

Title: Impact Assessment on a Statutory Instrument implementing Regulation (EU) 1169/2011 on the provision of food information to consumers IA No: DEFRA 1443 Lead department or agency: DEFRA Other departments or agencies: FSA, DH, BIS, equivalents in other UK Governments	Impact Assessment (IA)		
	Date: 25/02/2014		
	Stage: Final		
	Source of intervention: EU		
	Type of measure: Primary legislation		
Contact for enquiries: Tom Stafford (020 7238 4903)			
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
£-0.007	£0	£0	No NA

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

Government intervention in food labelling is necessary to: correct the potential market failure of asymmetric information in the provision of nutritional and allergen labelling information to consumers and ensure consistency in food labelling requirements across the EU, reflecting current and future business practice. The directly applicable EU Regulation 1169/2011 on the Provision of Food Information to Consumers Regulation (FIC) aims to do this. To meet the UK's legal obligations, enforcement provisions for FIC must be introduced and overlapping UK legislation removed. We must also decide which optional derogations and other national measures to adopt, and which existing national measures to retain or revoke.

What are the policy objectives and the intended effects?

The UK aims to introduce a new Statutory Instrument to: consolidate and update general food and nutrition labelling to remove confusing overlaps between the UK and EU legislation and to ensure a level playing field between EU and UK Food Business Operators (FBOs); minimise unnecessary regulatory burden on FBOs by taking advantage of appropriate national measures available in FIC and introducing a proportionate, risk-based enforcement regime; Infraction will be avoided by introducing enforcement provisions and removing overlapping legislation. There will be consistent and clear labelling of minced meat to enable consumers to make better informed choices.

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

Option 0; Baseline. Make national legislation necessary to enable the EU FIC in England and remove overlapping or conflicting Regulations; retain existing national measures.

Option 1; Make national legislation necessary to enable the EU FIC in England and remove overlapping or conflicting Regulations. Retain those existing national measures that continue to be in the interest of business and consumers (QUID on loose meat products, Name of food on loose foods), revoke those that are better served by voluntary or other measures (cheese, cream, Ice-cream). Allow derogation on minced meat for 2 years, allowing time for business adjustment.

Option 2; Recommended Option. As option 0 except to allow derogation on minced meat indefinitely (subject to review following 3 years of operation), and approach to national measures as in option 1.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 12/2019					
Does implementation go beyond minimum EU requirements?			Yes		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 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: _____ **George Eustice** _____ Date: _____ **14th July 2014** _____

Summary: Analysis & Evidence

Policy Option 1

Description: Provides for proportionate offences and penalties to enforce EU Regulation. No new national measures adopted. Retains current practice through national measures where in the interests of businesses and consumers in England; revokes them where not. Derogation on minced meat allowed for limited period only and then withdrawn, making this option 'gold plated'. Derogation on doorstep milk (reusable glass bottles) allowed indefinitely.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £-1.03m	High: Optional	Best Estimate: £ 8.07m

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	0	Optional
High	Optional	Optional	Optional
Best Estimate	£1.03m	£3.89m	£33.29m

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

Familiarisation cost for food business operators (FBO's) with the new regulations (£0.99m PV).
 Familiarisation Cost for local authorities (£0.007m PV).
 Reformulation cost for beef mince producers (£32.26m PV)
 Relabelling cost for mince producers (£0.04m PV)

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

There may be some transitional costs of moving towards to the new enforcement regime, both for businesses and enforcers.
 There may be a loss of consumer surplus from the change in price of minced meat products, and associated demand impacts.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	0	Optional
High	Optional	Optional	Optional
Best Estimate	0	£4.98m	£41.37m

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

Health benefits to consumers (£41.37m PV).

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

There may be benefits - for businesses and enforcers - from the consolidation of fourteen Statutory Instruments into one piece of legislation. However, the total amount of legislation has not been reduced. The new enforcement regime may also provide for more flexible and proportionate enforcement procedures.

Key assumptions/sensitivities/risks Discount rate (%) 3.5%

Key assumptions for the calculations of health benefits and reformulation costs are set out in the evidence base/Annex. These are the major drivers of the NPV and therefore changes in these assumptions could affect the overall NPV. The response of businesses and consumers to the the withdrawal of high-fat mince would affect the extent of costs and benefits of this policy option (see evidence base).
 There is a significant uncertainty about the potential costs of meeting collagen limits due to incomplete data. The cost could be significantly larger than stated.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OITO?	Measure qualifies as
Costs: £3.19m Benefits: 0 Net: £3.19m	Yes	IN

Summary: Analysis & Evidence

Policy Option 2

Description: Recommended option. Provides for offences and penalties to enforce EU Regulation proportionately. No new national measures adopted. Retains current practice through national measures where in the interests of businesses and consumers in England; revokes them where not. Derogations on minced meat and doorstep delivery milk (in reusable glass bottles) allowed indefinitely.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: £-0.007

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	£0.007m	0	£0.007m

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

There would be some small time costs for local authorities in order to familiarise themselves with the new enforcement provisions (£6,700 PV).

There are no other additional costs of this option compared with the directly applicable FIC.

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

There may be some transitional costs of moving towards to the new enforcement regime, both for businesses and enforcers

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'

There are no additional monetised benefits from this option compared with the directly applicable FIC.

