Title: SR amending enforcement provisions for Food for Special Medical Purposes.	Impact Assessment (IA)
Lead department or agency: Food Standards Agency in Northern Ireland	**Date:** 10th September 2018
Other departments or agencies: **N/A**	**Stage: Consultation**
	Source of intervention: Domestic
	Type of measure: Secondary legislation
	Contact for enquiries:

Summary: Intervention and Options

RPC Opinion: Not Applicable

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, Two-Out?**	**Measure qualifies as**
	£0m	£0m	No	NA

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

EU Delegated Regulation 2016/128 which sets new composition and labelling rules for Food for Special Medical Purposes (FSMP) will come into force from 22 February 2019. This supplements the EU Framework Regulation 609/2013 concerning Foods for Specific Groups and it is directly applicable across EU member states.

A new Statutory Rule (SR) is needed to enforce this Regulation.

What are the policy objectives and the intended effects?

Our aim is to amend domestic legislation, i.e. The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016, (the FSI&C Regulations) to implement the minimal requirements of the FSMP Delegated Regulation, and to provide for the offences and penalties for breaching the composition and labelling rules that fall under this Regulation.

The rationale is our responsibility under the EU Treaty to enforce European legislation up to the date that the UK leaves the EU (currently 29 March 2019). Failure to enforce EU legislation prior to then would result in infraction proceedings.

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

Option 0: Do nothing - Delegated Regulation (EU) 2016/128 on food for special medical purposes will not be enforced.

Option 1: Introduce an SR amending the FSI&C Regulations to include enforcement provisions for the FSMP Delegated Regulation.

Option 1 is the preferred approach. Framework Regulation (EU) 609/2013, implemented by the the FSI&C Regulations, provides for delegated acts to supplement the framework regulation with specific compositional and labelling rules. The most efficient method of implementing the FSMP Delegated Regulation is to amend the domestic the FSI&C Regulations.

Will the policy be reviewed? To be confirmed **If applicable, set review date:** To be confirmed

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

Summary: Analysis & Evidence

Policy Option 0

Description: Do not enforce the regulations ("do nothing")

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 0**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

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

By convention, costs and benefits are set to zero for the do nothing option, with other options expressed relative to that zero baseline.

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

In this case, doing nothing means that the regulations will be legally unenforceable, which creates a risk of labelling or compositional breaches going unchallenged, with no support provided to the industry to solve such problems.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		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

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Summary: Analysis & Evidence

Policy Option 1

Description: Introduce SR to enable enforcement provisions

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				
High				
Best Estimate				

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

This impact assessment finds that as a result of the new enforcement provisions that are part of this SR, businesses and district councils will primarily face familiarisation costs (total of £406) significantly below £1 million. There will also be an unquantified reduction in recurring costs resulting from a simpler enforcement approach.

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

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

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

To note:

Key assumptions/sensitivities/risks

Discount rate (%) 3.5

BUSINESS ASSESSMENT

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

Introduction

1. Foods for Special Medical Purposes (FSMP) are intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods[1].
2. Such products are regulated, with labelling and compositional requirements set out in law. These regulations are changing, with new rules coming into force from 22 February 2019. The new rules have already been agreed, but the associated provisions for enforcing them have not. This impact assessment focuses on the options available for that enforcement regime.
3. In detail, Delegated Regulation (EU) 2016/128 concerning FSMP comes into force on 22 February 2019, except in respect of FSMP developed to satisfy the nutritional requirements of infants (bullets c and d – below), to which it shall apply from 22 February 2020. The Delegated Regulation supplements Framework Regulation 609/2013 on Foods for Specific Groups (FSG) which came into force on 20 July 2016 and is directly applicable across EU Member States[2].
4. The new delegated Regulation:

    a. Maintains the existing rules of Directive 1999/21/EC with some changes to the labelling requirements to ensure consistency with horizontal rules of Regulation (EU) No 1169/2011 on the provision of food information to consumers, taking into account the specificities of the products;
    b. Introduces the prohibition to make nutrition and health claims on foods for special medical purposes, in order to ensure legal clarity and avoid inappropriate promotion of the products
    c. Extends to foods for special medical purposes intended for infants all rules on labelling, presentation, advertising and marketing applicable to infant formulae for healthy infants that would not be contrary to the products' intended use. This will ensure consistency of EU rules and contribute to avoiding misclassification of products;
    d. Extends to foods for special medical purposes intended for infants and young children the same rules on pesticides that apply to infant formula, follow-on formula, processed cereal-based foods and baby foods.

