EXPLANATORY MEMORANDUM TO

THE FOOD SUPPLEMENTS AND FOOD FOR SPECIFIC GROUPS (MISCELLANEOUS AMENDMENTS) (NO. 2) REGULATIONS 2023

2023 No. 131

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.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments (JCSI).

2. Purpose of the instrument

2.1 The Food Supplements and Food for Specific Groups (Miscellaneous Amendments) (No. 2) Regulations 2023 (the "correcting SI") amends the commencement provision (regulations 1(2)(a) and 1(2)(b)) of the Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023 (the "Miscellaneous Amendments Regulations") to provide that the regulation comes into force on 10 February 2023 as intended. The current drafting of the commencement provision of the Miscellaneous Amendments Regulations renders the legislation inoperable.

2.2 The correcting SI also inserts transitional provisions into the Food Supplements (England) Regulations 2003, the Food Supplements (Scotland) Regulations 2003 and the Food Supplements (Wales) Regulations 2003 ("2003 GB Food Supplements Regulations"). The provisions provide a defence in any relevant enforcement proceedings in respect of the sale of food supplements which used copper and zinc in the manufacturing process and were marked or labelled prior to the coming into force of the respective amendments in regulation 6(2) of the Miscellaneous Amendments Regulations.

2.3 Upon consultation with the SI Registrar, as the SI corrects an error contained in the Miscellaneous Amendments Regulations, the statutory instrument is being issued under the free issue procedure.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This correcting SI will be of special interest to the JCSI as the regulations breach the parliamentary requirement to allow a minimum of 21 days to elapse between any secondary legislation which is made and comes into force "the 21-day rule". This breach of the 21-day rule is necessary in this instance to align the coming into force dates of the correcting SI and the Miscellaneous Amendments Regulations which it amends to ensure both sets of Regulations commence appropriately.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is Great Britain (England, Wales, and Scotland).

4.2 The territorial application of this instrument that is, where the instrument produces a practical effect varies between provisions.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

6. Legislative Context

6.1 This SI amends the commencement provisions contained within the Miscellaneous Amendments Regulations. The commencement provisions bind to all the specific provisions within the regulations and therefore it is necessary to cite all the powers used in the Miscellaneous Amendments Regulations in this SI.

6.2 In exercise of powers conferred in section 5(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, regulations 3, 4, 5 and 6 insert transitional provisions into each of the 2003 GB Food Supplements Regulations.

7. Policy background

What is being done and why?

7.1 This correcting SI is being made to rectify an error in the commencement provision of the Miscellaneous Amendments Regulations. The policy intention was for the Miscellaneous Amendments Regulations to come into force on 10 February 2023 except for regulation 6(2)(a) (in respect of the units of measurement used for the labelling of copper in food supplements) which was intended to come into force on 10 August 2024. The correcting SI remedies the error in which the commencement provision was stated to come into force on 10 August 2024, not 10 February 2023.

7.2 The correcting SI also inserts transitional provisions into each of the 2003 GB Food Supplements Regulations. These provide a defence to relevant enforcement proceedings for the sale of food supplement products containing copper and zinc labelled prior to the coming into force of the provisions in regulation 6(2) of the Miscellaneous Amendments Regulations (which change the units of measurement for these substances with which such products must be marked or labelled) providing there would not have been an offence under the regulations as they were at the time before the amendment was made. These provisions as they pertained to copper food supplements were omitted in error in the Miscellaneous Amendments Regulations. It has been considered appropriate to make the same provisions in respect of food supplements containing zinc.

7.3 The Food Standards Agency have been consulted and have reconfirmed that there are no safety concerns with this instrument.

Why is it being changed?

7.4 The current drafting of the commencement provisions in the Miscellaneous Amendments Regulations makes them inoperable as it provides the commencement provisions themselves do not come into force until 10 August 2024.