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

There may be benefits - for businesses and enforcers - from the consolidation of fourteen Statutory Instruments into one piece of legislation. However, the total amount of legislation has not been reduced. The new enforcement regime may also provide for more flexible and proportionate enforcement procedures.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%
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BUSINESS ASSESSMENT (Option 2)

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

Executive Summary

i) What is the problem?

Government has a role in regulating food labelling and the information provided to consumers, chiefly to:

- Ensure essential information regarding food safety is provided to consumers.
- Act against the market failure of asymmetric information between producers/retailers and consumers.
- Ensure the proper functioning of the internal European and wider international markets.

EU Food Information Regulations have been updated and consolidated into the Food Information to Consumers Regulations 1169/2011 (EU FIC). Without Domestic Regulations being brought in to enable the EU Regulations in England (as well as other UK countries) EU treaties will be breached.

We have to decide;

1. How best to create enforcement provisions to enable the EU FIC in England.
2. How to deal with inconsistent or overlapping legislation consequent to the adoption of EU FIC.
3. The extent to which we can or should retain existing national measures which go beyond the strict minimum provisions in FIC.
4. Whether or not to take up flexibilities allowed in FIC, including the allowable derogation on minced meat.

ii) What solution is proposed?

1. Domestic Regulations must introduce offences and penalties which ensure compliance with the EU Regulations thus avoiding infraction proceedings. The enforcement regime proposed is proportionate, reducing criminal sanctions to civil notices where this remains an effective means of enforcement. Criminal sanctions will remain where there is any risk to health, or where civil notices are not complied with.
2. Overlapping or inconsistent legislation will be re-drawn or revoked where necessary. 14 existing Statutory Instruments will be revoked fully and others partially as their provisions are consolidated into the single FIC.
3. Some existing national measures have widespread support from business and consumer interests and do not represent an excessive regulatory burden on business. These will be retained. Other existing measures, while not currently seen as burdensome, may act as a barrier to innovation in their sectors. These will be revoked either immediately or following a transition period.
4. A number of flexibilities are allowed for in EU FIC which Member States may adopt in order to go further than the minimum requirements of FIC. These would

increase burdens on business and/or Government and do not reflect current practice in England. These include the provision of additional nutrition information for particular population groups, for example. These will not be adopted.

5. We propose to allow a derogation for minced meat composition and designation requirements. This derogation will be reviewed jointly by Defra and DH within three years from the derogation coming into force in order to assess the public health impacts.

iii) Risks

There is a divergence of views on some available national measures and whatever decision is made will not have universal support.

Current industry practice in some of the minced meat market is incompatible with the Regulations and will need to change. Although it will not remove the need for some current industry practice to change, allowing the minced meat derogation will help ease this necessary transition for business. The preferred option will attract adverse comment from some, though not all, relevant stakeholders.

Since the 'horsemeat issues' early in 2013, attention has been focussed on whether consumers are properly informed about the food they buy. How these Regulations are enabled in England will be under additional scrutiny as a result.

Summary of Costs and Benefits of the options (Option 2 is recommended)

Option 1		Present Value (£m)
Costs	Familiarisation cost (enforcers)	0.007
	Familiarisation cost (business)	0.99
	Re-labelling cost (business)	0.04
	Reformulation cost (business/consumers)	32.26
Benefits	Health benefits	41.37
Net Present Value		8.07
Option 2		
Costs	Familiarisation cost (enforcers)	0.007
Benefits	N/A	0
Net Present Value		-0.007

Evidence Base (for summary sheets)

1. Policy Landscape

1.1. Defra, in common with other Government Departments, has as a high priority the reduction of legislative burdens to business and to society as a whole. In the field of food labelling, this is balanced against the necessity for accurate honest and informative information that consumers need in order to make safe and informed purchasing decisions. Food information for consumers is a necessarily detailed and complex area of policy. However, through the introduction of the EU Food Information to Consumers Regulation (1169/2011), there is an opportunity to remove from businesses and consumers some of the complexity that previously existed, especially where this was as a result of a large number of legislative instruments which now may be brought together into one. This will also simplify matters for food importers and exporters, bringing as it does a largely common set of provisions together throughout the EU. Finally, the opportunity has been taken to review the enforcement of food information legislation.

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

2.1. Food labelling legislation has developed in a piecemeal way since the 1970's. Government intervention is necessary to:

- Correct for the potential market failure of asymmetric information in the provision of nutritional and allergen labelling information to consumers;
- Ensure consistency in food labelling requirements across the EU, reflecting current and future business practice; and
- Allow consumers to choose products based on their attributes.

2.2. The directly applicable EU Regulation 1169/2011 on the Provision of Food Information to Consumers Regulation (FIC) aims to do this. To meet the UK's EU legal obligations, enforcement provisions for FIC must be introduced and overlapping UK legislation removed. We must also decide which optional national measures to adopt.

3. What are the policy objectives and the intended effects?

3.1. It is necessary for the Government to put in place domestic legislation in order to enforce the FIC provisions in England and in order to take advantage of derogations that serve UK interests (and which otherwise would not apply).

