Title: SI for Foods for Specific Groups **IA No:** DH3147 **RPC Reference No: RPC-3046(2)-DH** **Lead department or agency:** Department of Health **Other departments or agencies: N/A**	**Impact Assessment (IA)** **Date:** 01/08/2016 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Department of Health, Health Improvement Analytical Team

Summary: Intervention and Options

RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
-£0.01m	-£0.01m	£1,320	In scope	Qualifying provision

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

Regulation (EU) no. 609/2013 is a new legal framework concerning foods for specific groups that came into force 20 July 2016, updating the legislation and repealing the former EU framework legislation for certain specialised foods. The new framework provides the legal base for current rules on composition and labelling, and provides for new rules that will apply from 2019 onwards via EU delegated regulation. The changes mean there will be a legal gap on how we enforce the EU rules in England, because the previous framework (PARNUTS) has been repealed, and this SI is required to effectively implement the EU regulation in England.

What are the policy objectives and the intended effects?

The rationale is our responsibility under the EU Treaty to enforce European legislation; Failure to implement EU legislation would result in infraction proceedings.

Our aim is to pass domestic legislation to implement the minimal requirements of Regulation (EU) no. 609/2013 concerning foods for specific groups, and to provide for the offences and penalties for breaching the composition and labelling rules that fall under this framework Regulation.

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

Option 0. Do nothing - Regulation (EU) no. 609/2013 on foods for specific groups (FSGs) will not be enforced

Option 1. SI with new enforcement provisions - Introduce Improvement Notices as the first formal action under the FSG Regulation.

Option 1 is the preferred approach. Under this option the first formal action under the FSG Regulation would be to issue an Improvement Notice rather than a fine. This will be a saving to industry (although out of scope of OI3O as a fine) and a more flexible approach giving industry additional time and support to resolve the problem identified in the Improvement Notice, enabling them to comply before it is escalated to a criminal offence.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** 0	**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister Nicola Blackwood : Date 26th January 2017

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2015	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -0.02	**High:** -0.01	**Best Estimate:** -0.01

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.01	1	0	**0**
High	0.02		0	**0**
Best Estimate	0.01		0	**0.01**

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

Businesses will face one-off familiarisation costs of £11,800. There are no other costs to business.

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

Local authorities will likely face some familiarisation costs. Additionally, there may be a requirement to provide funding for the Tribunals who will be determining appeals against an Improvement Notice. These costs are not included as it is beyond the scope of a validation stage impact assessment.

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

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

N/A

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

Businesses may benefit from reduced costs resulting from fewer prosecutions in a system where an Improvement Notice will precede any legal prosecution. There may also be a benefit in the form of reduced administrative burden for new firms entering the market as a result of fewer SIs. We have not estimated these benefits because we expect them to be negligible.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0.0	**Benefits:** 0.0	**Net:** 0.0	0.0

Evidence Base

1. The Statutory Instrument (SI) for Foods for Specific Groups has been recognised as applicable for "Fast Track" clearance status. The economic case presented in this validation stage impact assessment is therefore restricted to the business impact of the proposed SI. There will likely be wider unavoidable impacts of EU regulation no. 609/2013 to businesses and other groups. However, because the impacts of the EU regulation are 'out of scope' of this economic assessment no attempt is made at quantifying these impacts in this IA. They have been quantified in an EU Impact Assessment[1].

2. The Regulatory Policy Committee validated the initial Regulatory Triage Assessment (RTA) by giving it a 'green' rating on 25th August 2015 (reference: RPC-3046(1)-DH).

Rationale for intervention

3. It is our responsibility under the EU Treaty to enforce European legislation; failure to implement new EU legislation would result in infraction proceedings. Regulation (EU) no. 609/2013 is a new legal framework concerning Foods for Specific Groups (FSG) that came into force from 20 July 2016, updating the legislation and repealing the former framework legislation (Directive 2009/39/EC referred to as PARNUTS) for these foods. Domestic legislation, in the form of this SI, is required to effectively implement the EU regulation in England.

