EXPLANATORY MEMORANDUM TO

THE NUTRITION (AMENDMENT) AND FOOD FOR SPECIFIC GROUPS (FOOD FOR SPECIAL MEDICAL PURPOSES FOR INFANTS, INFANT FORMULA AND FOLLOW-ON FORMULA) (INFORMATION AND COMPOSITIONAL REQUIREMENTS) (AMENDMENT) REGULATIONS 2021

2021 No. 168

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 Her Majesty.

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

2. Purpose of the instrument

2.1 This instrument amends the date of application of the provisions relating to infant formula and follow-on formula made from protein hydrolysates under Commission Delegated Regulation 2016/127 from 22 February 2021 to 22 February 2022. This date change would be for England, Scotland and Wales. It also amends the date of enforcement of the same provisions in England. (Scotland, Wales and Northern Ireland (NI) will similarly amend their enforcing SIs to reflect this new date).

2.2 The detail of the provisions is not being altered other than in respect of the date of application in respect of infant formula and follow-on formula made from protein hydrolysates.

2.3 This is needed as the EU Commission has made legislation to defer the application date of these provisions to 22 February 2022 and we want to ensure that we do not unintentionally diverge from NI. We also want to ensure we are fully prepared for the change in respect of how Great Britain (GB) will scientifically assess these protein hydrolysates formulae now we no longer have access to the scientific committee that provides this assessment function in the EU (The European Food Safety Authority – EFSA).

Explanations

What did any relevant EU law do before exit day?

2.4 The Food for Specific Groups (FSG) legislation Regulation (EU) No 609/2013, lays down general requirements for the following categories of food:

a) infant formula and follow-on formula;
b) processed cereal-based food and baby food;
c) food for special medical purposes;
d) total diet replacement for weight control.

2.5 In terms of labelling, there are only general requirements established under this legislation for not misleading the consumer or attributing to the food the property of preventing, treating or curing a human disease. There are additional requirements for infant formula and follow-on formula which require the labelling, presentation and

advertising to be designed so as not to discourage breastfeeding and must not include pictures or text idealising the use.

2.6 Infant formula and follow-on formula are products designed to satisfy the specific nutritional requirements of healthy infants and young children.

2.7 Infant formula is suitable from birth and is the only food which can be marketed as satisfying by itself the nutritional requirements of infants during the first months of life. Follow-on formulae are foods intended for older infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants.

2.8 Commission Delegated Regulation (EU) 2016/127 ("CDR 2016/127") of 25 September 2015, supplemented Regulation (EU) No 609/2013 to provide specific compositional and information requirements for infant formula and follow-on formula. CDR 2016/127 applied from 22 February 2020, except in respect of infant formula and follow-on formula made from protein hydrolysates to which is was due to apply from 22 February 2021.

What will it now do?

2.9 Until the provisions relating to infant formula and follow-on formula manufactured from protein hydrolysates come into effect, the provisions in the existing legislation (Directive 2006/141/EC) applies. The amendment to CDR 2016/127 made by the EU Commission means the status quo remains for a further year until the new provisions of 2016/127 relating to protein hydrolysates take effect on 22 February 2022.

2.10 This change applies automatically in NI under the operation of the European Union (Withdrawal) Act 2018 ("the Withdrawal Act"). Therefore the coming into force date of the application of the requirements of CDR 2016/127 relating to protein hydrolysates is being delayed for GB to avoid unintended divergence with NI and therefore any impact the UK internal market, for example, a formula made from protein hydrolysates would still be allowed to be sold in NI without pre-assessment until 22 February 2022, while that same product would not be legally compliant in GB.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 DHSC regrets that this instrument breaches the rule that statutory instruments subject to the negative procedure should normally be laid, and copies provided to the Committee, 21 days before the instrument comes into force. The reason for breaching the rule is that DHSC was not aware of the EU amending CDR 2016/127 until the amending legislation was notified to us by the clerks of the House of Lords' European Union Committee and the House of Commons' European Scrutiny Committee on 25 January 2021. This instrument delays the introduction of new legal requirements with the current requirements remaining in place so there is no change to impact on business or the public due to this instrument. Failure to breach the 21 day rule so as to bring the amendment into force before 22 February 2021 would have meant the new requirements applying to infant formula and follow-on formula made from protein hydrolysates. We could not have easily amended this after 22 February, once the new requirements had come into effect. There would have been divergence between the legislation applying in NI and the rest of the UK with infant formula and follow-on

formula made from protein hydrolysates under the existing legislation being able to be placed on the NI market but not on the GB market from 22 February 2021.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As this instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England, Wales and Scotland only.

