PARTIAL REGULATORY IMPACT ASSESSMENT

Title: Statutory instrument amending enforcement provisions for Food for Special Medical Purposes

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 Food 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 food for special medical purposes, in order to ensure legal clarity and avoid inappropriate promotion of the products
    c. Extends to food 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 food 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 food and baby food.

5. These are sensible rules that industry are 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.

[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/

Rationale for intervention

6. The Delegated Regulation updates the legislation on composition and labelling of FSMPs and replaces the former FSMP Directive 1999/21/EC, implemented by the Medical Food (Wales) Regulation 2000. This change would lead to a legal gap in how we enforce the EU rules in Wales once the previous Directive has been repealed.

7. It is necessary to ensure there is continuity in the legal base to enable local authorities to continue protecting the public by ensuring businesses comply with the rules. Failure to implement EU legislation would result in infraction proceedings.

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 Statutory Instrument will not cover rules 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 a Statutory Instrument (SI) to amend the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016, SI 2016 No. 639 (W.175) (the FSG Regulations).

10. The amendments will allow effective implementation of the minimal requirements of Delegated Regulation (EU) 2016/128 concerning FSMP.

11. The SI 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 1: Do nothing – Delegated Regulation (EU) 2016/128 on Food for Special Medical Purposes will not be enforced. Other legislation, for example the Food Safety Act 1990, 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 Wales. 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 2: SI amending the Food for Specific Groups Regulations to include enforcement provisions for Delegated Regulation 2016/128 compositional and labelling requirements for FSMPs

Option 2 is the preferred approach. Framework Regulation (EU) 609/2013, implemented by the FSG Regulations in Wales, 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 FSG Regulations and repeal the relevant part of the Medical Food (Wales) Regulations 2000.

13. 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 new FSMP Delegated Regulation.

14. 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.

15. Option 2 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

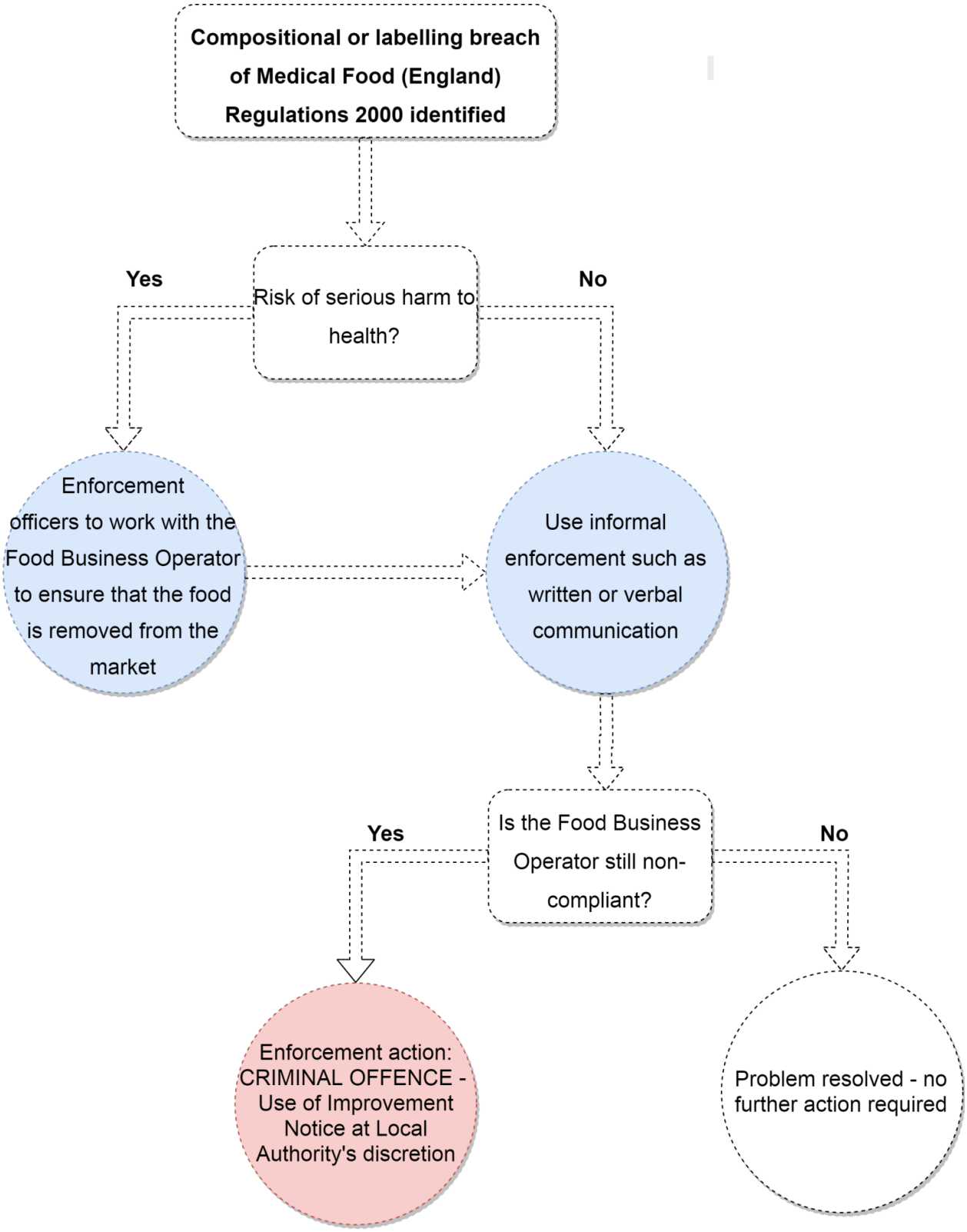
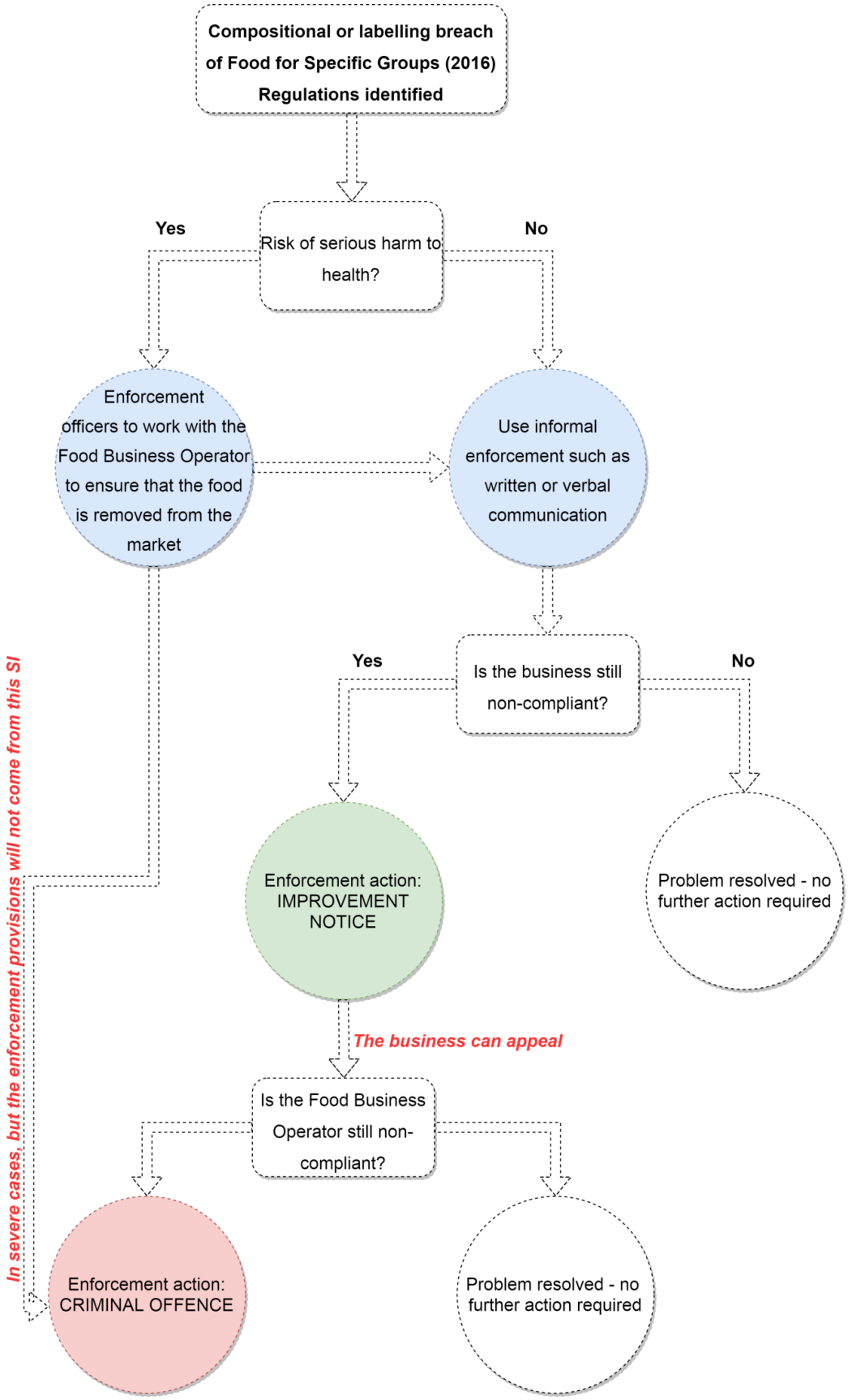


