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FOOD STANDARDS AGENCY NORTHERN IRELAND CONSULTATION

Title: The Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
2nd October 2018	30th October 2018

Who will this consultation be of most interest to?

District councils, manufacturers, wholesalers and retailers of food for specific medical purposes. The consultation may also be of interest to health professionals, consumer groups and others with an interest in food labelling legislation.

What is the subject of this consultation?

The draft Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019 which will introduce provisions for the enforcement of the requirements of Delegated Regulation (EU) 2016/128, which supplements Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes, both of which are directly applicable across the EU. The Northern Ireland Regulations need to come into operation by 22 February 2019 in line with the provisions of the EU Regulations.

What is the purpose of this consultation?

To seek stakeholders views on plans to introduce domestic legislation, in the form of an amending Statutory Rule (SR), so that Delegated Regulation (EU) 2016/128 which supplements Regulation (EU) No 609/2013 on food for special medical purposes can be enforced in Northern Ireland. We are asking for stakeholders' views on the appropriateness of the proposed approach to enforcement, which is based on Improvement Notices.

Is an Impact Assessment included with this consultation?	Yes X	No

Responses to this consultation should be sent to:

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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.

POSITIVE ABOUT DISABLED PEOPLE

The Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019

DETAIL OF CONSULTATION

Summary

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.

The Food Standards Agency in Northern Ireland is seeking views on plans to introduce domestic legislation, in the form of an amending Statutory Rule (SR), so that Delegated Regulation (EU) 2016/128 which supplements Regulation (EU) No 609/2013 on food for special medical purposes, can be enforced in Northern Ireland. We are asking for stakeholders' views on the appropriateness of the proposed approach to enforcement, which is based on Improvement Notices.

The SR to be amended is the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016, SR 2016 No. 251.

This is a limited technical consultation; a list of interested parties is at Annex C.

Timing

The informal consultation will start on 2nd October 2018 and end on 30th October 2018. Responses should be submitted to executive.support@food.gov.uk by **5pm on 30th October 2018.**

Background to the Regulation

Regulation (EU) 2016/128 on Food for Special Medical Purposes (hereafter referred to as FSMP) is a Commission Delegated Regulation under the Framework Regulation (EU) No 609/2013 on food for specific groups (FSG). It was approved on 25 September 2015 to adopt specific compositional and information requirements for food for special medical purposes, taking into account the provisions of Directive 1999/21/EC, the existing harmonised legislation on dietary foods for special medical purposes, which is implemented in Northern Ireland by the Medical Food Regulations (Northern Ireland) 2000.

The FSG Regulation 609/2013 lays down general compositional and information requirements for different categories of food, including FSMP. This is enforced in Northern Ireland by the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016.

The FSMP Delegated Regulation 2016/128 applies to all member states from **22 February 2019**, except in respect of FSMP developed to satisfy the nutritional requirements of infants, which shall apply from **22 February 2020**. As the United Kingdom will leave the European Union on 29 March 2019, we cannot yet confirm the status of the changes due to apply from 22 February 2020. As such, this draft SR will not cover the provisions for FSMP for infants. More information on that will be made available once the UK's position post EU Exit is finalised.

This proposed SR will amend the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 to enforce the FSMP Delegated Regulation and will revoke the Medical Food Regulations (Northern Ireland) 2000 for FSMP other than those designed to satisfy the nutritional needs of infants, to which the Medical Food Regulations (Northern Ireland) 2000 will continue to apply.
This SR will also 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, which come into force from the date of application of Delegated Regulation.

The transitional period for complete compliance with the new information and compositional requirements will end on 22 February 2019. From that date, all FSMP (excluding those for infants) placed on the market must comply with Delegated Regulation 2016/128.

Focus of Consultation: Enforcement

We are consulting on a proposal to extend the existing enforcement regime applicable to the FSG legislation (609/2013 – see Figure 1) to include provisions for the new FSMP Delegated Regulation (2016/128) and for Article 15 and the Annex to the FSG Regulation 609/2013. Currently if a food business operator (FBO) is found guilty of an offence under the Medical Food Regulations (Northern Ireland) 2000 then the FBO may be liable to a criminal sanction. Those Regulations were amended by the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 to allow the option to use Improvement Notices (IN) as an alternative first step. We propose that the first formal action for enforcing the new Delegated Regulation and Article 15 and the Annex of the

FSG Regulation would be to issue an IN rather than a criminal sanction. The proposed extension to the use of INs backed up with a criminal offence for a 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).

INs are already in use for the FSG Regulation by way of the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 and for other areas of food labelling (e.g. the Food Information Regulations (Northern Ireland) 2014), so they are already understood by the industry and appear to be working well. 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.

