

Explanatory Memorandum to the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) (Amendment) Regulations 2022

This Explanatory Memorandum has been prepared by the Healthy and Active Team within the Health Improvement, Prevention, and Inequalities Division and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) (Amendment) Regulations 2022.

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
15 December 2022

1. Description

1.1 These Regulations amend the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004 (S.I. 2004/314 (W. 32)) (“the 2004 Regulations”) to permit the addition of calcium-L-methylfolate in the manufacture of processed cereal-based foods and baby foods and to correct a previous missed amendment to add ferrous bisglycinate and zinc chloride as permitted sources of vitamins and minerals to be added to processed-cereal based foods and baby foods. Additionally, where a processed cereal-based food or baby food is labelled with the average quantity of those substances, the effect of these Regulations is that this must be done in a manner which complies with certain labelling requirements set out in regulation 8(2) and (3) of the 2004 Regulations.

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

2.1 None.

3. Legislative background

3.1 Sections 16(1)(a) and (e) of the Food Safety Act 1990 (“the 1990 Act”) enable the Welsh Ministers to, by regulations, make provision for requiring, prohibiting or regulating the presence in food or food sources of any specified substance, or any substance of any specified class, and generally for regulating the composition of food, and for imposing requirements or prohibitions as to, or otherwise regulating, the labelling, marking, presenting or advertising of food, and the descriptions which may be applied to food.

3.2 The relevant functions in sections 16(1)(a) and (e) of the 1990 Act, formerly exercisable by “the Ministers”, were conferred on the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (“the 1999 Act”). Those functions, so far as exercisable in relation to Wales, were then transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act. Those functions are now exercisable by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006.

3.3 In accordance with section 48(4A) of the 1990 Act, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency.

3.4 These Regulations are being made under the negative resolution procedure.

4. Purpose and intended effect of the legislation

4.1 The purpose of these Regulations is to allow manufacturers of processed

cereal-based foods and baby foods 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 they 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 depending on their availability and affordability.

4.2 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 processed cereal-based foods 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 they have no safety concerns with the addition of authorising this form of folate as permitted.

4.3 The purpose of these Regulations is also to correct a previous missed amendment to add a source of zinc (zinc chloride) and iron (ferrous bisglycinate) as permitted sources of vitamins and minerals for use in processed based baby foods and baby foods. These substances had previously been permitted for use in the manufacture of processed cereal-based foods and baby foods whilst the UK was an EU Member State. However, at the end of the EU-Exit transition period, an oversight occurred, and the 2004 Regulations were not updated to include these substances. These Regulations therefore correct that omission, as was intended at the end of the EU-Exit transition period.

4.4 In 2006, the 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. The amendments made by these Regulations will align with changes already made in the EU. It is understood that there is equivalent legislation being made in England and Scotland to avoid any divergence across Great Britain.

5. Consultation

5.1 Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, requires open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it. On 12 November 2021, the UK Government's Department of Health and Social Care in conjunction with Devolved Administrations launched a three-week UK wide consultation, inviting comments from the food and

nutrition industry, representative groups, the public and other interested parties across the UK on the proposed approach and policy objectives. A limited consultation was considered appropriate in this case due to the very technical nature of the amendments. The consultation document was placed on the Knowledge Hub, a closed forum for Local Authorities to discuss views on enforcement issues. The consultation closed on 6 December 2021.

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 to include calcium-L-methylfolate. Respondents welcomed the amendment and indicated that as use of these substances is not mandatory, the amendment will not negatively impact on manufacturing.

5.2 The consultation did not include questions regarding the inclusion of ferrous bisglycinate and zinc chloride as permitted forms of iron and zinc that may be used in the manufacture of processed cereal-based foods and baby foods, respectively. This is because it was identified through the consultation feedback that a previous missed amendment to add these as permitted nutritional substances had occurred at the end of the EU-Exit transition period. However, the inclusion of ferrous bisglycinate and zinc chloride as permitted substances in the UK was already considered, consulted on and agreed previously when the UK was an EU Member State.

6. Regulatory Impact Assessment

6.1 An RIA has not been produced for this instrument as it is making technical amendments required to change the wording of the law rather than its purpose or effect and factual amendments to update subordinate legislation, which do not alter the policy (or its impact) in any significant way or how it is applied in a given situation. This is in line with the policy set out in the Welsh Ministers' code of practice for carrying out regulatory impact assessments for subordinate legislation.