3.2. The UK aims to introduce a new Statutory Instrument to:

- consolidate and update general food and nutrition labelling to remove confusing overlaps between the UK and EU legislation and to ensure a level playing field between EU and UK Food Business Operators (FBOs);
- minimise unnecessary regulatory burden on FBOs by taking advantage of appropriate national measures available in FIC and introducing a proportionate, risk-based enforcement regime; and,

- ensure key public health information such as nutrition and food allergy information is clearly presented to allow consumers to make informed and safe choices.

3.3. In addition, infraction will be avoided by introducing enforcement provisions and removing overlapping legislation.

3.4. The EU FIC is a directly applicable Regulation and therefore, except in respect of allowable national measures, it must be assumed that it will apply regardless of decisions made by national Governments. As the purpose of this Impact Assessment is to inform policy decisions, it considers only the impacts of those provisions over which there is a choice available for implementation. This affects the baseline we use for the analysis. The baseline policy option (option 0) is not 'Do nothing; Do not implement FIC', rather it is; implement the directly applicable FIC whilst retaining all existing national measures (where these do not conflict). The policy options consider variants of implementing the directly applicable regulation, for example to allow further national measures. The overall impacts of FIC were assessed separately for the consultation stage Impact Assessment¹. Details on what FIC entails are set out below.

3.5. Separate IAs are being carried out for amendments to other domestic legislation, such as the domestic Meat Products (England) Regulations 2003, from which overlaps with the FIC need to be removed and other existing domestic measures need to be reviewed.

4. EU FIC

4.1. FIC sets out the general requirements for information to be provided by Food Business Operators (FBOs) so that consumers have the information they need to make informed, safe and healthy food choices. It is a largely technical Regulation covering a number of issues including:

- Country of origin/place of provenance labelling;
- Mandatory nutrition declaration and voluntary front of pack nutrition labelling;
- Ingredients and nutrition labelling of alcoholic drinks;
- Consumer information about non-prepacked foods;
- Food Allergen labelling and information;
- Clarity of food labels and minimum font size;
- Labelling of plant origin of vegetable oil including palm oil;
- Labelling of engineered nano-materials; and
- Quantity labelling.

4.2. The main changes effected by EU FIC are presented in **Annex E**.

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/82667/consult-fic-ia-20121107.pdf. Also see the the European Commission FIC Impact Assessment is at http://ec.europa.eu/governance/impact/ia_carried_out/cia_2008_en.htm under 'Proposal for a Regulation on the provision of food information to consumers'.

5. Responsibilities and Devolved Administrations

5.1. Overall responsibility for this dossier lies with Defra as the lead department. However, we work closely with the Department of Health, Food Standards Agency and National Measurement Office on those issues where they have the policy lead. As food policy is a devolved matter there has been close co-operation between the UK Administrations and other Government Departments responsible for food labelling policy across the UK in negotiating the EU Regulation. We will continue to work closely with the UK Administrations in relation to the making of the domestic legislation to underpin FIC in order to ensure a consistent and coordinated approach where possible. However, the UK Administrations, who have the responsibility to bring in enforcement provisions in their countries, may take a different approach to take account of their legal structure and policy views.

6. National Measures

6.1. The FIC allows some limited flexibility for member States to adopt measures or continue existing national measures, on that basis that these do not adversely affect the functioning of the internal market or present a barrier to trade. Those relevant to the UK are examined below together with a recommendation on whether to retain/include the measures or not.

Meat Quantitative Ingredient Declaration (QUID) and Name of Food for loose products

6.2. During consultation, consultees were asked specifically about the costs and benefits of current business practice in relation to giving the name of food and meat content QUID for non-prepacked foods and whether they should be maintained. The very clear view of most consultees, including those from food businesses, was that these measures should be retained. These have therefore been included in the preferred option here rather than, as suggested in consultation, relying on the provisions of the Unfair Commercial Practices Directive (UCPD)².

Milk in glass bottles intended for re-use

6.3. The SI will contain a derogation in relation to milk and milk products in glass bottles intended for reuse, removing the requirement that nutritional information must be provided with these products. All three policy options include taking of this derogation, therefore it is not assessed separately under the options. Instead, the rationale for taking the derogation is set out below.

6.4. Adopting this derogation avoids costs to business arising from:

- Changes in packaging to provide the information either through printing on bottles or providing “collars” with the relevant information where labels were not previously used.

² The Unfair Commercial Practices Directive (UCPD) provides that consumers must not be misled by either the provision of, or absence of, information that, were it correctly given, would lead them to make a different purchasing decision. The scope of FIC is wider than the provision of information to prevent consumers being misled and extends to the provision of information to consumers for the sake of making sure that they are well-informed about the food available to them.

- Changes to production systems to ensure the correct bottles are used on the correct lines.

6.5. The 'doorstep' share of the milk market is approximately 6%, of which 79% is in returnable glass bottles, with those bottles being reused an average of 19.6 times³. Therefore, not taking this derogation could incur significant costs, both in terms of changing delivery and production practices and additional non-reusable packaging. However, taking the derogation also has a small potential disadvantage to consumers through not providing additional information. Due to the small size of the sector and the lack of requests from consumers for this information, this disadvantage is not considered to be significant. Most of the products consumed are repeat purchases of homogenous produce (i.e. milk), rather than less frequent purchases, so the lack of immediate information to consumers is less of an issue, and could easily be obtained through alternative means.

Ice cream, cream, cheese, labelling of 'low/no alcohol'.

