Food Standards Agency in Northern Ireland Consultation

Delegated Regulation (EU) 2016/128 on Foods for Special Medical Purposes to meet the nutritional requirements of infants

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

Consultation summary page

Date consultation launched:	14 November 2019
Closing date for responses:	12 December 2019

Who will this consultation be of most interest to?
Dietitians, district council officers, infant formula manufacturers, paediatricians.

What is the subject of this consultation?
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.

What is the purpose of this consultation?	
The Food Standards Agency (FSA) intends to introduce domestic legislation, in the form of an SR, so that the provisions of both Delegated Regulations and Article 15 of the FSG Regulation shall apply and be enforceable in NI. We are seeking stakeholder views on our intention to extend the existing enforcement regime to these new provisions i.e. the use of Improvement Notices (INs) as the first formal enforcement action in the case of non-compliance with the Regulations.	
Responses to this consultation should be sent to:	
Name: Maria Hilbert **Division/Branch: Executive Support Unit** **Food Standards Agency** **Tel: 02890 417701**	**Postal address:** **10a-10c Clarendon Road, Belfast** **BT1 3BG** **Email:** executive support@food.gov.uk

Is an Impact Assessment included with this consultation?	**Yes** ☒	**No** ☐ **See Annex A for reason**

Summary

1. Foods for Special Medical Purposes (FSMP) are specialist foods intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods. Commission Delegated Regulation 2016/128[1], adopted in September 2015, provides EU rules for the composition and labelling of FSMP. The first part of this regulation started to apply on 22nd February 2019. The second part relating to FSMP for infants is set to apply from 22nd February 2020.

2. Commission Delegated Regulation (EU) 2016/127[2] (as amended by Commission Delegated Regulation (EU) 2019/828[3] of 14 March 2019), which sets new EU rules for the composition, labelling and advertising of infant formula and follow-on formula (IFFOF), was adopted in September 2015. The new rules are set to apply from 22nd February 2020, providing a transition period of 4 years for industry to comply. For IFFOF made from protein hydrolysates, industry has been given an additional period of transition meaning they have until 22nd February 2021 to comply.

3. Both these Delegated Regulations supplement framework Regulation (EU) No 609/2013 on Food for Specific Groups (FSG).

4. Article 15 and the Annex of the FSG Regulation provides the list of substances that can be added to FSMP for infants and to IFFOF. This provision is set to apply from the date of application of the Delegated Regulations i.e. from 22nd February 2020 or 22nd February 2021.

5. The FSA intends to introduce domestic legislation, in the form of an SR, so that the provisions of both Delegated Regulations and Article 15 of the FSG Regulation shall apply and be enforceable in NI. We intend to implement the EU provisions in NI, and we are seeking stakeholder views on our intention to extend the existing enforcement regime to these new provisions i.e. the use of Improvement Notices (IN's) as the first formal enforcement action in the case of non-compliance with the Regulations.

6. The other three UK countries will be making similar Instruments to copy the EU provisions into domestic legislation and include the penalties for non-compliance.

7. The policy is considered low cost and non-controversial as the provisions were agreed by the UK as a Member State of the EU in 2015 and businesses have been working for several years to meet the 22nd February 2020 and 22nd February 2021 deadlines. Many products reformulated to comply with the updated rules are already on the market.

8. This is a limited technical consultation.

Timing

9. The consultation will start 14 November 2019 and end 12 December 2019. Responses should be submitted to executive.support@food.gov.uk by 5pm on 12 December 2019.

[1] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32016R0128
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.025.01.0001.01.ENG
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.137.01.0012.01.ENG&toc=OJ:L:2019:137:TOC

Background to the regulations

Food for Specific Groups (FSG)

10. The Food for Specific Groups Regulation (EU) No. 609/2013 (the FSG Regulation) lays down general compositional and information requirements for four categories of food, including FSMP, IFFOF, baby foods and foods for weight control. It is enforced in NI by the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 ("the 2016 Regulations"). Similar legislation applies in England, Scotland and Wales.

Food for Special Medical Purposes (FSMP)

11. Delegated Regulation (EU) 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).

12. It was adopted on 25 September 2015 and the provisions for FSMP other than FSMP for infants have applied since 22nd February 2019. These are enforced by the 2016 Regulations as amended by the Food for Specific Groups (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019.

