Food Standards Scotland
Inbhe Bìdh Alba

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

The Foods for Specific Groups (Medical Foods for Infants) and Addition of Vitamins, Minerals and Other Substances (Scotland) Amendment Regulations 2020
and
The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020

Date:	9 January 2020
Stage:	Final
Source of intervention:	EU
Type of measure:	Regulation
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1. Title of Proposals

The Foods for Specific Groups (Medical Foods for Infants) and Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2020.

The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020

2. Purpose and intended effect

- **Objectives**

The purpose of these Scottish Statutory Instruments are as follows:

i. The Foods for Specific Groups (Medical Foods for Infants) and Addition of Vitamins, Minerals and Other Substances (Scotland) Amendment Regulations 2020

- To enable the enforcement of and provide penalties for non-compliance with Article 8 and Annex III of Regulation (EC) No. 1925/2006, which lists substances in respect of which use in foods is prohibited or restricted
- To amend the Foods for Specific Groups (Scotland) Regulations 2016 (FSG Regulations) to mirror and enable the enforcement of the Delegated Regulation (EU) No. 2016/128 which provides new rules for the composition and labelling of foods for Specific Medical Purposes (FSMP) for infants
- provide for the enforcement of 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
- To repeal the Foods for Special Medical Purposes (Scotland) Regulations 2000 from 22nd February 2020, subject to savings provisions.

ii. The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020

- To execute and enable the enforcement of Delegated Regulation (EU) No. 2016/127 which sets new rules for the composition, labelling and advertising of infant formula and follow-on formula (IFFOF)
- To repeal the Infant Formula and Follow-on Formula Regulations (Scotland) 2007 from 22nd February 2020 as it applies to IFFOF, other than IFFOF made from protein hydrolysates for which it will repeal the 2007 Regulations from 22nd February 2021

- **Background**

Addition of Vitamins, Minerals and Other Substances

The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 provides for the enforcement of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods “the EC Regulation”.

Article 8 and Annex III of the EC Regulation provide for substances that could represent a potential risk to consumers. Such substances may be:

- Prohibited under Part A of Annex III
- Restricted with certain conditions of use under Part B of Annex III
- Kept under scrutiny subject to evidence of safety under Part C of Annex III.

The provisions of the EC Regulation are directly applicable in Scotland as an EU Member State.

However, an omission in the Scottish Regulations meant that the Article 8 and Annex III provisions were not included in the offences and penalties section of the original instrument.

FSS consulted on the proposal to amend the Scottish Regulations to include a provision for Article 8 on the prohibition or restriction of substances listed in Part A or B of Annex III. This will make it a punishable offence if a food business operator uses a prohibited substance listed in Part A or is non-compliant with the conditions of use for substances listed in Part B of Annex III.

Food for Specific Groups (FSG)
Regulation (EU) No. 609/2013 ("the FSG Regulation") lays down general compositional and information requirements for four categories of food, including food for specific medical purposes (FSMP), infant formula and follow-on formula (IFFOF),processed cereal-based food and baby food and total diet replacement foods for weight control. It is enforced in Scotland through the Food for Specific Groups (Scotland) Regulations 2016 ("the 2016 Regulations").

Food for Special Medical Purposes (FSMP)
Delegated Regulation (EU) No. 2016/128 on Food for Special Medical Purposes (FSMP) supplements the FSG Regulation with the specific compositional and information requirements for FSMP taking into account the provisions of earlier harmonised legislation on FSMP (Directive 1999/21/EC).

The Delegated Regulation was adopted on 25 September 2015 and the provisions for FSMP other than FSMP for infants have applied since 22nd February 2019. The enforcement provisions in respect of FSMP (other than FSMP for infants) are in the Foods for Specific Groups (Scotland) Regulations 2016, as amended by the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018.

Therefore, the FSMP Delegated Regulation 2016/128 has applied and been enforceable in Scotland since 22 February 2019, except in respect of FSMP developed to satisfy the nutritional requirements of infants, in respect of which it is due to apply from 22 February 2020.

The SSI relating to medical foods for infants will implement and provide for the enforcement of the rules on FSMP for infants and repeal the Regulations that implement the earlier Directive i.e. the Foods for Special Medical Purposes (Scotland) Regulations 2000. These will, however, continue to apply for the purposes of a transitional arrangement whereby stocks of FSMP for infants may be continue to be marketed if they were placed on the market or labelled before the date of application of Delegated Regulation No. 2016/128, until those stocks are exhausted.

Infant Formula and Follow-on Formula (IFFOF)
Delegated Regulation (EU) No. 2016/127 on Infant Formula and Follow-on Formula (IFFOF) supplements the FSG Regulation. It was adopted on 25 September 2015 to update the specific compositional and information requirements for IFFOF, taking into account the provisions of earlier harmonised legislation on IFFOF (Directive 2006/141/EC) and the latest scientific evidence.

Delegated Regulation (EU) No. 2016/127 on IFFOF is due to apply from 22nd February 2020, except in respect of IFFOF made from protein hydrolysates for which the provisions are due to apply from 22nd February 2021. We consulted on the enforcement of both the 2020 and 2021 provisions.