6.6. In the public consultation held between September 2012 and January 2013 consultees were asked for views on whether or not to retain national measures on;

- Compositional requirements for Ice-cream
- Compositional requirements for cheese
- Compositional requirements for cream
- Permitted designations of no/low alcohol wine

6.7. Responses on these items came from the representative industry bodies (Dairy UK, Provisions Trade Federation for example) and from a small number of producers. While consultees generally supported the existence of commonly understood terms and standards for these items, there was a call for greater flexibility on the use of terms for cheese and ice-cream.

6.8. In order to introduce greater flexibility in the use of terms while retaining the mandatory nature of the national measures, additional regulation would have needed to have been made, against the Government's better regulation principles.

6.9. To avoid additional regulation, we have opted to allow, for the cheese, cream and; low/no alcohol wines regulations, a 'sunset period' of 4 years following the application date of FIR (13th December 2014) following which time the existing national requirements will lapse. This will give industry the opportunity to make other arrangements to ensure the continued quality of the products concerned while allowing flexibility to introduce, for example, 'low fat' variants of popular cheeses.

6.10. For ice-cream, there is already in existence a European voluntary standard that is widely used by the industry. This being the case, we intend to allow the national regulations placing requirements to the composition of ice-cream to lapse on the application date of FIR (13 December 2014) whereupon the voluntary standards will take over.

³ Email correspondence from Dairy UK

- 6.11. Main industry bodies have been consulted on these measures and are content.
- 6.12. Most FBOs affected by these changes will not be required to make any changes. Most have indicated that they will largely carry on as before, applying voluntary standards where currently they apply mandatory standards. Any changes that they do make will be made on a voluntary basis. We do not account for any changes in this IA.
- 6.13. For designations of low/no alcohol drinks, further consultation is taking place. Options include revocation of, or changes to existing national rules and/or a voluntary agreement with industry on the consistent use of terms ensuring consumer understanding.

Minced meat

- 6.14. Under the conditions laid down in the Food information to Consumers Regulations 2011/1169 Annex VI part B, designations of minced meat may only be used where the minced meat complies with certain compositional standards, checked on the basis of a daily average, as set out in the following table (point 1);

Table 1

	Fat content	Collagen/Meat protein ratio
Lean minced meat	≤7%	≤12%
Minced pure beef	≤20%	≤15%
Minced meat containing pigmeat	≤30%	≤18%
Minced meat of other species	≤25%	≤15%

- 6.15. In addition, the following expression must appear on the labelling;
- *'percentage of fat content under ...' and 'collagen/meat protein ratio under ...'* (point 2)
- 6.16. Point 3 of Part B states that 'The Member States may allow the placing on their market of minced meat which does not comply with the criteria laid down in point 1 of [Part B] under a national mark...'
- 6.17. We take 'a national mark' to mean an indication to the potential consumer that the product does not comply with the criteria laid down in the FIC, and specifically that either fat or collagen content is higher than the upper limit allowed under the Regulations.
- 6.18. The derogation only allows minced meat outside the upper fat and collagen limits to be placed on the national market under a national mark. It does not allow in addition a change of meaning of the designation 'lean minced meat', which may only be used for meat that, on the basis of a daily average, falls within the relevant composition limits.

6.19. Minced beef currently on sale in UK supermarkets ([percentage] of UK sales) tends to fall into one of five broad categories:

- Value minced beef, around 20% fat content
- Pure/standard minced beef, somewhere between 16 and 20% fat content
- Lean minced beef, targeted at around 12% fat content
- Extra lean minced beef, 7% or lower fat content.
- ‘Premium’ branding, for example ‘steak’ or ‘Aberdeen Angus’ can be anywhere along the range of fat levels

6.20. These correspond to the practical implementation of previous guidance and industry practice on labelling of minced beef.

6.21. In determining whether, and to what extent there may be an impact of allowing the minced meat derogation, the following table illustrates, for beef mince (by far the biggest sector), what the different impacts are.

Table 2

	Current	With derogation	Without derogation
Minced beef more than 20% fat and/or higher than 15% collagen/meat protein ratio	Is marketed as ‘value’ minced beef	May be marketed as ‘minced beef, for UK market only’ Must state fat content and collagen/meat protein ratio	May be placed on the market but may not be called ‘minced beef’ or anything similar. Need not state fat content and collagen/meat protein ratio as it will not fall within the scope of Annex VI Part B.
Minced beef 19% fat	Is marketed as minced beef	Market as ‘minced beef’. Must state fat content and collagen/meat protein ratio	Same as with derogation.
Minced beef 10 - 15% fat	Is marketed as ‘lean minced beef’	May be marketed as ‘minced beef’, or as ‘reduced fat’ (but not ‘lean’) provided that the fat content is at least 30% lower than that of a representative range of ‘minced pure beef’. As ‘reduced fat’ is a health claim, nutrition information will be mandatory. Must state fat content and collagen/meat protein ratio	Same as with derogation.
Minced beef 7% fat or under and 12% collagen/meat	Is marketed as ‘extra lean minced beef’	May be marketed as ‘lean mince beef’. Must state fat content and collagen/meat protein ratio.	Same as with derogation.

protein ratio or under			
Minced beef 3% fat	Is marketed as 'low fat minced beef'	May be marketed as 'low fat minced beef'. If collagen levels are sufficiently low, may additionally be designated 'lean (i.e. 'Low fat lean beef')' Must state fat content and collagen/meat protein ratio. As 'low fat' is a nutrition claim, nutrition information will be mandatory (as now) for products marketed as low fat products. In any event, in line with the general FIC provisions, nutrition information for minced meat will become mandatory for minced meat from 13 th December 2014.	Same as with derogation.
Steak mince (Note that Industry may be asked to explain fully what is meant by 'steak mince')	'steak' as descriptor may be used across the different fat levels and is not legally an indication of fat content.	No change. 'Steak' as descriptor may be used across the different fat levels provided the meat that has been minced is 'steak meat'. It is not legally an indication of fat content.	Same as with derogation.