13. Therefore, the FSMP Delegated Regulation 2016/128 has applied and been enforced in Northern Ireland since 22nd February 2019, except in respect of FSMP developed to satisfy the nutritional requirements of infants for which it is due to apply from **22nd February 2020**.

14. The proposed SR will implement and enforce the rules on FSMP for infants and revoke the Regulations that implement the earlier Directive i.e. the Medical Food Regulations (Northern Ireland) 2000.

Infant Formula and Follow-on Formula (IFFOF)

15. Delegated Regulation (EU) 2016/127 on Infant Formula and Follow-on Formula (IFFOF) supplements the FSG Regulation. It was adopted on 25th 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.

16. Delegated Regulation (EU) 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 are consulting on enforcement of both the 2020 and 2021 provisions.

17. The SR will implement and enforce the new IFFOF rules and will revoke the Regulations that implement the earlier Directive i.e. The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 from 22nd February 2020 for the majority of IFFOF. However, the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 will continue to apply in respect of IFFOF made from protein hydrolysates until 22nd February 2021.

Union list of substances that can be added to Food for Specific Groups

18. Article 15 and the Annex to the FSG Regulation 609/2013 provide the Union list of substances that can be added to FSMP for infants and to IFFOF. The provision and the Annex are set to come into force from the date of application of the Delegated Regulations. Therefore this SR will also implement and enforce this provision as it applies to these groups.

Implementation

19. The UK agreed the provisions of these 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 proposed SR will implement in Northern Ireland the adopted EU provisions for FSMP for infants and provide the enforcement regime for non-compliance.

Summary

20. The proposed SR will:

- implement and enforce the Delegated Regulation 2016/128 rules on FSMP for infants
- implement and enforce the Delegated Regulation 2016/127 rules on 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.

21. The transitional period for complete compliance with the new compositional and labelling requirements will end on 22nd February 2020 and 22nd February 2021 in respect of IFFOF made from protein hydrolysates. From those dates, all FSMP and IFFOF placed on the market in Northern Ireland must comply with the new rules.

Focus of Consultation: Enforcement

22. We are consulting on a proposal to extend the existing enforcement regime applicable to the FSG legislation (see figure 1) to include provisions for FSMP for infants, IFFOF and for Article 15 and the Annex to the FSG Regulation 609/2013. Previously if a food business operator (FBO) was found guilty of an offence under the Medical Food Regulations (Northern Ireland) 2000 or the Infant and Follow-on Formula Regulations (Northern Ireland) 2007 then the FBO would be liable to a criminal sanction. These Regulations were amended by the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 ("the 2016 Regulations") to allow the option to use INs as an alternative first step. We propose that the first formal action for enforcing the new provisions would be to issue an IN rather than taking formal criminal action. This is consistent with the enforcement of the FSMP provisions which have applied since 22 February 2019. The proposed extension to the use of INs backed up with a criminal offence for failure to comply with an IN effectively decriminalises regulatory offences in appropriate cases. However, criminal sanctions can still be used for serious offences breaching other relevant legislation (e.g. if the food was rendered injurious to health, contrary to Article 6 of the Food Safety (Northern Ireland) Order 1991).

23. INs are already in use for the 2016 Regulations and other areas of food labelling (e.g. the Food Information Regulations (Northern Ireland) 2014), so they are already understood by industry and by enforcement. It is a more flexible approach giving industry additional time and support to resolve the problem identified in the IN, enabling them to comply before it is escalated to a criminal offence.

24. A breach in the FSMP or IFFOF Regulations may relate to an offence in either (i) the compositional requirements or (ii) the information requirements. The approach to enforcement is risk based and for the most part it is envisaged that informal enforcement provisions will be used in the first instance to ensure that products are compliant. If the authorised officer has reason to believe that an informal approach will not result in a successful outcome, then a more formal approach should be considered, and an IN may be issued. However, where there is an immediate risk to public health (e.g. compositional requirements) the authorised officer should work with the business to ensure the food is promptly removed from the market under the powers of the Food Safety (Northern Ireland) Order 1991. Once the risk to vulnerable consumers is minimised, then informal enforcement provisions may be used to ensure the food is compliant.

25. Following the risk-based principles means that most breaches will result in informal enforcement action which may escalate to issuing an IN. Failure to comply with an IN can result in criminal sanctions.

Appeals

26. An IN, once served, may be appealed to a Magistrates Court, if the business does not agree with the conditions of the Notice. The appeals process will be in line with INs used for the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016.

