Explanatory Memorandum to the Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2021

This Explanatory Memorandum has been prepared by the Health and Social Services Group and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister/Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2021

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
26 August 2021

PART 1

1. Description

1. The Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2021 amends the Infant Formula and Follow-on Formula (Wales) Regulations 2020 to reflect an amendment made to the the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476) ("the EU Exit Regulations"). The EU Exit Regulation were amended to amend the date of application of the provisions relating to infant formula and follow-on formula made from protein hydrolysates under Commission Delegated Regulation 20216/127 from 22 February 2021 to 22 February 2022. These regulations amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020 which make enforcement provisions in Wales in relation to those provisions to reflect the change to the date of application.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2.1 None

3. Legislative background

3.1 Welsh Ministers have the powers to make the proposed Regulations under sections 6(4), 16(1)(a) and (e) and 2(b), 17(1) and (2), and 48(1) of the Food Safety Act 1990 ("the 1990 Act").

3.2 Powers under the 1990 Act, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, as read with Section 40(3) of the Food Standards Act 1999, and were transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 ("GOWA 2006").

3.3 These Regulations are being made under the negative procedure.

4. Purpose and intended effect of the legislation

4.1 In 2016, the EU implemented the Food for Specific Groups Regulation (EU) 609/2013 (the FSG EU Regulation) which sets general compositional and labelling rules for the following four food categories:

- infant formula and follow-on formula (IFFOF);
- processed cereal-based food and baby foods;
- food for special medical purposes (FSMP) (foods necessary for the management of particular medical conditions);

- total diet replacement for use in energy restricted diets for weight reduction.

4.2 Four Delegated Regulations sit under the FSG EU Regulation and supplement the FSG EU Regulation to reflect developments in a particular area. The four Delegated Regulations provide for the detailed composition and labelling requirements for each of the four food categories listed above.

4.3 One such Delegated Regulation is (EU) 2016/127. This Regulation set specific compositional and labelling requirements for infant formula and follow-on formula (IFFOF). The majority of these requirements applied from 22nd February 2020 but, the requirements relating to IFFOF made from protein hydrolysates were not due to come into force until 22 February this year. Until 22 February 2021, infant and follow-on formula manufactured from protein hydrolysates will continue to be regulated by Commission Directive 2006/141/EC.

4.4 The use of protein hydrolysates as a source of protein in infant formula and follow-on formula has been allowed for many years and its use in the manufacturing of formula is widespread in the market. This is due in part to the associated health claims that infant formula manufactured from protein hydrolysates 'reduces the risk of developing allergy to milk proteins'.

4.5 Under 2016/127 health claims such as 'easy to digest', or 'reduce the risk of developing allergies to cows' milk' will be prohibited unless substantiated by scientific assessment.

4.6 Last year the EU had issued an amendment to Delegated Regulations 2016/217 Regulations 2016/217 to delay the implementation of the new requirements until 22 February 2022 (1 year delay) https://data.consilium.europa.eu/doc/document/ST-5528-2021-INIT/en/pdf.

4.7 The UK Government replicated this amendment for England, Scotland and Wales by way of 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 ("the 2021 GB SI").

4.8 Since the making of the 2021 GB SI the 4 Nations Nutrition Labelling Composition and Standards Policy group has been finalising an appropriate scientific assessment regime for infant formula manufactured from protein claims ready for February 2022.

4.9 These Regulations amend the Infant Formula and Follow-on Formula (Wales) Regulations 2020 to reflect the new rules relating IFFOR products made from protein hydrolysates now apply from 22 February 2022.

4.10 These Regulations amend domestic law to ensure the enforcement regime for Wales reflects the 2021 GB SI.

4.11 This is purely a technical amendment and the Regulations will not impose any new requirement on businesses or enforcement bodies nor will it impose any new costs.

5. Consultation

5.1 A limited technical consultation was held for four weeks from 10 May 2021. A limited consultation was considered appropriate in this instance as the change proposed is purely technical and corrects a reference which is now obsolete. The domestic SI will not impose any new requirements on businesses or enforcement bodies nor will it impose any new costs.

5.2 The consultation was shared with enforcement bodies, industry stakeholders, health professional and consumer groups and other relevant non-government organisations.

5.3 Four responses were received to the consultation, one from a member of the public, one from First Steps Nutrition Trust and two from health care professionals. The response from the member of the public was supportive of the proposed Regulations. The responses from First Steps Nutrition Trust and the health care professionals shared concerns regarding the use of hydrolysed formula for allergy prevention and the availability of evidence based information to health care professions. Both these points relate to the policy rather than the enforcement of the policy and were therefore not covered by this consultation.

5.4 Consultations were also held in the other UK countries.

5.5 No amendments were made to these or the other equivalent UK Regulations as a consequence of the consultations.

6. Regulatory Impact Assessment (RIA)

6.1 No impact assessment has been produced in relation to these Regulations as no impact on the private, voluntary or public sectors is foreseen. This legislation has no impact on the statutory duties (sections 77-79 of the Government of Wales Act 2006) or statutory partners (sections 72-75 of the Government of Wales Act 2006).