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Llywodraeth Cymru
Welsh Government

Welsh Government
Consultation Document

Enforcement provision for foods for special medical purposes

Consultation on a draft statutory instrument to provide enforce for EU delegated regulation on foods for special medical purposes in Wales.

Date of issue: 3 October 2018
Action required: Responses by 31 October 2018

Mae'r ddogfen yma hefyd ar gael yn Gymraeg.
This document is also available in Welsh.

Overview

The Welsh Government is seeking views on plans to introduce domestic legislation, in the form of an amending Statutory Instrument (SI), so that EU Regulation [2016/128](#) on food for special medical purposes can be enforced in Wales. We are asking for stakeholders' views on the appropriateness of the proposed approach to enforcement, which is based on Improvement Notices.

How to respond

Submit your comments by 31 October 2018 in any of the following ways:

- **Via the online form**
- **Via email or post using the contact details below.**

Further information and related documents

Large print, Braille and alternative language versions of this document are available on request.

Contact details

For further information:

Healthy and Active Branch
Public Health Division
Welsh Government
Cathays Park
Cardiff
CF10 3NQ

email: **Lifestyles@gov.wales**

General Data Protection Regulation (GDPR)

The Welsh Government will be data controller for any personal data you provide as part of your response to the consultation. Welsh Ministers have statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions. Any response you send us will be seen in full by Welsh Government staff dealing with the issues which this consultation is about or planning future consultations. Where the Welsh Government undertakes further analysis of consultation responses then this work may be commissioned to be carried out by an accredited third party (e.g. a research organisation or a consultancy company). Any such work will only be undertaken under contract. Welsh Government's standard terms and conditions for such contracts set out strict requirements for the processing and safekeeping of personal data.

In order to show that the consultation was carried out properly, the Welsh Government intends to publish a summary of the responses to this document. We may also publish responses in full. Normally, the name and address (or part of the address) of the person or organisation who sent the response are published with the response. If you do not want your name or address published, please tell us this in writing when you send your response. We will then redact them before publishing.

You should also be aware of our responsibilities under Freedom of Information legislation. If your details are published as part of the consultation response then these published reports will be retained indefinitely. Any of your data held otherwise by Welsh Government will be kept for no more than three years.

Your rights

Under the data protection legislation, you have the right:

- to be informed of the personal data holds about you and to access it
- to require us to rectify inaccuracies in that data
- to (in certain circumstances) object to or restrict processing
- for (in certain circumstances) your data to be 'erased'
- to (in certain circumstances) data portability
- to lodge a complaint with the Information Commissioner's Office (ICO) who is our independent regulator for data protection.

For further details about the information the Welsh Government holds and its use, or if you want to exercise your rights under the GDPR, please see contact details below:

Data Protection Officer:
Welsh Government
Cathays Park
CARDIFF
CF10 3NQ

e-mail:

Data.ProtectionOfficer@gov.wales

The contact details for the Information Commissioner's Office are:

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Tel: 01625 545 745 or
0303 123 1113

Website: <https://ico.org.uk/>

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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 Welsh Government is seeking views on plans to introduce domestic legislation, in the form of an amending Statutory Instrument (SI), so that EU Regulation [2016/128](#) on food for special medical purposes can be enforced in Wales. We are asking for stakeholders' views on the appropriateness of the proposed approach to enforcement, which is based on Improvement Notices.

The SI to be amended for Wales is the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016, SI 2016 No. 639 (W. 175).

Background

Regulation (EU) no. 2016/128 on Food for Special Medical Purposes (hereafter referred to as FSMP) is a Delegated Regulation under the Framework Regulation 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 Wales by the Medical Food (Wales) Regulations 2000).

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

The FSMP Delegated Regulation 2016/128 applies to all Member States from **22 February 2019**, except in respect of FSMPs developed to satisfy the nutritional requirements of infants, to which it 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 come into force on 22 February 2020. As such, this draft SI will not cover the provisions for FSMP for infants. More information on that will be made available once the UK's position post exit is finalised.

This SI will amend the Food for Specific Groups (Wales) Regulations 2016 to enforce the FSMP Delegated Regulation in Wales and repeal the Medical Food Regulations 2000 for FSMP other than those designed to satisfy the nutritional needs of infants, to which the Medical Food (Wales) Regulations 2000 will continue to apply.

This SI 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 FSMPs, which come into force from the date of application of the Delegated Regulation.

The transitional period for complete compliance with the new compositional and labelling requirements will end on 22 February 2019. From that date, all FSMPs

(excluding those for infants) placed on the market must comply with Delegated Regulation 2016/128.

Enforcement regime proposed

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 (Wales) Regulations 2000 then the FBO may be liable to a criminal sanction. These Regulations were amended by the FSG Regulations in 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 section 7 of the Food Safety Act 1990).

INs are already in use for the FSG Regulation and other areas of food labelling (e.g. the Food Information Regulations 2014), so they are already understood by the industry and by Trading Standards Officers 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 FSMPs. The approach to enforcement is risk based and would therefore look the same as for FSGs 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 Act 1990. 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 mean 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 process

An IN, once served, may be appealed to the 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 for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 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 “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>. FSMP INs should be used in line with the Local Authority’s enforcement policy and must be considered as part of the escalation of enforcement action in line with the hierarchy of enforcement.

Potential costs

The cost associated with the proposed SI is negligible for Wales. It is estimated that it will take local authorities in Wales approximately one hour to read and understand the new SI at a cost of £27 per hour. This equates to £594 for the whole of Wales.

It is estimated it will take businesses in two hours at a cost of £53.40 to familiarise themselves with the new requirements. However there are no known FSMP businesses that operate in Wales. The cost to industry in Wales is therefore estimated at zero.