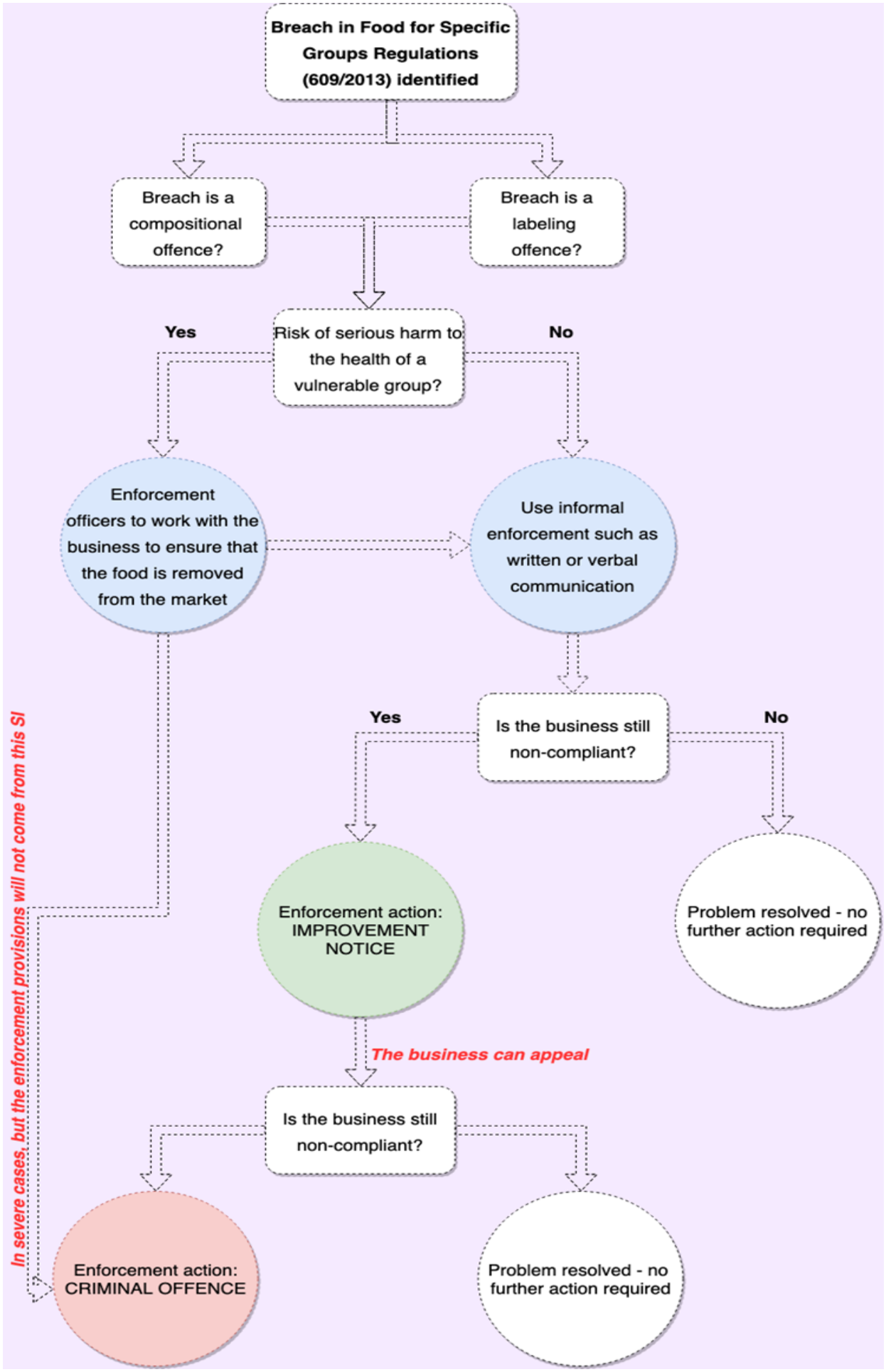
27. The primary objective of any enforcement action must be to achieve compliance in the most effective way and the approach should be in line with the "hierarchy of enforcement" as set out in the Enforcement chapters of the Food Law Practice Guidance[4]. FSMP INs should be used in line with the district council's enforcement policy and must be considered as part of enforcement action in line with the hierarchy of enforcement.