4. It is necessary to ensure there is continuity in the legal base after 20 July 2016 when the FSG Regulation revokes the PARNUTS Directive, to enable local authorities to enforce the food labelling and composition rules for potentially vulnerable groups, and continue to protect the public by ensuring businesses comply with the rules. The SI will contain the offences and penalties for non-compliance of compositional, labelling and advertising rules, making the FSG Regulation workable and enforceable in England. The SI also repeals rules which are no longer necessary.

5. The simplification of the FSG Regulation is in line with the Government's "Red Tape Challenge" which aims to rationalise the number of regulations by reviewing their purpose and balancing the benefits against the burden they impose on industry.

Policy objective and intended effects

6. Our policy objective is to legislate to implement the minimal requirements of the FSG Regulation and make provision for the offences and penalties for non-compliance of compositional, labelling and advertising rules. This will make the FSG Regulation workable and enforceable in England.

7. The intended effect of the new regulatory proposal will be to simplify the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses.

Description of options considered

8. The following Options are under consideration:

9. **Option 0**: Do nothing - Regulation (EU) no. 609/2013 on foods for specific groups (FSGs) will not be enforced

   As an EU Regulation, the FSG Regulation is binding in its entirety and directly applicable in all Member States. It is therefore not necessary to transpose the provisions of the FSG Regulation into domestic law. Doing nothing would mean that the FSG Regulation will still come into force, but we would not have the domestic legislation to make it workable and enforceable in England. National legislation must be in place by 20 July 2016, if not the UK would be in breach of its legal obligations under the EU Treaty and may face infraction procedures. Option 0 is therefore disregarded as an option, but it is the baseline against which other options are appraised.

[1] http://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/index_en.htm

10. **Option 1**: SI with new enforcement provisions - Introduce Improvement Notices as the first formal action under the FSG Regulation.

11. The Statutory Instrument (SI) will implement the minimal requirements of the FSG Regulation which will come into force from 20 July 2016. The new framework FSG Regulation provides the legal base for current rules on composition and labelling, and provides for new rules that will apply from 2019 onwards, via delegated regulation, concerning four new categories of food: (i) infant and follow-on formulae (ii) processed cereal-based food and baby food (iii) medical foods (iv) total diet replacement for use in energy restricted diets for weight control.

12. The SI also repeals rules that are no longer necessary[2] and will be amended in future to repeal existing rules when the four EU Delegated Regulations apply from 2019 onwards. At that time we will consolidate existing domestic laws into one single Instrument, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses. In the meantime the majority of the compositional, labelling and advertising rules will continue to be enforced by existing SIs and their amendments, until their date of revocation[3].

13. We are also proposing the use of improvement notices rather than criminal offences to achieve compliance with the legislation. The offences and penalties relating to the Delegated Regulations will be put in place nearer to their dates of application (2019 at the earliest) by future amendments to the SI.

14. A SI with Improvement Notices is a further step towards decriminalising regulatory offences. The first formal action under the FSG Regulation would be to issue an Improvement Notice rather than a fine. If the food business operator (FBO) fails to comply with the Notice then the FBO is guilty of a criminal offence.

15. A move from frontline criminal offences to Improvement Notices backed up with a criminal offence for a failure to comply with an Improvement Notice is in line with the Government's policy on decriminalising regulatory offences in appropriate cases.

16. Option 1 is the preferred approach and the one for which we estimate the impact on business.

Estimation of the impact on businesses

Costs to businesses

17. Option 1 (preferred option) would change the current enforcement regime in a manner that results in no additional costs to businesses. Currently, if an FBO is found guilty of an offence then

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[2] In particular the following SIs were revoked on 20 July 2016:

(i) The Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007
(ii) The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2010.