6.22. During consultation, representatives of the meat industry contested that a key reason that they wanted the derogation to be taken up was not so much to allow 'high fat' minced meat (above 20% for beef, 30% for mince containing pig meat and 25% for minced meat of other species), rather, it was to allow them to continue to market meat under the descriptor 'lean', that did not meet the EU compositional criteria for 'lean meat'.

6.23. However, businesses **will** have to change practice in respect of minced meat labelled 'lean' as these products will, regardless of whether the derogation is allowed, need to meet the requirements, i.e. no more than 7% fat and a collagen/meat protein ratio of no greater than 12%.

6.24. This means that the only impacts of taking the derogation will be to continue to allow the sale of products with greater than 20% fat and/or 15% collagen/meat protein ratio (for beef mince). In these cases re-labelling will be required, in the form of the addition of a 'national mark', where minced meat is marketed with higher than the

allowed levels of fat and/or collagen, and stating that the product is for the UK market only.

6.25. The Department of Health (DH) has expressed concerns that if the derogation is allowed, products containing higher levels of fat are likely to be marketed to more economically disadvantaged consumers, with the attendant risk of exacerbating health inequalities. On the other hand, the 'Annex VI' provisions do require better labelling of fat levels, so consumers wishing to reduce intake will be able more easily to do so.

6.26. In terms of collagen, businesses have provided data which shows that current practice in selecting the cuts to use for minced meat may lead to an overall collagen/meat protein ratio that in many products can be variable and frequently exceeds the permitted level for beef of 15%. If they were no longer to be able to use these cuts industry claims that significant costs would result.

6.27. Both the overall derogation and the 'lean product' issue will have less of an impact on independent butchers as they sell beef mince that is markedly lower in fat than that sold by major retailers and supermarkets.⁴

6.28. Considering the factors outlined above, the desired outcome under the preferred option is that industry practice continues in terms of carcass utilisation, but that fat levels are kept within the FIC limits. Higher collagen levels do not contribute to detrimental public health outcomes and are therefore not a concern in this respect, though consumers should be given information on this quality aspect of minced meat in order that they are able to make choices in their interest.

6.29. The SI **will contain a derogation** allowing minced meat that does not meet the compositional requirements of FIC to be placed on the UK market. Defra will work with business to encourage them to use the derogation only to continue the utilisation of those sections of the carcass that otherwise would be excluded (so products marketed with the 'national mark' could have elevated collagen levels) rather than to place high-fat minced meat on the market. To ensure that these outcomes are achieved, a review will take place at three years following the derogation coming into place with the possibility of the derogation being withdrawn if it is widely used to sell high-fat minced meat.

7. Transitional Period and Review

7.1. The provisions of the FIC have staggered dates at which they come into force. The provisions of the FIC relating to the designation of minced meat apply from 1st January 2014. Most of the provisions of FIC will apply from 13 December 2014. Some provisions, namely the requirement to provide nutrition information on a mandatory basis for the majority of pre-packed food, will apply from 13 December 2016. These dates are detailed in the table below.

⁴ <http://www.lacors.gov.uk/lacors/NewsArticleDetails.aspx?id=24053> p17

7.2. We have taken an approach that will allow businesses to make changes to their labels in line with their scheduled labelling cycles. To facilitate this, the SI coming into force early in 2014 will remove a legislative obstacle to allow businesses to provide information on mandatory nutrition labelling in the new format early, on a voluntary basis. Without doing this, businesses deciding to update their labels early as permitted under FIC would not be compliant with existing UK rules. While FBOs would be protected by case law from being prosecuted, amending domestic legislation in this way means that the provisions in the domestic legislation will be updated to reflect the transitional provisions in FIC. This will support the choice of business, when providing voluntarily nutrition information, to use either the FIC or existing form (from the Food Labelling Regulations) of the nutrition declaration until (and including) 12th December 2014.

Table 3

Provisions	Date according to FIC	Relevant English law date
Ability to use minced meat labelling provisions about percentage of fat content and collagen/meat protein ratio in the FIC format.	13 December 2011	31 December 2013 The date shown is the coming into force date of the Food Hygiene (England) (Amendment) Regulations 2012.
Ability to choose between the old (FLR 1996) and new (FIC) format for nutrition declaration.	13 December 2011	Late 2013
Date at which the minced meat information must be given in the FIC format. Products labelled correctly before this date can be sold until stocks are exhausted.	1 January 2014	1 January 2014
Application date for the majority of provisions. Products labelled correctly before this date can be sold until stocks are exhausted.	13 December 2014	13 December 2014
Date at which the FIC format must be used when the nutrition declaration is given voluntarily or is required because a nutrition or health claim has been made or vitamins and /or minerals have been added to the food.	13 December 2014	13 December 2014
Date at which existing rules (2000/13 and FLR) are removed.	13 December 2014	13 December 2014
Date at which nutrition declarations become mandatory for the majority of pre-packed food. Pre-packed products placed on the market or labelled before this date which do not comply with the mandatory nutrition requirement may be sold until	13 December 2016	13 December 2016

stocks are exhausted. (N.B. Products in respect of which a nutrition or health claim has been made or to which vitamins or minerals have been added must carry nutrition labelling in compliance with the FIC from 13 December 2014.)		
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7.3. Other provisions in the domestic SI will come into force at different times to match the relevant FIC application dates, as shown in the table above. This will ensure businesses and enforcers are clear about when the provisions will apply.