5. These are sensible rules that industry is expecting; the enforcement of which will provide greater consumer confidence and protection, together with providing industry with a harmonised set of rules. This is especially important to ensure the continuity of supply of niche products where the use by individual countries is small, thus requiring manufacture for a number of countries at the same standards and provisions to make production viable. The UK supported the adoption of this Delegated Regulation, which we now need to enforce.

Rationale for intervention

6. The Delegated Regulation updates the legislation on composition and labelling of FSMP and replaces the FSMP Directive 1999/21/EC, implemented by the Medical Food Regulations (Northern Ireland) 2000. This change would lead to a legal gap in how we enforce the EU rules in Northern Ireland once the previous Directive has been repealed.
7. It is necessary to ensure there is continuity in the legal base to enable district councils to continue protecting the public by ensuring businesses comply with the rules. Failure to implement EU legislation would result in infraction proceedings. Moreover, this is another opportunity for enacting the policy on decriminalising regulatory offences in appropriate cases.
8. The timing is such that the rules for FSMP other than those for infants will be introduced before the UK leaves the European Union on 29 March 2019. The need for intervention is thus unaffected by EU Exit. The rules on FSMP for infants are due to come into force in February 2020, after the UK leaves the European Union, therefore this SR will not cover rules

[1] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/medical_en

[2] https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/

on FSMP for infants but these will be considered separately once the UK's position post exit is finalised.

Policy objectives

9. The proposed policy aims to use an SR to amend the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016, SR 2016 No. 251 (the FSI&C Regulations).
10. The amendments will allow effective implementation of the minimal requirements of Delegated Regulation (EU) 2016/128 concerning FSMP.
11. The SR also aims to provide for the offences and penalties for breaching the composition, labelling and advertising rules that fall under this Regulation.

Policy options

12. The following options are under consideration:

Option 0: Do nothing – Delegated Regulation (EU) 2016/128 on Food for Special Medical Purposes will not be enforced. Other legislation, for example the Food Safety (Northern Ireland) Order 1991, would provide enforcement powers in the most severe cases breaching food safety.

The EU Delegated Regulation is binding in its entirety and directly applicable in all member states. It is therefore not necessary to transpose the provisions of the Regulation into domestic law. Doing nothing would mean that the Regulation will still come into force, but we would not have the domestic legislation to make it workable and enforceable in Northern Ireland. 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 procedures.

Option 1: SR amending the FSI&C Regulations to include enforcement provisions for Delegated Regulation 2016/128 compositional and labelling requirements for FSMP.

Option 1 is the preferred approach. Framework Regulation (EU) 609/2013, implemented by the FSI&C Regulations in Northern Ireland, provides for delegated acts which will supplement the framework regulation with specific compositional and labelling rules. The most efficient method of implementing the Delegated Regulation is to amend the FSI&C Regulations and repeal the relevant part of the Medical Food Regulations (Northern Ireland) 2000.

13. The FSI&C 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 IN then the FBO is guilty of a criminal offence. This SR will extend those enforcement provisions to the requirements of the new FSMP Delegated Regulation. The use of INs is in line with the policy on decriminalising regulatory offences.
14. Improvement notices are already in use to enforce other areas of food law, for example the FSI&C Regulations and the Food Information Regulations (Northern Ireland) 2014 and are therefore well understood by enforcement officers. Enforcement bodies and industry consider INs a less burdensome approach to resolving problems of non-compliance. We have not been able to quantify costs in relation to the use of INs but evidence gathered during the development and consultation of the FSI&C Regulations from 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 INs 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.

15. Option 1 is the preferred approach for which we estimate the impact in the following section.

Figure 1: A flowchart representing the current enforcement provisions for FSMP.