4.2 The territorial application of this instrument varies between provisions. Regulation 2 applies to England only.

5. European Convention on Human Rights

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

6. Legislative Context

6.1 Regulation (EU) No 609/2013, which started to apply from 20 July 2016, brings in new simplified EU legislation on food for specific groups. In respect of legislation covering infant formula and follow-on formula, Regulation (EU) No 609/2013 replaces Directive 2006/141/EC.

6.2 Under this Regulation, the EU Commission is required to adopt specific rules for the composition and labelling of the different categories of these foods through delegated acts. For example, Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 set specific requirements for foods for special medical purposes and applied from 22 February 2019, except in respect of foods for special medical purposes developed to satisfy the nutritional requirements of infants, to which it applied from 22 February 2020.

6.3 As set out above, CDR 2016/127 sets the specific requirements for infant and follow on formula with a similar staggered application date. The new requirement applied from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which they were due to apply from 22 February 2021.

6.4 Regulation (EU) No 609/2013 became retained EU legislation on 1 January 2021 with appropriate amendments made on a UK wide basis with consent from the Devolved Administrations (DAs): the Nutrition (Amendment etc) (EU Exit) Regulations 2019 (SI 2019/651). A follow up SI was made in 2020 : the Nutrition (Amendment etc) (EU Exit) Regulations 2020 (SI 2020/1476), to give effect to the Northern Ireland Protocol and to make appropriate amendments to EU legislation that came into force in relation to further categories of product during the Implementation Period, including the two Commission Delegated Regulations referenced above. In relation to the anticipated application of CDR 2016/127 to infant and follow-on formula made from protein hydrolysates, SI 2020/1476 provided for a modification of the retained CDR 2016/127 from 22 February to apply to these products.

6.5 In the debate on the Nutrition (Amendment etc) (EU Exit) Regulations 2020 in Grand Committee on 25th November 2020, Lord Bethell acknowledged concerns raised re divergence in this area and responded that 'no divergence is anticipated. We are not putting in place mechanisms for divergence, because we are not planning to create it'. (Hansard HL Deb 25 November 2020 vol 808, c7GC)

6.6 Food law is a devolved area. Apart from directly applicable EU legislation, England and each of the DAs has a separate body of legislation which in the main is equivalent given that it implemented Directives and provided for enforcement of the directly applicable EU legislation.

6.7 Enforcement of CDR 2016/127 for England is covered by The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020 (SI 2020/43). That instrument also provided for the revocation, with appropriate transitional provision of the Infant and Follow-on Formula (England) Regulations 2007 that covered enforcement for the requirements under Directive 2006/141/EC.

7. Policy background

What is being done and why?

7.1 This instrument amends SI 2020/1476 to amend the modification of CDR 2016/127 so that the requirements imposed by that Regulation will not apply to infant formula and follow-on formula made from protein hydrolysates until 22 February 2022, and makes a consequential amendment to SI 2020/43 in respect of enforcement of the new requirements. The effect is that the requirements of the current legislation, Directive 2006/41/EC, continue to apply to these products.

7.2 This change is being made so that the new legislative requirements will apply in GB from the same date as for Northern Ireland to avoid an unintended divergence. Any unintended divergence in nutrition legislation between GB and NI would impact the UK internal market, for example, a formula made from protein hydrolysates would still be allowed to be sold in NI without pre-assessment after 22 February 2021, but while that same product would not be legally compliant in GB due to the Protocol it would have unfettered access to the GB market.