7.4. Review

7.5. A review of these Regulations will be carried out before the end of a period of five years following the main application date of the EU FIC (13 December 2014)

8. Enforcement

8.1. Traditionally, enforcement of the Food Labelling Regulations 1996 has been done on a risk based approach. Where there is not a significant risk to human health, enforcement officers' work with businesses in their area to ensure food information complies with legal requirements. They do this through visits the timing of which is determined on a risk basis as well as through collaborative relationships under the primary and home authority principles. Enforcement action is often only pursued where informal action has been unsuccessful.

8.2. The approach to sanctions taken in the FIR SI is taking this concept further; Informal action will continue to be used, broadly, as it is now. However where this fails, or where there is repeated or gross breaches of labelling regulations an additional formal sanction will be made available in the shape of an 'improvement notice'. In fact apart from where there is a serious allergens offence, the first formal action would be an improvement notice. Criminal offences (in respect of labelling regulation) would only be available where businesses do not comply with the improvement notice or for failure to provide correct food allergen information which could have significant, potentially fatal consequences for allergic consumers.

8.3. There was not universal support for this approach from consultees. Some in retail thought that Improvement Notices were an additional and unwelcome sanction where none was necessary, noting that there was a risk that they would be used as replacements for minor issues currently dealt with by informal action. On the other hand the view was put forward that the Improvement Notice (IN) approach 'decriminalised' food authenticity offences at a time when this was just the wrong message to send to industry (since the horsemeat scandal).

8.4. On the first of these points, we intend to ensure that enforcement officials are given very clear guidance that INs should only be used where otherwise more stringent action would have been used, rather than to replace informal action. On the second, we believe that the concern is based around a misconception about INs. They are an effective means by which the regulations can be enforced. Cases of deliberate fraud may still be dealt with under fraud or other consumer protection legislation and, should a business not comply with the terms of an IN, criminal sanctions will be available.

8.5. On balance, we have proposed that the IN approach as described in the consultation is a proportionate and effective means of enforcing the Regulations.

9. What policy options have been considered including alternatives to legislation?

9.1. Introduction

9.1.1. In line with the coalition Government's EU principles, use of a non-regulatory route has been explored. Options considered included a concordat with businesses to ensure compliance was achieved. However, considering that a significant proportion of businesses in the food sector are small or medium sized enterprises (SMEs), as well as the rapid turnover of businesses in the sector, it was thought impossible to gain comprehensive consent of the industry rendering this approach ineffective as a means of ensuring that the UK's EU obligations were met.

9.1.2. Moreover, because a directly applicable EU Regulation is involved, we are legally obliged by EU law to directly put in place provisions that ensure that the EU Regulation is enforced. Failure to do so carries a risk of infraction fines which can be significant depending on the timescale at which the UK remained without an enforcement regime. The minimum infraction fine that can be imposed on the UK is 9.6 million Euros. An entirely non-regulatory route is not an option

9.2. Option 0; Do minimum

9.2.1. The do minimum option in this Impact Assessment is not a typical 'do nothing' option. Because we are dealing with a directly applicable regulation, 'do nothing' is represented by the implementation of FIC into UK law, in a way that is consistent with directly transposing the directive and making no other changes and keeping existing national measures. This amounts to:

- Allowing the derogation on minced meat so that higher fat/collagen minced meat (which can be produced in any country allowed to import into the UK) must carry a national mark indicating that it is for the UK market only.
- National measures on name of food and QUID continue to apply, as do national measures on the composition of cheese, ice cream and cream

9.3. Option 1;

As 'do minimum' except:

- New enforcement provisions allowing for the use of enforcement notices would be introduced
- The permitted derogation on minced meat composition would only be allowed to be used for two years following the application date of these provisions (1 January 2014).
- National measures on name of food and QUID continue to apply,
- National measures on the composition of ice-cream are revoked. National measures on the composition of cheese and cream are revoked after 4 years.

9.4. Option 2; This is, as presented for consultation, the preferred option:

As 'do minimum' except:

- New enforcement provisions allowing for the use of improvement notices would be introduced.
- National measures on name of food and QUID continue to apply.
- National measures on the composition of ice-cream are revoked. National measures on the composition of cheese and cream are revoked after 4 years.

Therefore Option 2 differs from the 'do minimum' option in that it brings in new enforcement provisions and revokes national measures on ice-cream, cheese and cream.

