Health, Social Care and Sport Committee

37th Meeting, 2022 (Session 6), Tuesday, 13 December 2022

UK statutory instruments - consideration of consent notifications

Introduction

1. This paper supports the Committee's consideration of 'type 1' consent notification sent by the Scottish Government relating to the following UK statutory instruments (SIs) —

   - SI notification: Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2022

2. The letter from the Minister for Public Health, Women's Health & Sport, containing the notification can be accessed in **Annexe A**.

3. A response from the Minister, to a request for further information from the Committee, is available at **Annexe B**.

Process for parliamentary scrutiny of consent notifications for UK statutory instruments

4. The process for the Scottish Parliament's consideration of consent notifications is set out in a protocol agreed between the Scottish Government and Scottish Parliament.

5. The protocol provides for the Scottish Parliament to scrutinise the Scottish Government's decisions to consent to certain secondary legislation made by the UK Government. Specifically, this relates to UK Government secondary legislation on matters which are within devolved competence and are in areas formerly governed by EU law.

6. The protocol establishes a proportionate scrutiny approach and categorises SIs into type 1 and type 2.

7. For type 1 SI notifications, the Scottish Parliament's agreement is sought *before* the Scottish Government gives consent to the UK Government making secondary legislation in devolved competence. Except in respect of urgent notifications, the Scottish Parliament will have a minimum of 28 days to consider type 1 notifications.

8. For type 2 SI notifications, however, the Scottish Government will notify the Scottish Parliament within five days *after* giving consent.

9. Type 2 applies where all aspects of the proposed instrument are either clearly technical, do not involve a policy decision or update references in legislation that are no longer appropriate following EU exit. All other proposals fall into the type 1 category. In line with the proportionate scrutiny approach, each type 1 notification will be considered by the Committee. Committees will be notified of all type 2 notifications which fall within their remit; it is not, however, anticipated that these will normally be considered at a committee meeting. The protocol includes a number of review mechanisms and the categorisation of type 2 notifications will be monitored in this way.

10. **The Committee's role in relation to type 1 notifications is to decide whether it agrees with the Scottish Government's proposal to consent to the UK Government making regulations within devolved competence**.

11. If members are content for consent to be given, the Committee will write to the Scottish Government accordingly. The Committee may wish to note any issues in its response or request that it be kept up to date on any relevant developments.

12. If the Committee is not content with the proposal, however, it may make one of the following three recommendations—

    (1) that the Scottish Government should not give its consent to the provision being made in a UK SI and that the Scottish Government should instead produce an alternative Scottish legislative solution;

    (2) that the Scottish Government should not consent to the provision being made in a UK SI laid solely in the UK Parliament and should instead request that the provision be included in a UK SI laid in both Parliaments under the joint procedure (N.B. joint procedure is not available in every case so the option of making this recommendation will not always be available); or

    (3) that the provision should not be made at all (that is, that the Scottish Government should not consent to the provision being included in a UK SI, nor should the Scottish Government take forward an alternative Scottish legislative solution).

For decision

13. The Committee is invited to consider whether the provisions set out in the notifications should be included in the UK SI.

Clerks to the Committee
8 December 2022

Annexe A

On 14 November 2022, the Scottish Government wrote to the Convener of the Health, Social Care and Sport Committee:

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.

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 bigylcinate 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 14th 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 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.

Annexe B

On 5 December 2022, the Scottish Government wrote to the Convener of the Health, Social Care and Sport Committee:

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.