7.5 The correcting SI rectifies an omission in which a provision ensuring a transition period for food supplements containing copper (which are labelled or marked in the way permitted before the amendments made in the Miscellaneous Amendments Regulations) was not included as was the policy intention as detailed in the limited

technical consultation and noted in the Miscellaneous Amendments Regulations explanatory memorandum. It was also decided that it would be appropriate to make provision for a similar transition period for food supplements containing zinc.

What will it now do?

7.6 This instrument will amend regulations 1(2)(a) and 1(2)(b)) of the Miscellaneous Amendments Regulations to ensure the regulations come into force on 10 February 2023 except for regulation 6(2)(a) (in respect of the units of measurement used for the labelling of copper in food supplements) which is intended to come into force on 10 August 2024. A transition period is now permitted in respect of food supplements containing copper and zinc labelled prior to the respective amendments to the labelling requirements in that a defence has been inserted into the 2003 GB Food Supplements Regulations provided it can be proved that the products were labelled before the coming into force of the amendments and there would not have been an offence under the regulations as they were at the time before the amendment was made.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union/ trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 DHSC currently has no plans to consolidate the legislation.

10. Consultation outcome

10.1 There is a statutory duty to consult on legislative changes to food policy.

10.2 Prior to the making of the Miscellaneous Amendments Regulations, the UK government and Devolved Governments held a limited technical consultation between 12th November – 6th December 2021 to seek the views of relevant industry stakeholders (including food industry, non-government organisations (NGOs), trade bodies and enforcement colleagues).

10.3 In particular, the consultation was sent directly to industry stakeholders and was also placed on the Knowledge Hub, a closed forum for Local Authorities. The consultation generated responses from local government, trade associations, a consumer healthcare association and an industry group representative, with overall support for technical amendments to food supplements and a welcoming of the changes. Further details are available in the Explanatory Memorandum to the original instrument.

10.4 The consultation document proposed an 18-month period before the coming into force of the amendments to the labelling requirements of food supplements which use copper in their manufacture, and, that those products labelled before the amendment may be sold until stocks are exhausted. One response requested that this period was extended. However, ultimately, it was decided that as these products may continue to be sold until the stocks are exhausted and the proposed lead in time aligned with the with the same change implemented by the EU in March 2021, that an 18-month period followed by a transition period was appropriate. It has also been decided it is appropriate to allow a similar transition period for food supplements containing zinc. The change of labelling requirements was also the subject of the aforementioned consultation.

10.5 This correcting SI is being made to correct a legislative oversight in which provisions permitting such a transition period were not included, notwithstanding the policy intention and consultation on this point, make similar transitional provisions in connection to an amendment of the labelling requirements of food supplements containing zinc (a change fully consulted upon) and to address a defective error of the commencement provisions, it is the Secretary of State's view that his duty to consult has been satisfied and, therefore, no further consultation has taken place.

10.6 We will inform stakeholders who were invited to comment through the limited technical consultation (November -December 2021) on the implications of this correcting SI on the Miscellaneous Amendments Regulations and the 2003 GB Food Supplements Regulations.

11. Guidance

11.1 Guidance relating to these amendments is not being issued.

11.2 Detailed guidance on the relative forms of nutrition legislation is available online at gov.uk (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet--2).

11.3 There is specific UK guidance for food supplements legislation: https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs

12. Impact

12.1 There is no, or no significant, impact on charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

13.3 The basis for the final decision on what action to take to assist small businesses is that there is no expected impact.

14. Monitoring & review

14.1 There are no plans for monitor or review the SI. A review is not seen as appropriate given no significant impact on business and particularly small business.

15. Contact

15.1 Bethany Knowles at the Department of Health and Social Care Telephone: 02079721370 or email: bethany.knowles@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Kevin Dodds, Deputy Director for Healthy Weight, Food and Nutrition, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Neil O'Brien MP, the Parliamentary Under Secretary of State for Primary Care and Public Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.