EXPLANATORY MEMORANDUM TO

THE FOOD SUPPLEMENTS AND FOOD FOR SPECIFIC GROUPS (MISCELLANEOUS AMENDMENTS) REGULATIONS 2023

2023 No. 28

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.

2. Purpose of the instrument

2.1 This Statutory Instrument (SI) makes a series of minor technical amendments to the legislation on food supplements, food intended for infants and young children and food for special medical purposes. The purpose of these amendments varies. They correct drafting errors update the units of measure for the labelling of zinc in food supplements and add zinc chloride and ferrous bisglycinate as permitted sources of vitamins and minerals for use in processed cereal-based foods and baby foods (here after referred to as "baby foods"). They are made at the request of industry to use different sources for certain vitamins and minerals which are already permitted to be added to food supplements, baby foods and infant formula and follow-on formula (here after referred to as "formula"). They allow for consistency in labelling between food supplements and other types of food containing copper and the amendment to the definition of pesticides is for clarity.

2.2 Upon consultation with the SI Registrar, the statutory instrument is being issued under the free issue procedure. The SI corrects an error contained in the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/651) and given the brevity of the instrument the presumption in favour of using this procedure has been maintained.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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. Regulation 2 applies to England only.

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 is being made using two powers for the first time: regulation 2(2) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and Articles 11 and 16 of retained Regulation (EU) No 609/2013[1].

6.2 Retained Regulation (EU) No 609/2013 sets out a general framework for formula; baby foods; food for special medical purposes and total diet replacement for weight control. Previously, these foods were regulated under Directive 2009/39/EC on foodstuffs intended for particular nutritional uses[2] (PARNUTS). Under PARNUTS there were further directives made setting out specific composition and labelling rules for each food category. For example, in respect of baby foods, the Commission made Directive 2006/125/EC[3] which was implemented by the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 SI 2003/327 (the 2003 Baby Foods Regulations)[4]. Regulation (EU) No 609/2013 repealed PARNUTS and empowered the Commission to make a delegated act for each relevant food group setting out specific compositional and information requirements.

6.3 Importantly for these purposes, upon making such a delegated act, the respective part of the Annex to Regulation (EU) No 609/2013, which provides the list of substances which may be added, relating to that particular food group would be commenced and the preceding Directive containing an equivalent annex would be repealed. As of the UK's exit from the European Union, the Commission had followed this procedure in respect of formula, food for special medical purposes (here after referred to as "FSMPs") and total diet replacement for weight control in making Commission Delegated Regulation (EU) 2016/1275, Commission Delegated Regulation (EU) 2016/1286 and Commission Delegated Regulation (EU) 2017/17987 respectively8. The Commission had not made a delegated act for baby foods.

6.4 DHSC's position, is that the Annex of Regulation (EU) No 609/2013, as it forms part of retained EU law, has not been commenced for baby foods and that the list that

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[1] Full title: 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 ("Regulation (EU) No 609/2013").

[2] Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (PARNUTS).

[3] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children ("Directive 2006/125/EC").

[4] The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003

[5] 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.

[6] 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.

[7] Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control.

[8] Commission Delegated Regulation (EU) 2017/1798 had not come into force as of the UK's exit from the European Union.

applies to determine what can be added for GB is that set out in the 2003 Baby Foods Regulations and equivalent for Scotland and Wales. Therefore, regulation 2(2)(a) amends Schedule 4 to the 2003 Baby Foods Regulations to insert calcium L-methylfolate and regulation 3(2) amends the Annex to Retained Regulation EU (No) 609/2013 to make the same amendment in respect of formula.

6.5 Similarly, regulation 2(2)(b)(i) of the SI makes the provision to insert ferrous bisglycinate into Schedule 4 of the 2003 Baby Foods Regulation. As set above, the substance had previously been added to the Annex to retained Regulation (EU) No 609/2013, whilst the UK was an EU Member State. This anomaly was uncovered during work undertaken on this instrument.

6.6 Similarly, it has been uncovered that at the time the EU replaced Directive 96/5/EC with Directive 2006/125/EC, zinc chloride was added to Annex IV to Directive 2006/125/EC having not formed part of its predecessor. The respective amendment had not been made to the implementing 2003 Baby Foods Regulations and regulation 2(2)(b)(ii) makes this insertion.

6.7 Food law is a devolved area and there is equivalent legislation to the 2003 Baby Foods Regulation in Scotland, Wales, and Northern Ireland. We understand that colleagues in Scotland and Wales intend on making equivalent legislative changes in their regulations. However, due to the terms of the Protocol on Ireland/ Northern Ireland, EU rules are directly applicable in Northern Ireland and those rules contained within Regulation (EU) No 609/2013 and Directive 2006/125/EC continue to apply.