A breach in the FSMP Regulation may relate to an offence in either (i) the compositional requirements or (ii) the labelling requirements for FSMP. The approach to enforcement is risk based and would therefore look the same as for FSG outlined in Figure 1. For the most part it is envisaged that informal enforcement provisions will be used in the first instance (e.g. verbal and written warnings) to ensure that labelling is 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.
Following the risk-based principles means that the majority of 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

An IN, once served, may be appealed to a court of summary jurisdiction, 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.

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 district council's enforcement policy and the "hierarchy of enforcement" as set out in the Enforcement chapters of the Food Law Practice Guidance https://www.food.gov.uk/about-us/food-and-feed-codes-of-practice.

Costs

Introduction of the new amended SR would result in familiarisation costs of approximately £106 for industry and £300 for enforcement (see draft Impact Assessment enclosed in the consultation package for information). Familiarisation costs are limited as these are more concerned with the EU FSMP Regulation and much less so with the SR.

Figure 1. Foods for specific groups (FSG) Regulation (609/2013) enforcement flow chart, which we propose to extend to the FSMP Regulation (2016/128)

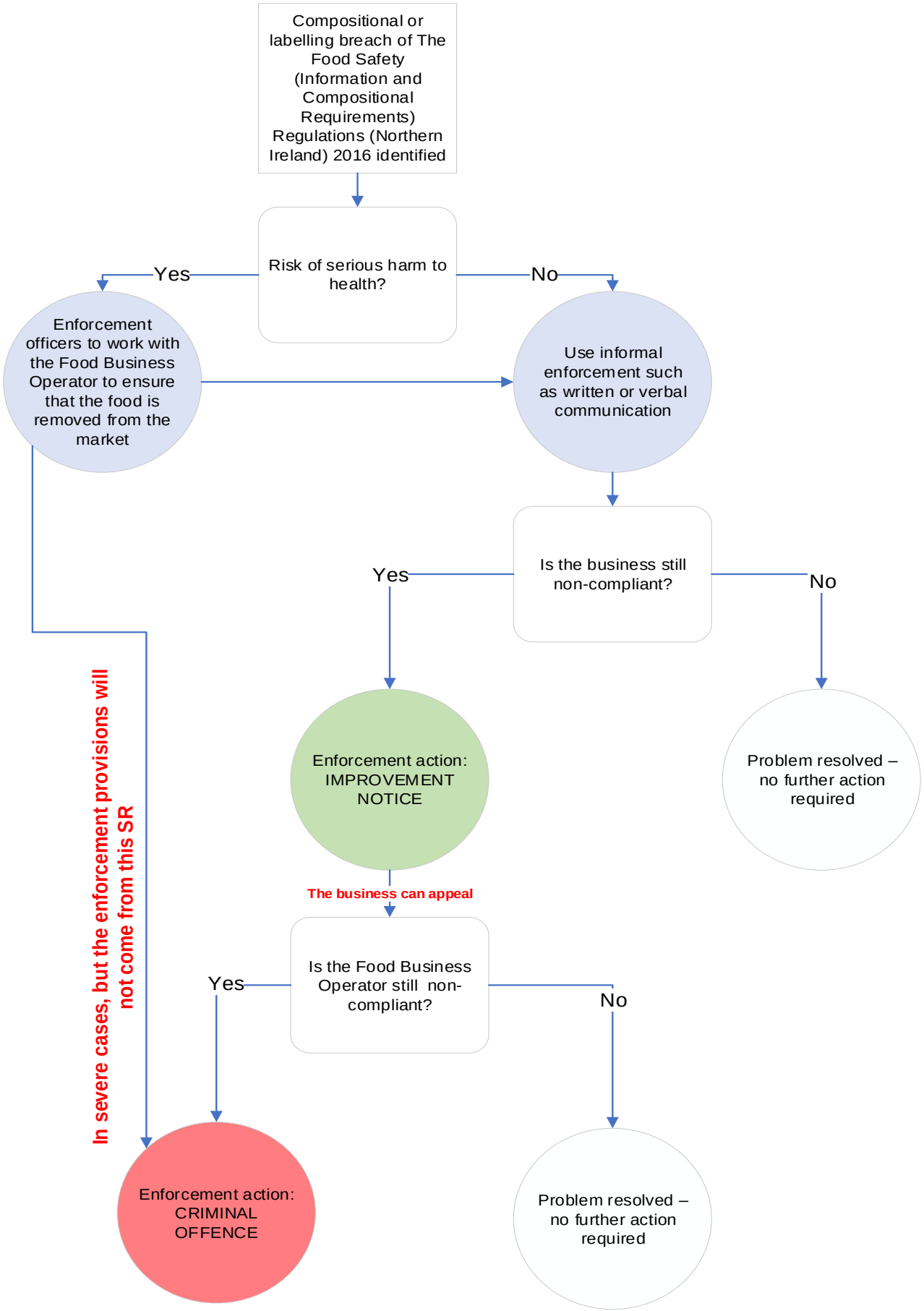


Figure 2. Offences relating to the Food for Special Medical Purposes Delegated Regulation 2016/128

