



Welsh Government
Consultation Document

Implementation of EU delegated regulations on food for specific groups

**Consultation on a draft statutory instrument to implement two EU
delegated regulations on foods for special medical purposes and infant
formula and follow-on formula in Wales.**

Date of issue: 8 November 2019
Action required: Responses by 6 December 2019

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 elements of EU Delegated Regulation 2016/128 on food for special medical purposes and EU Delegated Regulation 2016/127 on infant formula and follow on formula, 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 6 December 2019 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

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.
2. Commission Delegated Regulation [2016/128](#), adopted in September 2015, provides the new EU rules for the composition and labelling of FSMP. The first part of this Regulation, regarding specific compositional and information requirements for food for special medical purposes for adults only (i.e. non-infants), started to apply on 22 February 2019, and therefore already applies in Wales. The second part relating to FSMP for infants is set to apply from 22 February 2020.
3. Commission Delegated Regulation (EU) [2016/127](#) (as amended by Commission Delegated Regulation (EU) [2019/828](#) 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 22 February 2020, which will have given industry a transition period of 4 years to comply. For IFFOF made from protein hydrolysates, industry has been given an additional period of transition meaning they have until 22 February 2021 to comply.
4. Both these Delegated Regulations supplement framework Regulation (EU) No 609/2013 on Food for Specific Groups (the FSG Regulation).
5. 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 22 February 2020 or 22 February 2021.
6. The Welsh Government intends to introduce domestic legislation, in the form of a statutory instrument, so that the provisions of both Delegated Regulations and Article 15 of the FSG Regulation shall apply and be enforceable in Wales.
7. We are seeking stakeholder views on our intention to extend the existing enforcement regime to these new provisions i.e. continuing to use Improvement Notices as the first formal enforcement action in the case of non-compliance with the Regulations.
8. England, Scotland and Northern Ireland will be making similar Regulations to copy the EU provisions into domestic legislation and include the penalties for non-compliance. Parallel consultations will be conducted across the UK on the proposals.
9. 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 towards meeting these for several years to meet the 22 February

2020 and 22 February 2021 deadlines. Many products reformulated to comply with the updated rules are already available on the market.

BACKGROUND

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 Wales by the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (“the 2016 Regulations”). Similar legislation applies in Scotland, England and Northern Ireland.

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 22 February 2019. These are enforced by the 2016 Regulations as amended by the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019.
13. Therefore, the FSMP Delegated Regulation 2016/128 has applied and been enforced in Wales since 22 February 2019, except in respect of FSMP developed to satisfy the nutritional requirements of infants for which it is due to apply from **22 February 2020**.
14. The SI will implement and provide for the enforcement of the rules on FSMP for infants and revoke the Regulations that implement the earlier Directive i.e. the Medical Food (Wales) Regulations 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 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.
16. Delegated Regulation (EU) 2016/127 on IFFOF is due to apply from **22 February 2020**, except in respect of IFFOF made from protein hydrolysates for which the provisions are due to apply from **22 February 2021**. We are consulting on enforcement of both the 2020 and 2021 provisions.

17. The SI will implement and provide for the enforcement of the new IFFOF rules and will revoke the Regulations that implement the earlier Directive i.e. The Infant Formula and Follow-on Formula (Wales) Regulations 2007 from 22nd February 2020 for the majority of IFFOF. However, The Infant Formula and Follow-on Formula (Wales) Regulations 2007 will continue to apply in respect of IFFOF made from protein hydrolysates until 22 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. This provision and the Annex are set to come into force from the date of application of the Delegated Regulations. Therefore, this SI will also implement and provide for the enforcement of this provision as it applies to these groups.

EU Exit

19. If the UK remains bound by EU rules as at 22 February 2020 (following an extension of Article 50 or during a transitional period having ratified a Withdrawal Agreement), the Welsh Ministers will be legally required to provide enforcement provisions for FSMP for infants and IFFOF, save in respect of IFFOF made from protein hydrolysates.

20. If the UK has left the EU by 22 February 2020, whilst there would be no legal obligation to implement the provisions of the Delegated Regulations we will copy across the provisions into domestic legislation in line with the rest of the UK and in accordance with Welsh Government policy. Not doing so would mean the FSG EU Regulations are only partially implemented in Wales and legislation will become out of date and not reflective of current evidence. Furthermore the provisions were agreed by the UK (as a Member State) in 2015 and many businesses are already working to or towards these requirements.

21. The Regulations proposed will ensure there is minimal disruption to nutrition regulation as a result of the UK's withdrawal from the EU and ensure Welsh legislation in this area reflects current evidence.

22. This SI will:

- implement and provide for the enforcement of Delegated Regulation 2016/128 rules on FSMP for infants (or in the event the UK has left the EU by 22 February 2020, copy out and provide for the enforcement of those rules)
- implement and provide for the enforcement of Delegated Regulation 2016/127 rules on IFFOF (or in the event the UK has left the EU by 22 February 2020, copy out and provide for the enforcement of those rules)
- implement and 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 (or in the event the UK has left the

EU by 22 February 2020, copy out and provide for the enforcement of those provisions)

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

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

Enforcement

24. 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 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 (Wales) Regulations 2000 or the Infant Formula and Follow-on Formula (Wales) Regulations 2007 then the FBO would be liable to a criminal sanction. These Regulations were amended by The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (“the 2016 Regulations”) 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 provisions would be to issue an IN rather than a criminal sanction. 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 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).