Costs

28. Introduction of the new amended SR would result in familiarisation costs of approximately £107 for industry (per manufacturer) and £54 for each enforcement officer (see Impact Assessment enclosed in the consultation package for information). Familiarisation costs are limited as businesses have had a long transition period to comply since the rules were adopted in 2015 and are therefore already familiar with the Regulations. We are currently not aware of any manufacturers in Northern Ireland. Please do provide us with any relevant information if this is not the case.

[4] https://www.food.gov.uk/about-us/food-and-feed-codes-of-practice

Figure 1. Foods for specific groups (FSG) Regulations enforcement flow chart, which we propose to extend to include the FSMP for infants and IFFOF Regulations.



Engagement and Consultation Process

Stakeholders have been kept informed during the various stages of the process with regards to this legislation and industry has been working towards implementation now for several years, therefore this consultation is a shortened one as it is not expected to raise any issues.

Questions asked in this consultation:

Question 1

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)?

Question 2

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?

Note that the proposed enforcement regime would not prevent criminal prosecution as a first step if the breach amounted to an offence under the Food Safety (Northern Ireland) Order 1991 (e.g. if the food was considered injurious to health contrary to Article 6). In those circumstances, the authorised officer would not be prosecuting for a breach of the FSMP or IFFOF regulations but for a breach of the Food Safety (Northern Ireland) Order 1991. In addition, failure to comply with an Improvement Notice served under the Regulations would attract criminal sanctions.

Please provide reasons for your response and suggest any alternative proposals.

Other relevant documents

Delegated Regulation (EU) 2016/127 on Infant Formula and Follow-on Formula[5]

Delegated Regulation (EU) 2016/128 on Food for Special Medical Purposes[6]

The Food for Specific Groups Regulation (EU) No. 609/2013[7]

[5] https://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=CELEX:02016R0127-20190612&qid=1572382390954

[6] https://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32016R0128&qid=1572382460442&rid=1

[7] https://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=CELEX:02013R0609-20170711&qid=1572381829522

Responses

Responses are required by close 12 December 2019. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the FSA for participating in this public consultation.

Yours

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Food Standards Lead

Food Standards Agency in Northern Ireland

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Enclosed

Annex A: Standard Consultation Information

Annex B: Partial Impact Assessment

Annex C: Interested Parties List

Annex A

Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8308). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form[8] Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us if you require this consultation in an alternative format such as Braille or large print.

7. This consultation has been prepared in accordance with HM Government consultation principles[9] .

[8] http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc
[9] http://www.bis.gov.uk/policies/bre/consultation-guidance

Annex B

Title: Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019 **Lead department or agency:** Food Standards Agency in Northern Ireland **Other departments or agencies:** DHSC, Food Standards Agency in Wales, Food Standards Scotland	**Impact Assessment (IA)** **Date: 1 November 2019** **Stage: Consultation** **Source of intervention: EU** **Type of measure: Secondary Legislation** **Contact for enquiries**: **Annie Chambers 02890417708**
Summary: Intervention and Options	

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
		0	NO	OUT

What is the problem under consideration? Why is government intervention necessary?

Delegated Regulation (EU) 2016/128 on food for special medical purposes and Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula were consulted on and adopted in 2015. We now need to make a Statutory Rule (SR) that will establish the enforcement regime for non-compliance.

What are the policy objectives and the intended effects?

The Delegated Regulations supplement earlier 'parent' legislation on food for specific groups (FSG), therefore, we propose extending the enforcement regime established in the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (the 2016 Regulations) to these new provisions. This means an Improvement Notice (IN)will be the first formal action in the case of non-compliance rather than a criminal prosecution. INs are already in use for the FSG 2016 Regulations 2016 and other areas of food labelling (e.g. the Food Information Regulations (Northern Ireland) 2014) so they are already understood by industry and by enforcement officers and appear to be working. It is a more flexible approach giving industry additional time and support to resolve the problem identified in the IN, enabling them to comply before it is escalated to a criminal offence.

Industry has been given a four-year transition period to comply with the Delegated Regulations, which are set to apply from 22 February 2020 or from 22 February 2021 in the case of formula made from protein hydrolysates.

We are not aware of any manufacturers currently in Northern Ireland who will be affected by this. Retailers will also need to comply with a provision in the Regulations that restricts the promotion of the relevant products, in relation to food for special medical purposes. Businesses are already aware of the EU provisions since the legislation was consulted on and adopted in 2015. Businesses that do not currently comply with the legislation may wish to familiarise themselves with the enforcement provisions. Otherwise we do not expect this SR to have any significant impact on business.

What policy Options have been considered, including any alternatives to regulation? Please justify preferred Option (further details in Evidence Base)

The Delegated Regulations are directly applicable across the EU, however we need to introduce national legislation to allow for their enforcement. This SR to implement and enforce the provisions will ensure there are no gaps in the legislation and that the rules are workable and enforceable in Northern Ireland. It will have minimal impact on business.

Will the policy be reviewed? N/A If applicable, set review date:					
Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro**	**< 20**	**Small**	**Medium**	**Large**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading Options.

Signed by the responsible SELECT SIGNATORY: Annie Crawford. Date: 01/11/19

Summary: Analysis & EvidencePolicy Option 2

Description: Implement the new requirements under one statutory rule.

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

Industry
One off costs: familiarisation £107.17 (PV)

Government
One off costs: familiarisation £54 per DC (one EHO training – 2 hours) (PV)

Other key non-monetised costs by 'main affected groups'

Industry: A more proportionate enforcement procedure for businesses

Government: Simpler enforcement procedures for enforcement officers

This legislation will benefit those requiring food for special medical purposes for infants and infant and follow-on formula as there will be better protection by way of compositional standards and labelling rules.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	n/a	Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

Key assumptions/sensitivities/risks	**Discount rate (%)**	3.5

Familiarisation costs

Industry -. To estimate this cost, we have assumed that it will take 4 hours per affected business to familiarise itself with the new SR. This may be an overestimate as much of the familiarisation required is expected to be subsumed under familiarisation with the EU legislation itself which will have taken place in 2015. Salary has been estimated using ASHE provisional 2018 median wage data for managers and directors, uplifted for 30% on-costs[1]. This results in a one-off cost of £107.17 per firm affected. There are no recurring costs for compliant businesses.
Government - It is estimated that it would take one Environmental Health Officer 2 hours to read and become familiar with the SR and the enforcement regime. The hourly pay rate for Qualified Environmental Health Officers is between £16 and £25 – averaging approximately £27 per hour once uprated to account for non-wage labour costs and overheads, taken as 30%. This equates to £54 for 2 hours. The total one-off cost to the 11 district councils is therefore estimated at approximately £600. This figure would increase if more than one enforcement officer in each district council needs to become familiar with the SR but would remain substantially less than £1m.
Ongoing workloads for local authorities are not expected to increase as a result of this SR, as enforcement work for the products affected is already required.
This Impact Assessment uses figures from a parallel consultation and Impact assessment by DHSC.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: 0	**Benefits: 0**	**Net: 0**	NO	OUT

[1] Annual Survey of Hours and Earnings, 2018: https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation2digitsocashetable3

Evidence Base (for summary sheets)

References

The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016

Problem under consideration

1. Delegated Regulation (EU) 2016/128 on food for special medical purposes and Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula were consulted on and adopted in 2015. Industry was given a long transition period to comply with the Regulations, which are set to apply from 22nd February 2020 or from 22nd February 2021 in the case of formula made from protein hydrolysates.
2. This impact assessment analyses the options on a Northern Ireland only basis.

Rationale for intervention

3. We intend to make a statutory rule (SR) that will copy the provisions of the Regulations into NI law and establish the enforcement regime for non-compliance. The Delegated Regulations supplement earlier 'parent' legislation on food for specific groups, therefore, we propose extending the enforcement regime established in the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (the 2016 Regulations) to these new provisions. This means an Improvement Notice (IN) will be the first formal action in the case of non-compliance rather than a criminal prosecution.

INs are already in use for the 2016 Regulations and other areas of food labelling (e.g. the Food Information Regulations (Northern Ireland) 2014) so they are already understood by industry and enforcement officers. It is a more flexible approach giving industry additional time and support to resolve the problem identified in the IN, enabling them to comply before it is escalated to a criminal offence.

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject, please notify the named person in this consultation.

Annex C

Interested Parties List

District Councils
Health & Social Care Trusts (Dietetics)
Department of Health
NI Food Advisory Committee (NIFAC)
NI Food & Drink Association (NIFDA)
Chartered Institute of Environmental Health (CIEH) NI
College of Agriculture, Food & Rural Enterprise (CAFRE)
Invest NI
University of Ulster
Queens University
Institute of Food Science Technology (IFST)
Public Health Agency (PHA)
Galen Ltd
Nualtra
The New You Plan
Tesco
Sainsburys
Asda
Lidl