[3] These are as follows:

(i) The Infant Formula and Follow-on Formula (England) Regulations 2007
(ii) The Processed Cereal-Based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003
(iii) The Medical Food (England) Regulations 2000
(iv) The Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997
(v) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009
(vi) The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010 (to be revoked by a separate SI).

the FBO is liable to a fine. Under Option 1 the first formal action under the FSG Regulation would be to issue an Improvement Notice rather than a fine. This will be a saving to industry (although out of scope of OI3O as a fine) and a more flexible approach giving industry additional time and support to resolve the problem identified in the Improvement Notice, enabling them to comply before it is escalated to a criminal offence.

18. Introduction of the new SI would result in familiarisation costs of approximately £11,800.

19. Familiarisation costs are limited as these are more concerned with the EU FSG Regulation and much less so with the SI. In addition, Improvement Notices are already in use in other areas of food labelling (e.g. the Food Information Regulations 2014), so they are already understood by the industry.

20. We estimate it would take a manager two hours to become fully familiarised 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 Annual Survey of Hours and Earnings provisional 2015 median wage data for corporate managers and directors, uplifted for 30% on-costs[4]. This results in a cost of £54.86 per firm affected.

21. The main firms that are likely to be affected are manufacturers of products where the FSG legislation has changed in relation to the PARNUTS legislation. The categories of foodstuffs covered by the FSG legislation is restricted to infant formulae, follow-on formulae, baby foods and foods for special medical purposes and total diet replacements for weight control (TDR). The FSG Regulation removes other foodstuffs regulated under the current framework, such as gluten-free foods, sports foods, and young child formulae which will in future be regulated under other existing food law measures.

22. The main food sectors affected include slimming foods, very low calorie diet foods (VLCDs), gluten-free foods, young child formulae and sports foods and drinks. Other sectors where little regulatory changes are proposed (baby foods, infant formulae, follow-on formulae, and medical foods), will nevertheless need to understand the changes to the legislation, and impact should be limited to familiarisation costs.

23. Euromonitor data reports that 13 firms accounted for 95.3% of the baby food market in 2015[5]. We generate an estimate for the number of remaining firms by comparing the remaining market share to the smallest market share recorded (0.2%). If each of the firms excluded had only a marginally smaller market share than this firm, we would estimate there to be an additional 24 firms in the baby food market. However, this may underestimate the number of smaller firms. As such, we estimate that double this number of firms are not captured by the Euromonitor data – resulting in a total market of 61 firms.

24. Euromonitor report 7 firms accounting for 100% of sales in 2015 in the milk formula market. [6]

25. The market for Foods for Specific Medical Purposes has been estimated using NHS prescription data. All FSMPs must be prescribed, so this data captures the market for FSMPs consumed in England. A manual search of the 831 products in the prescription dataset indicates that the market is comprised of approximately 139 manufacturers.[7]

26. The Total Dietary Replacement market has been examined using Kantar sales data[8]. Products from 8 manufacturers in total were found to have sales in 2014.

Table 1: Number of affected firms

[4] ONS: Annual Survey of Hours and Earnings, 2015 provisional results: http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/2015provisionalresults

[5] Euromonitor analysis of baby food market, 2015. http://www.euromonitor.com/baby-food

[6] Euromonitor analysis of milk formula market, 2015. http://www.euromonitor.com/baby-food

[7] HSCIC: Prescription Cost Analysis England 2015. http://www.hscic.gov.uk/searchcatalogue?productid=20437&q=title%3a%22prescription+cost+analysis%22&sort=Relevance&size=10&page=1#top

[8] Kantar Worldpanel 2014. http://www.kantarworldpanel.com/global

Category	Estimated number of firms	Source
Baby food	61	Euromonitor & DH estimates
Milk formulae	7	Euromonitor & DH estimates
Foods for Specific Medical Purposes	139	NHS prescription data
Total dietary replacement	8	Kantar

27. This results in a total of approximately 215 manufacturers. However, this is inflated by some double counting – some manufacturers can be found in all of these markets. In assessing the costs to business of familiarisation, it may not be inappropriate to assess these separate wings of the business as distinctly individual, as the organisational structure will likely mean that some activity will need to be mirrored across the different departments. As such, the £54.68 cost is applied to all 215 manufacturers, at a total cost of £11,800. While this figure is sensitive to the estimate for the number of firms in scope, we have performed a sensitivity analysis and found that for any reasonable high estimate of the number of firms total costs are in the low tens of thousands of pounds.