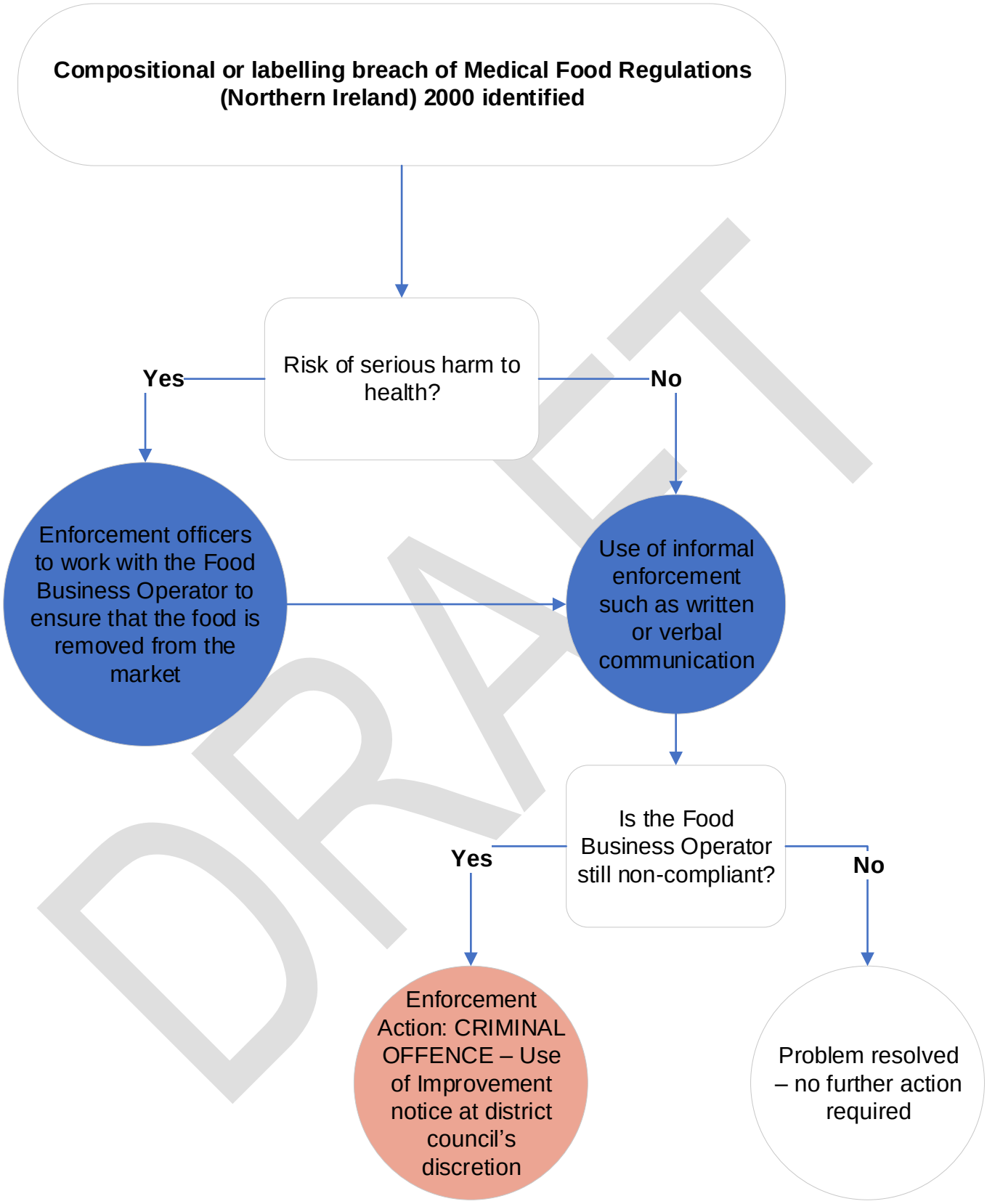
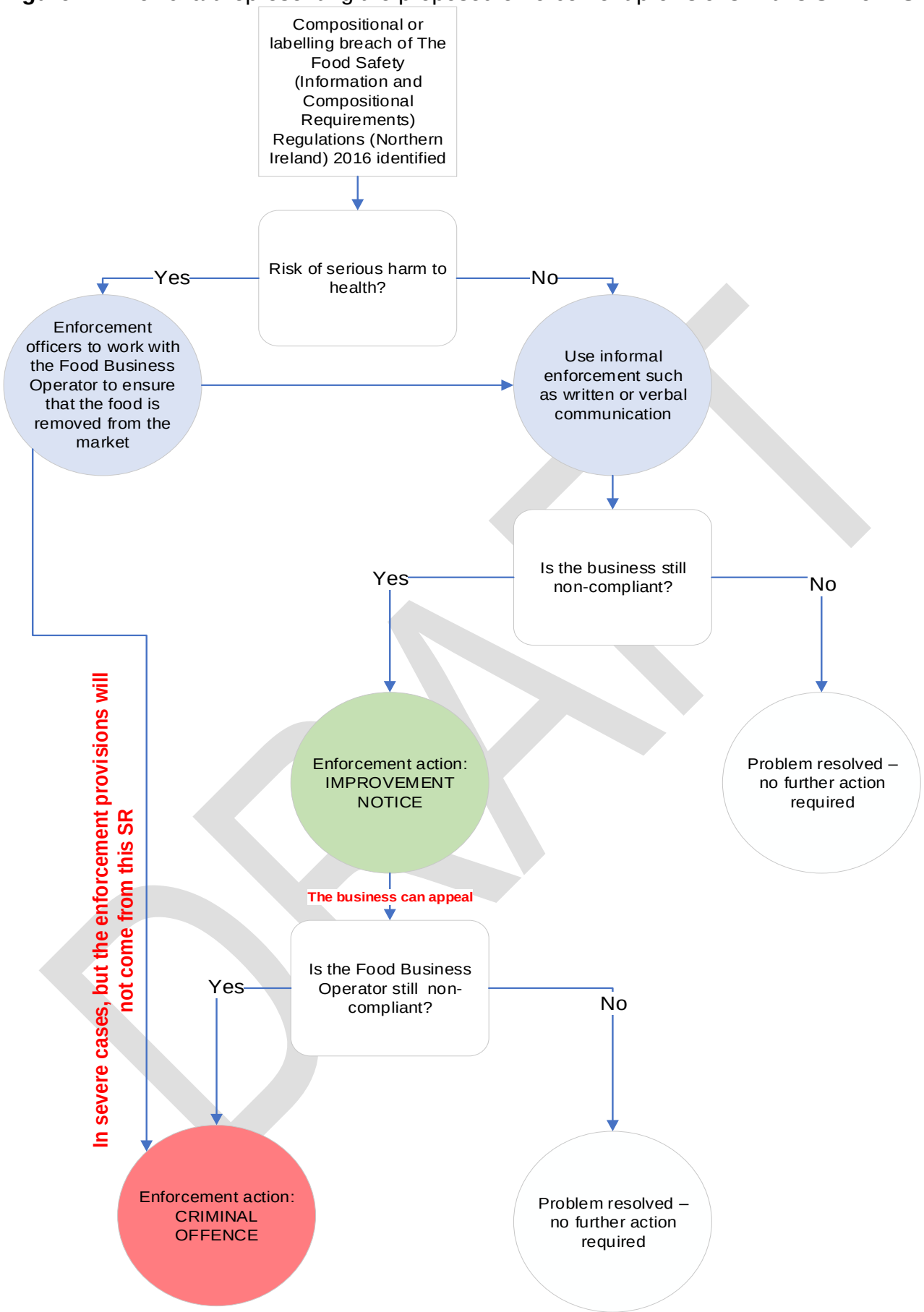