10. Options Appraisal: Costs and Benefits

10.1. Option 0 – Do nothing option

10.1.1. The EU FIC will result in some costs to businesses. An estimate of these costs was included as Annex A in the consultation stage Impact Assessment (for information, given that FIC is a directly applicable regulation, rather than as a part of the cost and benefit assessment)⁵. These stem chiefly from the requirement to provide mandatory information that is currently provided voluntarily, and from the requirement in many cases to alter the way that this information is presented to the consumer. Examples of the latter include the order in which nutrients are presented, the method of highlighting allergens and the placement of 'best before' information.

10.1.2. The 'do nothing' option as described above is the reference option against which other options are assessed.

10.2. Option 1; Costs

10.2.1. Minced meat

Industry/Consumer:

10.2.2. The major deviation from the baseline option here is that the derogation on minced meat (as described in detail above) will be taken for a period of two years only. Beyond that year, the derogation will no longer apply, and products will need to reduce their fat and collagen/meat protein percentages below the stipulated amount (e.g. 20% and 15% respectively for beef). Taking the derogation for a time period would allow businesses time and flexibility to reformulate their products to comply with the new rules, or otherwise to re-label them, appropriately. There are therefore two costs of this measure:

- Relabeling costs to include the national mark on packaging
- Reformulation costs to bring minced meat products below the required fat and collagen proportions.

We have made an estimate of the costs for the minced beef industry in the following paragraphs.

10.2.3. In order to assess **re-labelling costs**, we estimate that there are around 20 stock-keeping units (SKUs) above the 20% fat percentage and collagen/meat protein ratio for beef mince. We assume that they take the derogation in 2014-15, and re-label their products. At the end of 2015, they will need to reformulate their product in order to comply with the new regulations.

10.2.4. In reality two labelling changes will be required: to include the national mark for 2014 and 2015, and to remove the national mark and update the nutritional information for 2016 onwards. However, one labelling change is anyway required under FIR, so only one of these labelling changes is additional, and as a result of national measures.

⁵ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/82667/consult-fic-ia-20121107.pdf

- 10.2.5. We estimate that there are 20 beef mince products which do not meet the requirements (out of a total number of beef mince SKUs of around 150⁶). Although economy mince makes up approximately only 5% (by value) of the market, we assume that there are disproportionately more SKUs (compared to market value) as it is a cheaper product. Assuming a labelling cost of £1,800 per product⁷, this equates to a one-off re-labelling cost of £36,000.
- 10.2.6. In terms of **compliance costs**, there are uncertainties about how the market might evolve in response to revised rules. There are a variety of responses which could be taken by businesses in order to meet new requirements. They may choose to rename their product so that it is no longer 'minced beef' (or similar) and therefore falls outside of the regulations. They may choose to reformulate their products so that they meet the new requirements and are able to continue to market their product as 'minced beef' (or similar). They may choose to exit the market altogether. Any of these responses could have second-round impacts. Consumers may or may not respond to whether a product is called 'minced beef' (or similar), or some alternative name. If companies decided to exit the market, there is a question of how other firms might respond to fill the gap, and how they might do so. With reformulation, the leftover fat and collagen will either need to be disposed of, or will make it into the food chain through other products. Prices elsewhere in the market could therefore be affected (and waste potentially increased).
- 10.2.7. In an ideal approach, we would assess the impacts on consumer surplus as a result of responses by firms. However, this requires information on demand curves and firm responses which we do not have. The approach we have taken to estimate the costs is assessing the direct cost to producers of reformulation, assuming the same market size (in volume terms). This approach is proportionate as it is likely to give a fair assessment of the impacts of this option. More details of the analysis are available at Annex C.
- 10.2.8. We have assumed that businesses will reformulate their products in order to continue to sell them as 'minced beef' on the market. Some businesses may in fact choose to use a different name, or to exit the market altogether, but it is reasonable to assume that consumer demand for minced meat will continue to be met. As an estimate of the cost of reformulation, we assume that lean mince is mixed with >20% fat economy mince to provide the required fat composition. In reality, there may be cheaper means by which industry could reformulate, so the estimates may be seen as conservative.
- 10.2.9. In terms of collagen we only have very limited data available to us. From this we understand that there is a range of products for which collagen limits may be currently being exceeded, compared to fat levels. We also understand that there may be within-product variation, according to when the product is manufactured (as collagen is not 'targeted' in the way that fat levels are by manufacturers). From the data there does, however, appear to be a relationship between fat content and the collagen level, although the magnitude of the relationship is not large. Therefore, by reducing fat levels, it also appears to be the case that collagen levels could also reduce as a by-product and would therefore move the industry towards compliance. However, given the limited information, we are not certain that dealing with fat levels would necessarily ensure compliance with collagen limits.