Further information on the potential cost to enforcement authorities and industry is set out in the impact assessment.

Flow chart showing proposed enforcement procedure

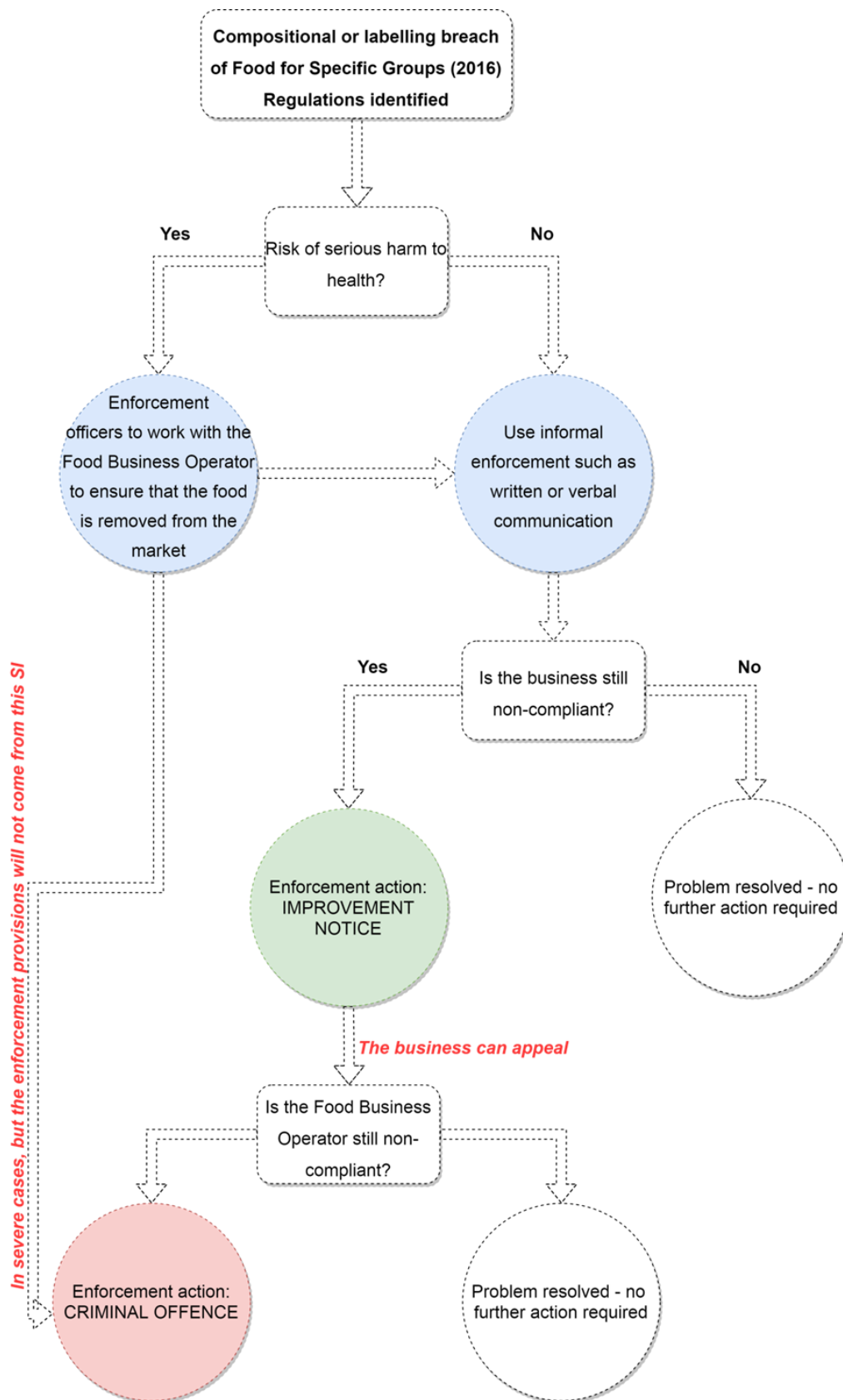


Table showing offences relating to FSMP Delegated Regulation 2016/128

Provision of the Food for Special Medical Purposes Delegated Regulation	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	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	

Questions

- 1. Are you content that the first formal action for breaches of the provisions for FSMPs (as shown in the table within the consultation document) be an Improvement Notice consistent with the enforcement provisions for the Food for Specific Groups (Information and Compositional Requirements) (Wales Regulations 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 Act 1990 (e.g. if the food was rendered injurious to health contrary to section 7). 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 Act 1990. 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.

- 2. Are you content that the correct provisions of Delegated Regulation 2016/128 have been identified for enforcement purposes in the table within the consultation document?**

- 3. Do you have any further comments to add?**

Enforcement provision for foods for special medical purposes consultation

Response Form

Your name:

Organisation (if applicable):

email / telephone number:

Your address:

Responses should be returned by 31 October 2018 to;

Healthy and Active Branch

Public Health Division
Welsh Government
Cathays Park
Cardiff
CF10 3NQ

Or complete electronically and sent to: **Lifestyles@gov.wales**

- 1. Are you content that the first formal action for breaches of the provisions for FSMPs (as shown in the table within the consultation document) be an Improvement Notice consistent with the enforcement provisions for the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (enforcing EU Regulation 609/2013)?**

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2. Are you content that the correct provisions of Delegated Regulation 2016/128 have been identified for enforcement purposes in the table within the consultation document?

3. Do you have any further comments to add?

Responses to consultations are likely to be made public, on the internet or in a report. If you would prefer your response to remain anonymous, please tick here: