

PARTIAL REGULATORY IMPACT ASSESSMENT

Title: Implementation of EU delegated regulations on food for specific groups

Introduction

1. In 2016, the EU implemented The Food for Specific Groups Regulation (EU) 609/2013 (the FSG EU Regulation) which sets general compositional and labelling rules for the following four food categories:
 - infant formula and follow-on formula (IFFF)
 - processed cereal-based food and baby foods
 - food for special medical purposes (FSMP) (foods necessary for the management of particular medical conditions)
 - total diet replacement for use in energy restricted diets for weight reduction.
2. The FSG EU Regulation was implemented in Wales by way of The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (The FSG Wales Regulations 2016).
3. Four Delegated Regulations sit under the FSG EU Regulation and they supplement the FSG EU Regulation to reflect developments in a particular area. In this instance, the Delegated Regulations provide for the detailed composition and labelling requirements for each of the four food categories listed above.

Food for Special Medical Purposes (FSMP)

1. 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).
2. 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 FSG Wales Regulations 2016 as amended by the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019.
3. 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**.
4. 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)

5. 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.
6. 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.
7. 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

8. 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

9. 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.
10. 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.
11. 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.

Enforcement

12. Delegated Regulation (EU) 2016/128 on FSMP and Delegated Regulation (EU) 2016/127 on IFOFF 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 22 February 2020 or from 22 February 2021 in the case of formula made from protein hydrolysates.
13. We intend to make domestic legislation that will implement, or copy out in the event that the UK has left the EU by 22 February 2020, the provisions of the Delegated Regulations into Welsh 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 FSG Wales Regulations 2016 to these new provisions. This means an Improvement Notice will be the first formal action in the case of non-compliance rather than a criminal prosecution.
14. There are no known manufacturers or importers of FSMP or IFOFF in Wales. There are however retailers who sell these products and they will need to comply with a provision in the Regulations that restricts the promotion of these products. Businesses are already aware of the EU provisions since the legislation was consulted on and adopted in 2015. Businesses that do not comply with the legislation may wish to familiarise themselves with the enforcement provisions. Otherwise we do not expect this legislation to have any significant impact on business.
15. These are sensible rules that industry are expecting; the enforcement of which will provide greater consumer confidence and protection, and will provide industry with a harmonised set of rules.

Rationale for intervention

16. 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.

Policy objectives

17. This SI will amend the FSG Wales Regulations 2016 to:
 - 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.

Policy options

18. The following options are under consideration:

Option 1:

Do nothing – 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), Delegated Regulation (EU) 2016/128 on Food for Special Medical Purposes (elements relating to infants only) and Delegated Regulation (EU) 2016/127 on composition and labelling requirements for infant formula and follow-on formula will be automatically transposed into UK law on that date. Doing nothing would mean that the Regulation will still come into force, but we would not have the domestic legislation in place to make it workable and enforceable in Wales. Other legislation, for example the Food Safety Act 1990, would provide enforcement powers in the most severe cases breaching food safety. This could result in several unwanted impacts including:

lack of legal clarity for enforcement officers and businesses;

- risk to vulnerable consumers if there are no sanctions for non-compliant products and such products therefore remain on the market;
- impact on the supply chain of these specialist products due to uncertainty by business
- lack of consumer confidence in enforcement of the law
- the UK would be in breach of its legal obligations under the EU Treaty and may face infraction proceedings..

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 (and therefore no risk of infraction proceedings), not doing so would mean that the FSG EU Regulations are only partially implemented in Wales and would not reflect the most up to date evidence. It would also result in Wales falling out of step with the rest of the UK.

Option 2:

19. To make an SI amending the FSG Wales Regulations 2016 to (i) implement and provide for the enforcement of the two Delegated Regulations if the UK remains bound by EU rules or (ii) copy out and provide for the enforcement of the two Delegated Regulations in the event the UK has left the EU by 22 February 2020.
20. FSG Regulations have enforcement provisions for using Improvement Notices (IN), prior to criminal prosecution and levying a fine. If the food business operator (FBO) fails to comply with the Notice then the FBO is guilty of a criminal offence. This SI will extend those enforcement provisions to the requirements of the two Delegated Regulation.
21. Improvement notices are already in use to enforce other areas of food law, for example the FSG Regulations 2016 and the Food Information Regulations 2014, and are therefore well understood by trading standards officers. Enforcement bodies and industry consider Improvement Notices a less burdensome approach to resolving problems of non-compliance. We have not been able to quantify costs in relation to the use of improvement notices but evidence gathered during the development and consultation of the FSG Regulations from both industry and enforcement bodies highlighted that the use of criminal sanctions as a first formal action can cause difficulties for enforcement thus limiting the public health outcome. The introduction of Improvement Notices was supported as a way of enabling enforcement to improve, leading to improved compliance, thus advancing equality of opportunity, fostering good relations and promoting better health outcomes.
22. Option 2 is the preferred approach for which we estimate the impact in the following section.