6.8 The unit of measure for zinc in food supplements is required to be amended due to a copying error in Schedule 1 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, where micrograms were incorrectly used rather than milligrams as per the original governing Directive 2002/46/EC.

7. Policy background

What is being done and why?

Regulation 2 and 3

7.1 These provisions allow manufacturers of baby foods and formula to use different sources for folate (calcium L-methylfolate), iron (ferrous bisglycinate) and zinc (zinc chloride). Manufacturers are not required to use these forms but are alternatives in addition to the sources of folate, iron and zinc which are already permitted as safe for use in these food groups. Alternative options allow industry to source and use different forms.

7.2 A 2019 scientific opinion of the European Food Safety Authority (EFSA) assessing the safety of calcium L-methylfolate, concluded that calcium L-methylfolate is bioavailable and is not a safety concern as a source of folate when used in formula and baby foods at the required levels. As an EU member state at the time of this assessment, the Food Standards Agency (FSA) was involved in the development of this opinion and has reconfirmed it had no safety concerns with the addition of authorising this form of folate as permitted. In 2006, EFSA confirmed there was a low risk of ferrous bisglycinate as a source of iron for use in the manufacturing of foods (including those intended for infants and young children) and in food supplements.

Regulation 4 and 5

7.3 The definition of pesticide residue used in the formula and foods for special medical purposes intended for infants (here after referred to as "FSMPs intended for infants") legislation will be updated. It will change the definition used in Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market) to a more precise definition of residues taken from Regulation (EC) No 396/2005 (on maximum residue levels of pesticides in or on food and feed of plant and animal origin). This provides more clarity and consistency with the definition which is used in the legislation for general food.

Regulation 6

7.4 This provision allows manufacturers of food supplements to use an additional form of niacin (nicotinamide riboside chloride) and magnesium (magnesium citrate malate). Manufacturers are not required to use these forms; these are alternatives in addition to the forms of both niacin and magnesium, which are already permitted for use in food supplements.

7.5 The EFSA 2018 scientific opinion on magnesium citrate malate concluded that it was a source of magnesium, which was bioavailable when added to food supplements for nutritional purposes. In 2019, EFSA confirmed the safety of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283 and the bioavailability of nicotinamide from this source, in the context of food supplements. The FSA has reconfirmed it had no safety concerns with the addition of authorising these form of nutrients as permitted in food supplements.

7.6 In addition, this provision updates the units of measure used for the labelling of copper and zinc in food supplements. Industry requested for the units of measurement used for copper in food supplements to be aligned with the units of measurement of copper on all other foods. The unit of measure for zinc in food supplements is required to be amended due to a copying error in Schedule 1 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 DHSC currently has no plans to consolidate the legislation.

10. Consultation outcome

10.1 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). The consultation was sent directly to industry stakeholders to allow them to comment on the technical aspects and implications of these proposed amendments.

10.2 A limited consultation was considered appropriate in this case due to the very technical nature of the amendments. The addition of ferrous bisglycinate and zinc chloride as permitted substances for the manufacture of baby foods has previously been consulted on and agreed when added to the Annex of Regulation (EU) No

609/2013 and the Annex of Directive 2006/125/EC respectively. Furthermore, the additional forms of substances which are to be permitted for use are for nutrients which are already approved for use. There are no safety concerns and, the changes are not mandatory requirements but offer additional options.

10.3 The consultation document was also placed on the Knowledge Hub, a closed forum for Local Authorities, to discuss views on enforcement issues. The impact of the technical amendments on business and relevant enforcement bodies are considered to be limited.

10.4 The consultation generated responses from one local authority, three trade associations, one consumer healthcare association and one industry group representative.

10.5 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. There was overall support for the technical amendments to food supplements and the respondents welcomed the changes which were proposed. One response requested a longer transition period for the change in unit of measurement used for labelling copper in food supplements. The concerns relating to the length of transition period were considered. It was agreed as these products may continue to be marketed until the stocks run out and the proposed length of transition aligns with the transition period for the same change, which was implemented by the EU in March 2021. Therefore an 18-month transition period was agreed.

10.6 Three respondents raised concerns regarding amending the definition of pesticide residues used in formula and FSMPs intended for infants 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 regarding the maximum residue levels for pesticides which are set in the legislation for these foods. The concerns raised were considered and the Health Safety Executive and FSA confirmed that there was no safety concern with making the change as the change as was proposed would improve clarity and certainty over the definition for pesticide residues. As the concerns raised were not focused on the definition it was agreed they were out of scope of this SI and would be for wider consideration.

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 and DHSC guidance on Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013) Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013): guidance - GOV.UK (www.gov.uk)

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 as there is no mandatory reformulation of products required and therefore a low level of impact per business. We consider the main costs which the SI will impose is that of the relevant enforcement colleagues familiarising themselves with the changes which are being made to the different forms of legislation.

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.