28. Please note that the cost figures estimated above differ slightly from those in the RTA. This is due to more recent data being used for the estimated number of firms and salary. Responses to the consultation did not suggest any further changes to the methodology or assumptions underlying the calculations of cost to business.

Benefit to businesses

29. The only regulatory change to be assessed is the move to a different enforcement regime. The broad benefit to industry in moving from the current frontline criminal sanctions regime to a new regime is that enforcement will be carried out by way of an Improvement Notice, 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.

30. 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 Improvement Notice does not comply with the Notice either from the outset or if, following an unsuccessful appeal against the Notice to the First-tier Tribunal, they continue to fail to comply with the Notice.

31. Additionally, there may be a small reduction in administrative burden, especially for firms newly entering into the market, as a result of two SIs being revoked (as detailed in para 12). This will not result in substantial savings as there were few national requirements to notify the marketing of food for particular nutritional uses in England, effectively impacting on only small markets such as gluten-free foods.

One in three out (OI3O) calculation

32. Apart from the proposed enforcement regime, the only impact on business is familiarisation time, because the change in legislative framework is a result of the directly applicable EU FSG Regulation. The only costs faced by business are one off familiarisation costs of £11,800. This results in a very slight in for OI3O purposes with an EANDCB of £1,320 which rounds to £0.0m over the 10 year assessment period.

Sensitivity analysis

33. We have doubled and halved the number of firms that will bear familiarisation costs. In each case, the familiarisation cost is well under £1m and the EANDCB rounds to £0.0m.

Number of firms	Familiarisation cost	EANDCB
430	£23,500	£2,629
108	£5,900	£660

Equality assessment

34. As these regulations implement the rules covering the composition, labelling and advertising of foods purchased and consumed by potentially nutritionally vulnerable people, our policy has taken account of public health, safety and consumer protection aspects. In this respect we have taken due regard of Secretary of State's duties to reduce inequalities in access to care and the outcomes of care, and in particular with respect to section 1C of the NHS Act 2006 (duty to reduce health inequalities) and the Equality Act 2010 (S.149 Public sector equality duty).

35. We have paid due regard to advancing equality of opportunity and, in particular, regarding the views of NGOs who could be considered as representing groups (e.g. women, maternity and pregnancy, and families with infants) with a protected characteristic. NGOs have concerns regarding the advertising and marketing of infant formulae in relation to the impact on parents' perceptions and decisions regarding infant feeding, and have advocated the maintenance of criminal sanctions in the SI. Whist this is their view, the current criminal regime has caused difficulties for enforcement which has limited the public health outcome. Evidence gathered during the development of these Regulations and from the consultation indicates that Improvement Notices will make businesses more compliant, thus advancing equality of opportunity and fostering good relations with the aim of promoting better health outcomes.

36. Regarding the power of entry for Authorised Officers such as Trading Standards Officers and Environmental Health Officers who have the right to enter any premises unannounced within their Authority's area, we have considered the case of private dwellings if used by food businesses and implications for The Human Rights Act 1998. In such cases we are satisfied that the power of entry is made subject to a magistrates warrant so that, in the case of an initial request, Authorised Officers have to get a warrant before they can request entry.

37. The implementation of updated food composition and labelling standards as required by the FSG Regulation to protect public health is evidence of complying with Secretary of State duties and the consultation responses support the introduction of Improvement Notices as a way of enabling enforcement to improve, with the aim of leading to improved compliance. This Instrument will be updated when the four Delegated Regulations start to apply (from 2019) and public sector equality duties and duties to reduce health inequalities will be considered again at that time.