Estimation of the costs and benefits

Costs to businesses

23. This Impact Assessment and the accompanying consultation focus on the costs and benefits of different enforcement options only. The impact of the actual regulations was previously considered and published by the EU (https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-special_groups_food-impact_assessment_en.pdf) and that analysis remains valid and unchanged. Given that this analysis may inform views on which enforcement option is preferable for FSMP, the full link to the Explanatory Memorandum (which includes a full Regulatory Impact Assessment) on the overarching FSG Regulation 609/2013 is provided here: <http://www.assembly.wales/laid%20documents/sub-ld10709-em/sub-ld10709-em-e.pdf>
24. Focusing on the enforcement options specifically, all businesses will need to familiarise themselves with the new rules. Once implemented, the proposed regime is deregulatory. That means that any business found not to be

complying with the regulations will (except in the most serious cases) face a non-legislative, less burdensome approach to resolving the problem. Compliance costs are thus expected to fall. Full details are set out below.

25. The proposed use of INs in the first instance provides a more proportionate approach to enforcement giving industry the ability to resolve the problem identified in the IN before it is escalated to a criminal offence.
26. Besides the one-off costs, there may be a change in longer-term recurring costs. This is difficult to quantify given uncertainties over the amount of enforcement action required. However, the principle of Improvement Notices is to give a 'soft touch' first approach once a breach is identified as a low cost way of trying to resolve issues without redress to court action. This is likely to be a benefit, albeit unquantified.
27. In the current enforcement regime for FSMP, if a Food Business Operator (FBO) is found guilty in a court of an offence, they could be directly liable to a fine (not exceeding Level 5 on the standard scale, which is currently £5,000¹).
28. As a direct cost of the new SI, we foresee that businesses may face a familiarisation cost. To estimate this cost, based on experience with a similar SI for FSG (2016) Regulations, we have assumed that it will take 2 hours per affected business to familiarise itself with the new SI. This may be an overestimate as much of the familiarisation required is expected to be subsumed under familiarisation with the EU legislation itself. Salary has been estimated using ASHE provisional 2017 median wage data for managers and directors, uplifted for 30% on-costs. This amounts to a cost of £53.40 per firm affected².
29. The UK market for FSMP has been estimated using notification data for FSMP products held by the Department of Health & Social Care. It is estimated that 17 businesses are likely to be affected by these Regulations. **There are no known manufacturers of FSMP of IFOFF products in Wales. No notifications of products from Wales have been received to date.**

Costs to local authorities

30. Although it would maintain the status quo regarding the enforcement of European regulation in this area, local authorities would need to become familiar with the new SI. It is estimated that it would take one Trading Standards Officer one hour to read and become familiar with the SI and the new enforcement regime. The hourly pay rate for Qualified Trading Standards Officers is between £16 and £25 – averaging approximately £27

¹ <http://www.legislation.gov.uk/ukpga/1982/48/part/III/crossheading/introduction-of-standard-scale-of-fines>

² Annual Survey of Hours and Earnings, 2017:

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation2digitsocashetable2>

per hour once updated to account for non-wage labour costs and overheads, taken as 30%. The total one-off cost to the 22 local authorities in Wales is therefore estimated at £594.

31. Ongoing workloads for local authorities are not expected to increase as a result of this SI, as enforcement work for the products affected is already required. We do not foresee additional ongoing costs but we will review this based on consultation responses.

Benefits to business

32. There is minimal change for businesses as the FSG Regulation already provides for IN as an option alongside criminal sanctions in the Medical Food (Wales) Regulations 2000. This SI will consolidate the use of IN as the first formal action for existing and new provisions under the FSG Regulation. The broad benefit to industry is moving from the possibility of facing criminal sanctions to the new regime where enforcement will be carried out by way of an IN as the first formal action, followed up by a criminal offence in cases where businesses continue to ignore the Notice. This may give FBOs a better chance to rectify issues before the matter comes before a criminal court.
33. The industry may benefit from reduced costs resulting from fewer prosecutions in a system where an Improvement Notice will precede any legal prosecution. In an ordinary case, criminal prosecution will result only if the business in receipt of the IN does not comply with the Notice either from the outset or if, following an unsuccessful appeal against the Notice to the Magistrates Court, they continue to fail to comply with the Notice.

Benefits to local authorities

34. Local authorities may also benefit from reduced costs from fewer prosecutions since issuing an Improvement Notice would be the first formal action rather than a prosecution.
35. We do not have information on the number of prosecutions or Improvement Notices that have been issued for non-compliance with current FSMP regulations. However, trading standards contacts have informed DHSC that this is not an area where there has been significant enforcement activity. The consultation may provide more information about the potential number of cases.

Benefits to consumers

36. This legislation will benefit those requiring FSMP or IFFF as there will be better protection by way of better defined compositional standards and tighter labelling restrictions.