Figure 2: A flowchart representing the proposed enforcement provisions in this SI for FSMP



Estimation of the costs and benefits

16. This Impact Assessment and the accompanying consultation focus on the costs and benefits of different enforcement option
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18. s 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

19. 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.

20. 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.

21. 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.

22. 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 £5,000[3]).

23. As described in Figure 2 above, FSG 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 2 (wherein we propose to extend these FSG 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

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

potential saving to industry, for example if something can be rectified without redress to intervention by the Courts.

Costs to business

24. 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 affected[4].

25. The UK market for FSMP has been estimated using notification data for FSMP products held by the Department of Health & Social Care. All FSMPs must be notified to the Department when being placed on the market so this data captures the market for all FSMPs consumed in the UK. Based on this information it is estimated that there are in the region of 149 manufacturers of FSMP across the UK, 146 in England, 3 in Scotland and 2 in Northern Ireland. **There are no known manufacturers of FSMP products in Wales. No notifications of products from Wales have been received to date.**

Costs to local authorities

26. 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 per hour once uprated 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.

27. 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

28. 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

[4] Annual Survey of Hours and Earnings, 2017:

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

ignore the Notice. This may give FBOs a better chance to rectify issues before the matter comes before a criminal court.

29. 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

30. 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.

31. 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

32. This legislation will benefit those requiring Food for Special Medical Purposes as there will be better protection by way of better defined compositional standards and tighter labelling restrictions.

Conclusion

33. 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 Regulations 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.

34. The estimated cost to Welsh business and local authorities as a result of the new SI at £594 in total is insignificant.

35. The SI repeals the current domestic law in relation to FSMP (excluding FSMP for infants) and starts to consolidate rules into one single Instrument, thus simplifying the legal framework making the legislation easier to enforce. Enabling enforcement officers to issue Improvement Notices 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 local authorities 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 Improvement Notices 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 Improvement Notice.

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