The SSI relating to infant formula and follow-on formula will implement and enforce the new IFFOF rules and will repeal the regulations that implement the earlier Directive (i.e. the Infant Formula and Follow-on Formula (Scotland) Regulations 2007) from 22nd February 2020 for the majority of IFFOF. However, the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 will continue to apply in respect of IFFOF made from protein hydrolysates until 22 February 2021 and for the purposes of a transitional arrangement whereby existing stocks of infant and follow-on formula can continue to marketed if they were placed on the market or labelled before the date of application of Delegated Regulation (EU) No. 2016/127, until those stocks are exhausted.

Union list of substances that can be added to Food for Specific Groups
The SSI also amends the Foods for Specific Groups (Scotland) Regulations 2016 to provide for the enforcement of Article 15 of Regulation (EC) No. 609/2013 with regard to the Union list of substances that can be added to foods for special medical purposes, infant formula and follow-on formula .

EU Exit
The UK is due to leave the EU on 31 January and it is now more likely that the UK will leave with a negotiated and agreed Implementation Period and the UK Government and devolved administrations would be legally obligated to implement the remaining part of Commission Delegated Regulation (EU) 2016/128 and part of Commission Delegated Regulation 2016/127 which apply from 22 February 2020.

- **Rationale for Government intervention**
  The UK agreed the provisions of the Delegated Regulations when they were adopted in 2015 and intends to abide by the new rules which reflect the latest scientific evidence. In addition, industry has been working to meet the changes since 2015 and many manufacturers are already meeting these new requirements. As such, this SSI will allow for the implementation and enforcement of the adopted EU provisions for FSMP for infants and IFFOF and provide the enforcement regime for non-compliance.

  Article 8 and Annex III of Regulation (EC) No. 1925/2006 are currently directly applicable in Scotland as an EU Member State. However, an omission in the Scottish Regulations meant that the Article 8 and Annex III provision was not included in the offences and penalties section of the original instrument.

  FSS consulted on the proposal to amend the Scottish Regulations to include a provision for Article 8 on the prohibition or restriction of substances listed in Part A or B of Annex III. This will make it a punishable offence if a food business operator uses a prohibited substance listed in Part A or is non-compliant with the conditions of use for substances listed in Part B.

3. Consultation

- **Within Government**
  This consultation package was discussed with Scottish Government (SG) officials from Child and Maternal Health and Food, Drink and Trade teams.

- **Public Consultation**
  A shortened 4 week consultation was carried out in Scotland on the policy underpinning these regulations from 4th November 2019 to 25th November. A total of 2 responses were received from the British Specialist Nutrition Association and Baby Feeding Law Group. Neither of the responses raised any concerns and were content with our proposals. However one respondent pointed out some areas for later consideration such as a closer alignment with the Wold Health Organisation Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions.

- **Business**
  The main new EU policy requirements will be contained within the specified regulations. As these statutory instruments in effect reinstate the previous enforcement provisions within the new framework, we anticipate the impact to be negligible. Our initial engagement with industry has not raised any concerns.

  The consultation was sent to a wide group of industry bodies, retailers and enforcement officers whose local knowledge would be able to identify manufacturers of foods for specific groups within Scotland. The responses from British Specialist Nutrition Association (BSNA) and Baby Feeding Law Group did not raise any concerns regarding the familiarisation costs and questions in the partial BRIA.

4. Options

Option 1 – Do nothing. This means that the legislation that businesses have been working towards since 2015 could not be enforced in Scotland.

Option 2 – Introduce legislation to implement and provide enforcement provisions in Scotland for the above Delegated Regulations and Regulation.

- **Sectors and groups affected**

While these proposed regulations apply to Scotland only, separate enforcement regulations will be introduced in England, Wales and Northern Ireland; as such the impact on the UK as a whole has been assessed.

Consumers – Non-monetised benefits to consumers from the establishment of clear definitions, composition and labelling of infant formula and follow-on formula, food for special medical purposes and increased safety with the enforcement of substances whose use in foods is prohibited, restricted or under scrutiny.

Enforcement Authorities – enforcement of the rules on foods for specific groups and the addition of vitamins and minerals is the responsibility of Local Authority Environmental Health Services.

Businesses – Manufacturers and retailers will be the main groups affected by these instruments.

- **Benefits**

Option 1

With this option, enforcement authorities would not have to familiarise themselves with these new regulations. As businesses have been working towards the FSG requirements for a number of years, there are no benefits associated with maintaining the current regime.

Option 2

As businesses have been working towards these requirements for a number of years and products meeting the EU requirements are already being placed on the market, they will be able to continue on without having to revert back to previous formulations. This allows for easier trade if businesses wish to trade with the EU at a later date. This option would also result in the domestic market and export market (to the EU) complying with the same safety, composition and labelling standards therefore it would minimise related export enquiries for enforcement authorities. Although these proposals do not affect consumers directly, it is worth nothing that these regulations will maintain the high level of consumer protection.

- **Costs**

Businesses – Option 1

If businesses are required to revert to previous formulations for the UK market, then there are likely to be large costs associated with maintaining two different formulations for the UK and EU markets. No detail was provided in the consultation responses and we are unable to ascertain any businesses in Scotland within these areas.