7.3 The use of protein hydrolysates in infant formula and follow-on formula has been permitted under Directive 2006/141/EC for many years and the use of protein hydrolysates in the manufacturing of formula is widespread in the market. This is in part because this Directive allows a health claim to be made on infant formula manufactured from protein hydrolysates, describing the role of such formula in reducing the risk of developing allergy to milk proteins. Under the Directive, infant and follow-on formula manufactured from protein hydrolysates must meet certain compositional requirements.

7.4 Infant and follow-on formula ingredients manufactured from protein hydrolysates are already subject to safety requirements under existing food law and would not be legally compliant or permitted to be sold on the market if the ingredients were deemed to be unsafe.

7.5 However, to be compliant with the new CDR 2016/127, manufacturers of infant formula and follow-on formula made from protein hydrolysates must demonstrate the

products suitability for infants has been established by generally accepted scientific data.

7.6 Compliance with CDR 2016/127 means clinical studies will be necessary to demonstrate if, and to what extent, a particular formula reduces the risk of developing short and long-term clinical manifestations of allergy in at-risk infants who are not breast-fed.

7.7 In effect in the EU this means pre-assessment by the European Food Safety Authority (EFSA) to ensure that the products have substantial evidence to demonstrate compliance with the Regulation, i.e. that they are fit for purpose and that they are able reduce the risk of allergies. In GB, this will be a new process by a domestic scientific committee.

7.8 Although no companies have approached GB to assess their protein hydrolysates formula since 1 January 2021, it would have been highly unlikely to complete such an assessment by 22 February 2021. We will use the additional year given by this date change to work up a robust process for assessing compliance with the new regime in GB, in a similar way to how the EU is operating. This will be set up and fully explained to industry in advance of the 22 February 2022 date of application.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not trigger the statement requirements under the European Union (Withdrawal) Act 2018.

8.2 This instrument is not being made to address a deficiency in retained EU law but relates to the withdrawal of the United Kingdom from the European Union because it is being made under sections 8C(1)(c) and 23 of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018.

8.3 Alongside the EU (Withdrawal) Act 2018 powers the instrument is also being made under sections 16(1)(a) and (e) and (2)(b), 26(1) and (3) and 48(1) of the Food Safety Act 1990 to amend the Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020 which provide for enforcement of these requirements in England.

9. Consolidation

9.1 DHSC currently has no plans to consolidate the legislation.

10. Consultation outcome

10.1 A consultation was not considered to be necessary as we previously consulted on the technical aspects via a limited technical consultation prior to the first part of CDR 2016/127 coming into effect in February 2020. Instead, we will communicate this change in application date, including to the stakeholders who were involved in the previous consultation.

10.2 Scottish and Welsh Ministers were consulted and have given their consent to the amendments to CDR 2016/127 being made GB wide.

11. Guidance

11.1 Guidance relating to this date change is not being issued. However, DHSC will issue detailed guidance on retained CDR 2016/127 during 2021, including the process by which businesses will apply to have their protein hydrolysates formula assessed by the GB domestic scientific committee. Interested parties will be informed when the new Regulations come into force and information about the key changes will be highlighted. Updated guidance will be published online at www.gov.uk.

12. Impact

12.1 As the status quo remains until the new provisions come into effect, there is no material change as products will continue to remain compliant with the existing legislation.

12.2 An Impact Assessment has not been prepared for this instrument because there is low impact level per business and not many businesses will be affected since the number of manufacturers of these products is small.

13. Regulating small business

13.1 This instrument applies to activities that are undertaken by small businesses, although these products are fairly niche with a limited number of companies and products on sale, and this instrument maintains the status quo for a further year, so there is no additional burden.

14. Monitoring & review

14.1 A statutory review clause is included in the current infant formula and follow-on formula in S.I. 2020/43 being amended but not in the EU Exit SI we are also amending. Therefore the review of the legislation will be carried out in accordance with the existing provision.

15. Contact

15.1 Debby Webb at the Department of Health and Social Care, Telephone: 020 7210 4850 or email: nutritionlegislation@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jenny Oldroyd, Deputy Director at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.

15.3 Nadhim Zahawi MP, Parliamentary Under Secretary of State for Covid-19 Vaccine Deployment at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.