

## **Delegated Regulation (EU) 2016/128 on Foods for Special Medical Purposes to meet the nutritional requirements of infants, and Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula.**

## **Consultation on the proposed regime for enforcing the provisions of the Delegated Regulations in Northern Ireland.**

### **Summary of stakeholder responses**

**November 2019**

### **Introduction**

This consultation was issued on 14 November 2019 and closed on 12 December 2019.

The proposal is to introduce domestic legislation, in the form of a proposed Statutory Rule (SR), so that both the above Delegated Regulations and Article 15 of the Food for Specific Groups (FSG) Regulation shall apply and be enforceable in Northern Ireland (NI) law through an amendment to the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016.

The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the issues considered.

The key proposals on which the consultation sought views were to:

- implement and enforce the Delegated Regulation 2016/128 rules on Food for Special Medical Purposes (FSMP) for infants
- implement and enforce the Delegated Regulation 2016/127 rules on Infant Formula and Follow on Formula (IFFOF)
- implement and enforce Article 15 and the Annex to the FSG Regulation 609/2013 with regard to the Union list of substances that can be added to FSMP for infants and IFFOF

- revoke The Medical Food Regulations (Northern Ireland) 2000 from 22nd February 2020
- revoke The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 from 22nd February 2020 as it applies to IFFOF, other than IFFOF made from protein hydrolysates for which it will revoke the 2007 Regulations from 22nd February 2021.

The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. No changes were made to the original draft regulations as a result of the responses received.

A list of stakeholders who responded can be found at the end of the document.

## Summary of substantive comments

### Question

Do you agree that the first formal action for breaches of the provisions of Delegated Regulation (EU) 2016/128 on food for special medical purposes for infants would be an Improvement Notice consistent with the enforcement provisions for the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (enforcing EU Regulation 609/2013) and the proposed regulations (which includes enforcement of the provisions for FSMP other than FSMP for infants)?

### Respondent

Baby Feeding Law Group

### Comment

Firstly, compliance should be assessed in relation to all provisions of the Delegated Regulation (EU) 2016/128, not just those related to composition and labelling as suggested in paragraph 24 and Figure 1. For example, they should include those related to marketing (presentation, advertising, promotion).

Secondly, while we agree that the first, formal action upon confirming that a suspected violation is a breach of any provision of this regulation should be the issuing of an improvement notice, we do not agree with an informal first step for tackling breaches which do not pose an immediate risk to public health (as per paragraph 24). Maintaining an informal first step belittles the purpose of the regulations to protect the health of infants in the short, medium and longer term by protecting breastfeeding and because diets in infancy have life-long health impacts.

With an informal first step, you state in paragraph 25 that the majority of breaches will result in informal enforcement action which is not recorded. It will therefore remain impossible to monitor the extent to which the regulations are complied with, or otherwise. Years of voluntary monitoring of the marketing of breastmilk substitutes (including iFSMPs available on supermarket, shop and pharmacy shelves) by Baby Milk Action, highlights that manufacturers and retailers continue to aggressively market their products to maximise sales. To improve compliance with the law all enforcement measures need to be formal to enable monitoring and evaluation, and this data should be publicly available at a central level.

## Response

Response acknowledged and considered. The SR provides local authorities with the tools to take appropriate and risk based action to tackle non compliance.

## Respondent

British Specialist Nutrition Association (BSNA) Ltd

## Comment

BSNA is content that the first formal action for breaches of the provisions for FSMPs for infants would be an Improvement Notice consistent with the enforcement provisions for the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (enforcing EU Regulation 609/2013) and the proposed regulations (which includes enforcement of the provisions for FSMP other than FSMP for infants).

## Response

Response acknowledged and considered.

## Question

Do you agree that the first formal action for breaches of the provisions of Delegated Regulation (EU) 2016/127 for infant formula and follow-on formula would be an Improvement Notice consistent with the enforcement provisions for the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (enforcing EU Regulation 609/2013) and the proposed Regulations?

## Respondent

Baby Feeding Law Group

## Comment

As above, firstly, compliance should be assessed in relation to all provisions of the Delegated Regulation (EU) 2016/127, not just those related to composition and labelling

as suggested in paragraph 24 and Figure 1; i.e. they should include those related to marketing (presentation, advertising, promotion etc).

Secondly, while we agree that the first (formal) action upon confirming that a suspected violation is a breach of any provision of this regulation should be the issuing of an improvement notice, we do not agree with an informal first step for tackling breaches which do not pose an immediate risk to public health (as per paragraph 24). Maintaining an informal first step belittles the purpose of the regulations to protect the health of infants in the short, medium and longer term by protecting breastfeeding and because diets in infancy have life-long health impacts.

With an informal first step you state in paragraph 25 that the majority of breaches will result in informal enforcement action which is not recorded. It will therefore remain impossible to monitor the extent to which the regulations are complied with, or otherwise. Years of voluntary monitoring of the marketing of breastmilk substitutes by Baby Milk Action, highlights that manufacturers and retailers continue to aggressively market their products to maximise sales. To improve compliance with the law all enforcement measures need to be formal to enable monitoring and evaluation, and this data should be publicly available at a central level.

## Response

Response acknowledged and considered. The SR provides local authorities with the tools to take appropriate and risk based action to tackle non compliance.

## Respondent

British Specialist Nutrition Association (BSNA) LtdBaby Feeding law Group

## Comment:

BSNA is content that the first formal action for breaches of the provisions of Delegated Regulation (EU) 2016/127 for infant formula and follow-on formula would be an Improvement Notice consistent with the enforcement provisions for the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (enforcing EU Regulation 609/2013) and the proposed regulation.

## Response

Response acknowledged and considered.

## **Actions to be implemented**

The FSA in NI has reviewed all stakeholders' responses. No changes were made to the original draft regulations as a result of the responses received.

## **List of respondents**

1. Baby Feeding Law Group UK
2. British Specialist Nutrition Association (BSNA) Ltd.