Figure 2: A flowchart representing the proposed enforcement provisions in this SR for FSMP



Estimation of the costs and benefits

16. 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.

    The main conclusions were:

    - The simplification of the FSI&C Regulations was to balance the benefits against the burden they impose on industry
    - the move from frontline criminal offences to INs backed up with a criminal offence for a failure to comply with an IN being in line with current policy on decriminalising regulatory offences in appropriate cases;
    - low familiarisation costs for businesses and district councils;
    - a potential benefit to both businesses and district councils from reduced costs resulting from fewer prosecutions in a system where an IN precedes any legal prosecution.

17. Focussing 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.

18. The proposed use of INs in the first instance is in line with the policy to decriminalise regulatory offences in appropriate cases. It provides a more flexible approach giving industry the ability to resolve the problem identified in the IN, enabling them to comply before it is escalated to a criminal offence.

19. 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 INs 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.

20. In the current enforcement regime for FSMP, if an 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 £5,000[3]).

21. As described in Figure 2, the FSI&C Regulations have the following enforcement provisions— if a company is found to be non-compliant with compositional or labelling rules, it will be approached by enforcement officers using informal written or verbal communication. If a risk to the health of vulnerable groups is detected, then the company will be required to remove its product(s) from the market. If the matter is not resolved by the company, an IN will be issued. Following this, the company may either file an appeal against the IN or resolve the issue. Continued failure to comply will escalate the matter to criminal prosecution, leading to unlimited penalty. Therefore, under Option 1 (wherein we propose to extend these FSI&C enforcement provisions to FSMP), the first formal action would be to issue an IN rather than a fine. Depending on the nature of the breach, it may be a potential saving to industry, for example if something can be rectified without redress to intervention by the Courts.