Businesses - Option 2

There is expected to be a one-off familiarisation cost for businesses. This figure is calculated by firstly taking the 2018 Provisional Office for National Statistics ASHE (Annual Survey of Hours and Earnings)[1] median figure for "production managers and directors" £21.82 – averaging approximately £28.37 per hour once uprated to account for non-wage labour costs and overheads, taken as 30%. It is estimated that the reading and understanding of the EU Regulations and the associated domestic legislation will take two hours, with a further two hours for dissemination to key staff within each firm (a total of 4 hours). This would yield an approximate one-off familiarisation cost of £113.46 per business. However no businesses in Scotland have been identified within these areas.

Consumers – Option 1

If businesses no longer require to comply with the changes, they may revert their recipes back and the cost of reformulating products may be passed onto consumers**.**

Consumers – Option 2

As businesses have been working towards these requirements for a number of years there is not expected to be a significant change to costs that will affect consumers.

Enforcement Authorities – Option 1

No costs associated as the new regulations would not be enforced.

Enforcement Authorities – Option 2

There are 32 local authorities in Scotland. It is estimated that each officer is expected to read and familiarise themselves with the EU Regulations and the associated domestic legislation and that it may take two hours to do so.

There are currently approximately 350 environmental health officers in Scotland, and the median hourly pay rate for an environmental health officer is £18.87[2] - averaging

[1] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

[2] figure taken from the provisional 2018 ONS ASHE (Annual Survey of Hours and Earnings,https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14

approximately £24.53 per hour once uprated to account for non-wage labour costs and overheads, taken as 30%.

The total one-off cost to the 32 local authorities is therefore estimated at approximately £17,172.

5. Scottish Firms Impact Test

The consultation was circulated to Local Authority Environmental Health departments and trade bodies with a specific request to help identify manufacturers of foods for special medical purposes within Scotland. No such manufacturers were identified. They were also requested to consider all questions posed in the partial BRIA and the cost estimates. There were no concerns raised on any aspect of the new regulations.

- **Competition Assessment**

The proposed legislation will apply to all businesses and individuals involved in foods for special medical purposes for infants, infant formula and follow-on formula and those who are involved with vitamin, mineral and certain other substance fortification equally, allowing them to trade across EU Member States, if appropriate. It should not limit the number or range of suppliers in Scotland either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to have a significant impact on competition.

Using the Competition and Markets Authority competition assessment framework developed by the former Office of Fair Trading, it has been established that the preferred policy option (Option 2) is unlikely to have any material negative impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

- **Test run of business forms**

No new or additional forms will be introduced by this proposal therefore no test run need be completed.

6. Legal Aid Impact Test

During the consultation period the Scottish Government Justice Directorate was contacted to ascertain whether the new regulations will have any legal aid implications. The Scottish Legal Aid Board confirmed that these Regulations will have no impact on the legal aid fund.

7. Enforcement, sanctions and monitoring

- **Enforcement**

Enforcement of the Regulations in Scotland will be the responsibility of local authorities. In Scotland, Enforcement Officers from Local Authority Environmental Health Services will need to familiarise themselves with the new requirements and ensure they are adhered to. Enforcement action is only pursued where informal action has been unsuccessful.

- **Sanctions**
  Regulation 4 of the Foods for Specific Groups (Scotland) Regulations 2016 lays down that the penalty on summary of conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale.

  Regulation 4 of the Addition Of Vitamins and Minerals and Other Substances (Scotland) Regulations 2007 lays down that the penalty on summary of conviction for an offence under the regulation is, on conviction on indictment, a term of imprisonment not exceeding two years or to a fine or both. On summary conviction, the relevant penalty is a term of imprisonment not exceeding three months or a fine not exceeding the statutory maximum or both.

  Regulation 4 the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 lays down that the penalty of summary of conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale.

- **Monitoring**
  The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

8. Implementation and delivery plan

The publication of the Scottish Regulations will be communicated to stakeholders by email. This will be issued shortly after the Scottish Statutory Instrument has been published on the legislation.gov.uk website.

9. Post-implementation review

A review to establish the actual costs and benefits and the achievement of the desired effects will take place in 10 years.

10. Summary and recommendation

Option 2 – This is the preferred option

11. Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental social policy and administrative
1	None	If businesses are required to revert to previous formulations for the UK market then there are likely to be large costs associated with maintaining two different formulations for the UK and EU markets. This cost may be passed onto the consumer. However no business have been identified as operating in this area in Scotland.
2	Business across the UK have been working towards these requirements for a number of years and products meeting the Regulations are already being placed on the market, they will be able to continue on without having to revert back to previous formulations. Enforcement Authorities will be working to a consistent legal standard throughout the EU	**Businesses:** an approximate one-off familiarisation cost of £113.46 per business. **Enforcement:** One-off familiarisation cost estimated at approximately £17,172 across Scotland.

Option 2 is considered to be the preferred option.

12. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister's signature Joe FitzPatrick
Minister's title Minister for Public Health, Sport and Wellbeing
Date ……9th January 2020

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