

## **POLICY NOTE**

### **THE FOODS FOR SPECIFIC GROUPS (INFANT FORMULA AND FOLLOW-ON FORMULA) (SCOTLAND) AMENDMENT REGULATIONS 2021**

**SSI 2021/123**

The above instrument was made in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e), 26(1) and (3) and 48(1) of the Food Safety Act 1990. The instrument is subject to negative procedure.

#### **Summary Box**

<p>The purpose of this instrument is to apply the law in existence before 21 February 2021 on compositional and labelling standards for infant formula and follow-on formula manufactured from protein hydrolysates, until 22 February 2022.</p>
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#### **Policy Objectives**

On the 1 February 2021 Food Standards Scotland became aware of an amendment to Commission Delegated Regulation (EU) No. 2016/127 as it applies in the EU, regarding the timing of the introduction of new composition standards for infant formula and follow-on formula made from protein hydrolysates. The amendment had the effect of delaying the application date of Commission Delegated Regulation (EU) No 2016/127 to 22 February 2022 and extending the application of the current EU law contained in Directive 2006/141/EC as it applies in the EU. This amendment to EU law is directly applicable in Northern Ireland under the Northern Ireland Protocol. The reason for this amendment is due to the impact of Covid-19 on the European Food Safety Authority's work plan and it has not been able to complete the pre-assessment work on protein hydrolysates. This seeks to ensure that there is substantial evidence to demonstrate the products comply with the Regulation, i.e. that they are fit for purpose and that they are able to reduce the risk of allergies, as required under EU law. Following EU Exit, in Great Britain (GB) there will be a new scientific assessment process established to consider these products.

With the agreement of Scottish Ministers, an amendment has been made to the retained EU law Commission Delegated Regulation (EU) No 2016/127 for Scotland (as well as England and Wales) by the UK government. This amendment has been introduced via 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 GB Statutory Instrument is also the subject of a notification to the Scottish Parliament. Consent was sought to avoid an unintended divergence from Northern Ireland and to avoid an imbalance between the rules across the UK. It also allows time for GB to work up a robust process for assessing compliance with the new regime.

That GB SI also amended the English enforcement regime in line with amendments to the retained EU law Commission Delegated Regulation (EU) No. 2016/127. This instrument makes equivalent amendments to domestic Scottish Law.

This instrument amends the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 (“the 2020 Regulations”). Those Regulations revoked the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (“the 2007 Regulations”) on 21 February 2021 insofar as those Regulations applied to the compositional and labelling standards for infant formula and follow-on formula manufactured from protein hydrolysates. This instrument re-creates the regulatory regime in the 2007 Regulations in relation to infant formula and follow-on formula manufactured from protein hydrolysates that was in effect until 21 February 2021. This regime will now be in place until 22 February 2022, which is the date when retained EU law Commission Delegated Regulation (EU) No 2016/127 will come into force bringing in the new regulatory regime in relation to infant formula and follow-on formula manufactured from protein hydrolysates.

There is a short period between 21 February 2021 and the coming into force of this instrument on the 26 March 2021 when no regulatory regime is in place in Scotland in relation to infant formula and follow-on formula made from protein hydrolysates. This is because there was insufficient time from becoming aware of the amendment to EU law made by the European Commission to introduce a SSI to come into force before 21 February 2021 extending the current regulatory regime. The gap is as short as possible; balancing bringing the instrument into force as soon as possible with allowing as much time as possible for Parliamentary scrutiny. We are also not aware of any manufacturers of any type of infant formula or follow-on formula in Scotland however this instrument would allow other UK manufacturers to place their products on Scottish market whilst working towards reformulation.

## **Consultation**

There is a statutory duty to consult on revisions of food law. However Food Standards Scotland was only notified of the European Commission’s decision to extend the transition period on the 1 February 2021, effectively maintaining the status quo, and we consider it is vital to introduce the statutory instrument as soon as possible. This minimises the gap between the regimes, as possible and maintains a level playing field across the UK. Failure to do so would result in divergence between the legislation applying in Northern Ireland and the rest of the UK. Therefore we feel that a consultation is not achievable in light of the urgent need to minimise the gap between the previous law applying which was revoked on the 21 February 2021 and this instrument which will recreate the law contained in those expired provisions relating to infant formula and follow-on formula manufactured from protein hydrolysates.

Continuing to apply the law in existence before 21 February 2021 on compositional and labelling standards for infant formula and follow-on formula manufactured from protein hydrolysates, until 22 February 2022 would only benefit businesses and therefore no negative effects of not consulting due to the urgency of the timings are foreseen.

To note, a previous consultation was carried out between the 5 November and 2 December 2019 on the original transitional measures for infant formula and follow-on formula made from protein hydrolysates. Around 40 interested parties and 32 local authorities were consulted and two responses were received from Baby Feeding Law Group and British

Specialist Nutrition Association. Neither responses raised any concerns and both organisations were content with our proposals.

### **Impact Assessments**

Impact assessments have not been prepared for this instrument due to the urgency and tight timescale to minimise the gap in regimes. Extending the transition period further would only benefit businesses therefore the impact of this policy is considered to be negligible.

### **Financial Effects**

Any financial impacts on competent and enforcement authorities arising from the required amendments to the existing domestic legislation are low.

Food Standards Scotland  
*8<sup>th</sup> March 2021*