Costs to business

22. As a direct cost of the new SR, we foresee that businesses may face a familiarisation cost. To estimate this cost, based on experience with a similar SR for the FSI&C Regulations (2016), we have assumed that it will take 2 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. Salary has been estimated

[3] http://www.legislation.gov.uk/ukpga/1982/48/part/III/crossheading/introduction-of-standard-scale-of-fines

using ASHE provisional 2017 median wage data for managers and directors, uplifted for 30% on-costs. This results in a cost of £53.40 per firm affected[4].

23. The market for FSMP has been estimated using notification data for FSMP products held by the Department of Health & Social Care in England. All FSMP must be notified when being placed on the market so this data captures the market for FSMP consumed in the UK. A search of the 989 products in the notification dataset indicates that the market is comprised of approximately 146 manufacturers. We are currently aware there are two such manufacturers based in Northern Ireland.

24. This data does not take account of products that have been removed from the market so this number may be an overestimate. As such, the £53.40 cost is applied to two manufacturers, at a total cost of £106.80. While this figure is sensitive to the estimate for the number of firms in scope, for any reasonable estimate of the number of firms total costs remain substantially below £1m.

25. As described in para 12, under Option 1, once an IN has been issued, in many cases the result may be that the product can no longer be traded on the market until the issue of non-compliance has been resolved. We expect this to be beneficial but will review the specific impact on sales in the light of consultation responses.

26. Given that the time taken to resolve the issue may vary substantially from business to business, we have not estimated a value in this consultation impact assessment. We will review the issue after consultation has ended.

Costs to district councils

27. Although it would maintain the status quo regarding the enforcement of European regulation in this area, district councils would need to become familiar with the new SR. It is estimated that it would take one environmental health officer one hour to read and become familiar with the SR and the new enforcement regime and cascade the information to colleagues. The hourly pay rate for qualified 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%. The total one-off cost to the 11 district councils is therefore estimated at approximately £300.

28. Ongoing workloads for district councils are not expected to increase as a result of this SR, 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

29. There is minimal change for businesses as the FSI&C Regulations already provide for IN as an option alongside criminal sanctions in the Medical Food Regulations (Northern Ireland) 2000. This SR 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 improvement notice. This may give FBOs a better chance to rectify issues before the matter comes before a criminal court.

30. The industry may benefit from reduced costs resulting from fewer prosecutions in a system where an IN 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 a court of summary jurisdiction, they continue to fail to comply with the notice.

Benefits to district councils

31. District councils may also benefit from reduced costs from fewer prosecutions since issuing an IN would be the first formal action rather than a prosecution.

32. We do not have information on the number of prosecutions or INs that have been issued for non-compliance with current FSMP regulations. However, we believe that this is not an area

[4] Annual Survey of Hours and Earnings, 2017: https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation2digitsocashetable2

where there has been significant enforcement activity and the we have not been made aware of any FSMP products where formal action is being considered in Northern Ireland since the FSI&C Regulations came into operation. The consultation may provide more information about the potential number of cases.

Benefits to consumers

33. This legislation will benefit those requiring Foods for Special Medical Purposes as there will be better protection by way of better defined compositional standards and more informed labelling.

Conclusion

34. As detailed in the IA, we are required to implement this Delegated Regulation and the enforcement powers proposed would bring this in line with the Framework Regulation 609/2013 that this supports. Failure to implement this Regulation would leave a legal gap in how we enforce the Regulation and could result in infraction proceedings from the Commission. The details of the Regulation are not in question – it is the enforcement provisions that this IA provides for.

35. The costs to business and district councils as a result of the new SR are estimated at £106 and £300 respectively (total of £406). This total is substantially below £1 million for any reasonable estimate.

36. The SR repeals the current domestic law in relation to FSMP (excluding FSMP for infants) and starts to consolidate rules into one single SR, thus simplifying the legal framework making the legislation easier to enforce. Enabling enforcement officers to issue INs in respect of breaches of the rules as an alternative to criminal action as a first step is considered proportionate and sensible, with potential cost savings to district councils and businesses. It gives enforcement officials flexibility to take whatever action they think necessary to protect the health of consumers and in other areas of food law it has led to improved compliance. It is recognised that INs should not be a complete substitution for criminal sanction e.g. for actions which are potentially harmful to human health. Therefore criminal sanctions are still an appropriate mechanism for a failure to comply with an IN.

37. This draft IA will be reviewed following the outcome of the consultation should responses indicate a requirement for a different approach.