25. INs are already in use for the 2016 Regulations and other areas of food labelling (e.g. the Food Information Regulations 2014), so they are already understood by the industry and by Enforcement 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.

26. 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 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 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 Act 1990. Once the risk to vulnerable consumers is minimised, then informal enforcement provisions may be used to ensure the food is compliant.

27. 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

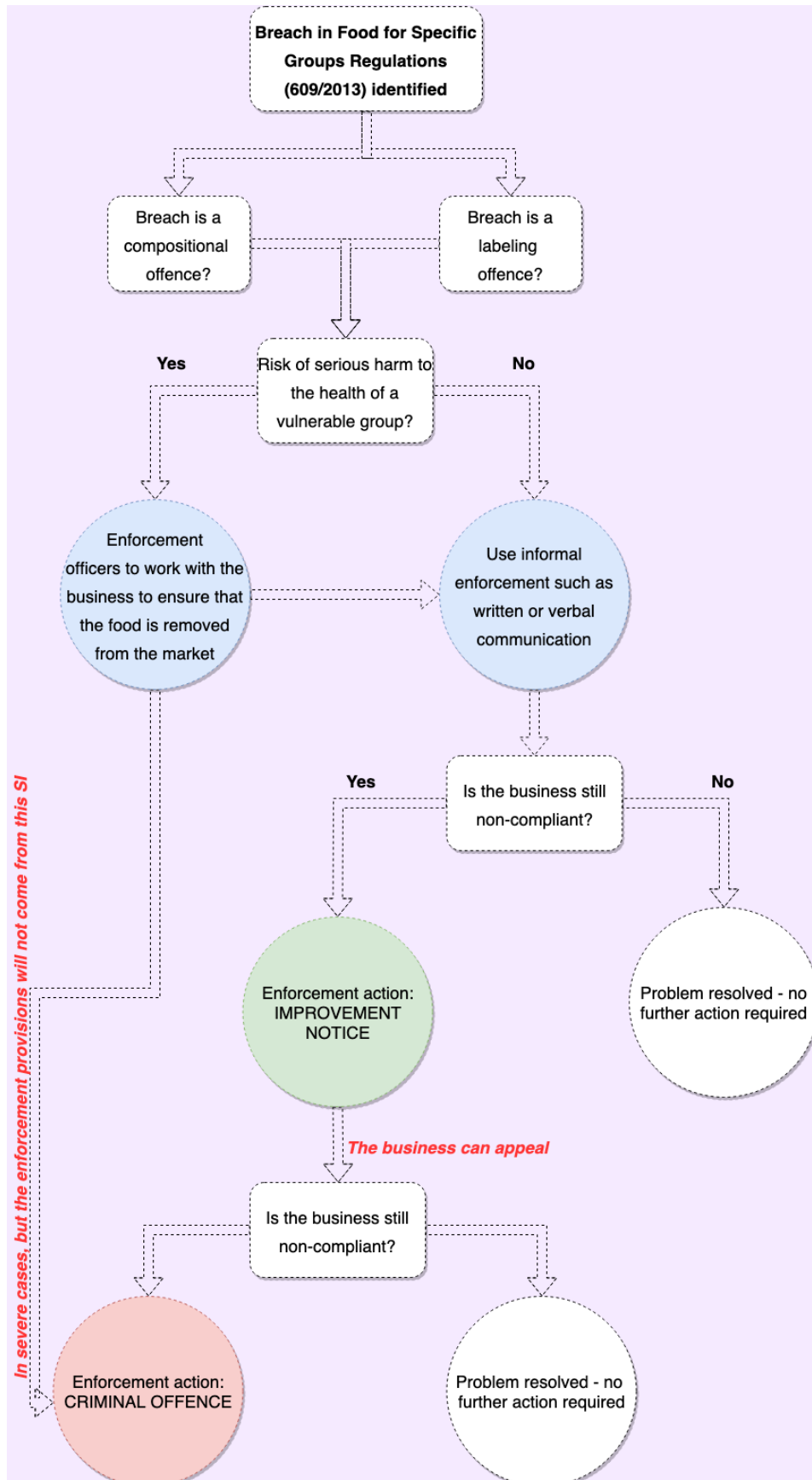
28. An IN, once served, may be appealed to the Magistrates Court in Wales, if the business does not agree with the conditions of the Notice. The appeals process will be in line with INs used for the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016.

29. 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.

Costs

30. 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.
31. It is estimated it will take businesses 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.

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.



Consultation Questions

- 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 for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (enforcing EU Regulation 609/2013) and the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019 (which includes enforcement of the provisions for FSMP other than FSMP for infants)?**

- 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 for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 and the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019?**

[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 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 or IFFOF regulations but for a breach of

the Food Safety Act 1990. In addition, failure to comply with an improvement notice served under the Regulations would attract criminal sanctions.]

- 3. We would like to know your views on the effects that these regulations will have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English.**

What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

- 4. Please also explain how you believe the proposed regulations could be formulated or changed so as to have positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.**

- 5. We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:**

Please enter here:

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:

Implementation of EU delegated regulations on food for specific groups consultation

Response Form

Your name:

Organisation (if applicable):

email / telephone number:

Your address:

Responses should be returned by 6 December 2019 to;

Healthy and Active Branch

Public Health Division

Welsh Government

Cathays Park

Cardiff

CF10 3NQ

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

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- 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 for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 and the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019?**

[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 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 or IFFOF regulations but for a breach of the Food Safety Act 1990. In addition, failure to comply with an improvement notice served under the Regulations would attract criminal sanctions.]

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