Provision of the Food for Special Medical Purposes Delegated Regulation – (EU) 2016/128 which supplements Commission Regulation (EU) No. 609/2013	**Provisions to be read with the provision of the Food for Special Medical Purposes Delegated Regulation**	**Was this enforced under current Medical Food Regulations? Yes/New**
Article 2(2) (requirement for the formulation to be safe, beneficial and effective)	Article 1	Yes
Article 2(3), second paragraph (compositional requirements for food to comply with Part B of Annex I)	Articles 1 and 2(4) and Part B of Annex I	Yes
Article 3(2) (requirement relating to residue levels) insofar as it applies to young children rather than infants.	Articles 1 and 3(1), (3) and (5) and Annex II	New requirement
Article 3(4) (prohibition on the use of plant protection products) insofar as it applies to young children rather than infants.	Articles 1 and 3(1) and (5) and Annex III	New requirement
Article 4 (requirements as to naming food)	Article 1 and Annex IV	Yes
Article 5(2) (a)-(i) (specific requirements on food information)	Article 1 and 5(1) and 5(3)	Yes
Article 6 (specific requirements on the nutrition declaration)	Article 1 and Annex I	New requirement
Article 7 (prohibition on nutrition and health claims)	Article 1	New requirement
Article 9 (notifying the competent authority about placing food for special medical purposes on the market)	Article 1	Yes

Provision of the Food for Specific Groups Regulation (EU) No 609.2013	**Provisions to be read with the provision of the Food for Specific Groups Regulation**	
Article 15(1) (Union list)	Article 1(1)(c) and 4(1) and the Annex insofar as it applies to food for special medical purposes	

Consultation Questions

Q1: Are you content that the first formal action for breaches of the provisions for FSMP (shown in figure 1), 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)?

Note that this 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 rendered injurious to health contrary to Article 6). In those circumstances, the authorised officer would not be prosecuting for a breach of the FSMP 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 FSMP Regulations could attract criminal sanctions. In providing your response, you may wish to consider:

- The relative costs of issuing/responding to an Improvement Notice, as compared to immediate court action;
- The relative speed with which issues can be resolved; and
- The relative effectiveness and deterrent effect of different enforcement approaches.

Any thoughts on these three factors will be appreciated.

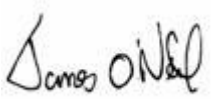
Q2: Are you content that the correct provisions of Delegated Regulation 2016/128 have been identified for enforcement purposes in figure 2?

Responses

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). We will summarise all comments received and the official response to each will be published on the FSA website within three months following the end of the consultation period.

Thank you on behalf of Food Standards Agency in Northern Ireland for participating in this public consultation.

Yours faithfully



James O'Neill
Executive Support Unit
FSA in Northern Ireland

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Northern Ireland Statutory Rule – The Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019– attached separately

Annex C: List of interested parties – attached separately

Annex D: Impact Assessment

Annex A: Standard Consultation Information

Disclosure of the information you provide

Information provided in response to this consultation may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Any automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

The Food Standards Agency will be what is known as the 'Controller' of the personal data provided to us.

Why we are collecting your personal data and what we do with it

Your personal data is being collected as an essential part of the consultation process, so that we can contact you regarding your response and for statistical purposes. We may also use it to contact you about related matters.

The Data Protection Act 2018 states that, as a government department, the Food Standards Agency may process personal data as necessary for the effective performance of a task carried out in the public interest. i.e. a consultation.

We retain personal information only for as long as necessary to carry out these functions, and in line with our retention policy. This means that this information will be retained for a minimum of 7 years from receipt.

All the personal data we process is located on servers within the European Union. Our cloud based services have been procured through the government framework agreements and these services have been assessed against the national cyber security centre cloud security principles.

No third parties have access to your personal data unless the law allows them to do so. The Food Standards Agency will sometimes share data with other government departments, public bodies, and organisations which perform public functions to assist them in the performance of their statutory duties or when it is in the public interest.

What are your rights?

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter.

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/, or telephone 0303 123 1113.

Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address: informationmanagement@food.gov.uk

Further information

If you require a more accessible format of this document please send details to the named contact for responses to this consultation and your request will be considered.