedule 1 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/651) and industry alerted GB authorities of this error it is assumed to be unlikely any labels have been updated with the incorrect unit of measurement. The proposed transition period for the change in unit of measurement for copper is 18 months, therefore it has been assumed any costs which are involved with relabelling should be absorbed as part of the natural labelling cycle.
17. The addition of nicotinamide riboside chloride, magnesium citrate malate and calcium-L-methylfolate as acceptable forms of ingredients in the relevant food categories will not lead to mandatory reformulation or relabelling costs that are a result of the SI. The additional forms are optional forms which can be used rather than mandatory requirements. It is considered that any cost associated with these amendments will be due to the small amount of time that may be needed to become familiar with the new options.
18. The change in the definition of pesticide residues will not result in any material differences to reformulation or labelling and so it is considered that any cost associated with this amendment will be due to the small amount of time that may be needed to become familiar with the change.
19. A Regulatory Triage Assessment has been completed by the UK Government to confirm that these costs are below £5 million per annum confirming a full impact assessment is not required to be completed for this SI.

SUMMARY NOTIFICATION TO THE SCOTTISH PARLIAMENT

SI NOTIFICATION: SUMMARY

Title of Instrument Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2022
Proposed laying date at Westminster 14 th December 2022
Date by which Committee has been asked to respond. Whilst the Committee has 28 days to consider this notification, it would be helpful if a decision could be given in advance of the proposed laying date.
Power(s) under which SI is to be made <ol style="list-style-type: none">1. Updating the forms of niacin and magnesium and updating the units of measure of copper and zinc in the manufacture of food supplements are being amended by the regulation making power of Part 2 paragraph 2 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, which allows regulations to be made to amend schedule 1 or 2 of the same Regulation (list of vitamins and minerals which can be added to food supplements).2. Updating the Annex (GB list) of Regulation (EU) No 609/2013 to include calcium L-methylfolate as a permitted alternative form of folate that may be added to IFFOF is being amended by the regulation making power in Article 16 (1) (a) of Regulation (EU) No 609/2013 which allows the removal or addition of a substance from the Annex. This particular change triggers a Type 1 Notification, since it is a new policy.3. The regulation making power of Article 11(b) of Regulation (EU) No 609/2013 enables the amendment to the definition of pesticide residue in Article 4 of regulation 2016/127 and the regulation making power of Article 11(b) and (g) of Regulation (EU) No 609/2013 enables the amendment to the definition of pesticide residue in Article 3 of regulation 2016/128.
Categorisation under SI Protocol Type 1
Purpose The proposed changes are being made to ensure uniform and coherent interpretation of the named Regulations; to safeguard the public by providing consistency and clarity for manufacturers, enforcement agents and the public; and ensures we align across the UK.
Other information The Scottish Ministers believe that the changes proposed in the Regulations are necessary so far as falling within devolved competence to secure alignment with NI in view of the NI protocol. This would provide continuation of an effective regulatory regime for Nutrition Composition matters, along with clarity for Enforcement officers and FBOs. Due to the minor nature of these amendments, and, since DHSC, in collaboration with the NLCS working group have developed the draft text for the legislation, we agree that it is in Scotland's interest to support a GB wide approach for amending the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (retained), considering also our present resource constraints.
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