⁶ Source: Kantar Worldpanel, 2013

⁷ See Annex B on estimating costs of label changes

- 10.2.10. We have estimated the reformulation costs as £4.86m per annum in this option, where the derogation is not taken. This represents around 1% of the overall market value, so is relatively small in those terms. However, we should note that this is based upon only incurring additional costs to reduce fat. Whilst minced meat is currently manufactured and routinely analysed for fat content, data for collagen is less complete and it may be, as industry sources have contested, that meeting the collagen criteria would be significantly more costly than our estimates. A figure of £300million has been cited by industry, though it is not at all clear how this could have been estimated given that the overall markets is only worth £400-500m. What is clear is that if the collagen levels are significantly in excess of 15% across a wider range of products, this may lead to significantly higher costs than estimated here.
- 10.2.11. Although this only assesses the beef element of the minced meat market, this represents by far the majority of the minced meat market, and is the only major concern of producers. The fat and collagen limits for minced meat of other species are well within current production levels, pigmeat in particular being lower in fat than prescribed by the FIC criteria.
- 10.2.12. Assuming a competitive market, and therefore that this cost is passed through, consumers will face the final burden of the increased cost. In which case, consumer demand may adjust in response to the higher prices. Consumers may substitute to other products, meat and otherwise, although there are reasons to think that demand will not be disproportionately affected by the increased cost. Demand may not be particularly elastic as the increased cost will be general to this class of mince product, rather than being product-specific. On the other hand, the increased cost of economy minced beef will be relatively significant – it is estimated to be an average increase of 24% for economy mince. Even a relatively inelastic demand, of -0.6⁸, would lead to a nearly 15% reduction in demand for affected minced beef products. Adjusted for expected demand changes, the direct cost is therefore reduced (this adjustment is already reflected in the £4.86m per annum cost above, estimated at £5.67m per annum without the demand adjustment).
- 10.2.13. However there will also be an element of lost consumer surplus which is not factored into this estimate. As well as some consumers substituting away from the product, consumers who continue to purchase lower value mince would lose some of their surplus utility. Producers may also lose producer surplus from the reduction in demand. In the absence of a known demand curve for this type of minced beef, we have not been able to take a consumer surplus approach to the analysis. However, we do know that the cost would be somewhat larger than £4.86m, although the difference may not be very significant. On the other hand, our initial cost estimate is likely to be an over-estimate of the cost of reformulation. Given these two uncertain impacts on the costs, which would work to offset each other, we use the £4.86m per annum estimate.
- 10.2.14. This cost estimate is uncertain. As noted above, the major risk to this estimate is significant changes in formulation are also required to reach required collagen levels. This cost is not known to us at present, but could be very significant, and represented a major concern for the industry. At the same time, if any of the alternative compliance routes are taken by businesses (for example, keeping the same fat content, but re-labelling), then the costs could be much lower, or close to zero. This dependency is mirrored in the analysis of health benefits (see below).

⁸ Family Food Survey 2011

10.3. Familiarisation Costs

10.3.1. Government:

- a. This cost has been monetised though it is contestable that these costs derive from the EU FIC rather than from the domestic Regulations (FIR). Enforcement authorities will need to become familiar with the updated Regulations and revised enforcement provisions. It is estimated that it would take one Trading Standards officer **1 hour** to read the guidance. Wage rates have been up-rated by 30% to account for non-wage labour costs and overheads, in accordance with the standard cost model.
- b. Based on the number of enforcement authorities (353) with responsibility for food this is estimated to **cost around £6,700**. Following a period of familiarisation, the burden of work will remain largely as before.

10.3.2. Industry:

- a. Industry will, in general, have to familiarise themselves with the directly applicable regulation. As discussed previously, we do not assess the impacts of that in this Impact Assessment. We instead are concerned whether there are any additional familiarisation costs as a result of the national measures, primarily in relation to the minced meat derogation. We assume that this element of familiarisation takes 1 hour for relevant manufacturers, retailers and wholesalers. The total familiarisation cost for these sectors is estimated to be £0.99m, occurring in the first year of revised regulations only. This is illustrated below in Table 4. The cost figure is a conservative estimate, because these cover all food and drink businesses in the relevant categories. Not all of these will need to familiarise themselves with the minced meat measure, and therefore costs could be lower.

Table 4: Industry familiarisation costs

	No. Of FBOs	Costs	
Manufacturers	5,910	£	157,367
Wholesale and Retailers	57,410	£	833,204
Total cost		£	990,571

10.4. Enforcement Costs

- 10.4.1. Enforcement costs are derived from the EU FIC rather than the national Regulations under examination here and are non-monetised. In the longer term, it is expected that the on-going costs to enforcement are likely to be comparable with

enforcement action currently taken by local authorities as part of a risk based approach to enforcement. However, in the short term there may be some additional enforcement costs from the new approach (which have not been monetised) arising from:

- Training on improvement notices and appeals for enforcers, although these may not be very significant as similar procedures are already being rolled out across food labelling and compositional regulations.
- Increased informal enforcement activity – enforcers are likely to have increased activity while businesses become familiar with the new requirements. This would be through the coaching role they play and through dealing with non-compliances under the new procedures.
- Potential for increased appeals – as this will be a new tool for enforcers and businesses. There may be increased appeals while all parties become familiar with the new requirements and processes.

Option 1 –Benefits

10.5. Industry: SI consolidation

10.5.1. Where currently there are 14 pieces of legislation to contend with, FIC and the SI consolidate these into one. There is an element of simplification in this though it should not be over-stated – the responsibilities on businesses do not reduce as a result of the number of SIs reducing. However, certainly those businesses which are inclined to get their information from primary sources in legislation rather than, and as well as, from guidance documents may derive a benefit from the provisions for their businesses being in one place.

10.5.2. Micro businesses will not tend to use legislative documents to access information on legal requirements, but will look to guidance from Government, local enforcement and trade bodies etc. Larger businesses however will, we assume, look to the legislation itself and therefore may derive simplification benefits from the consolidation of food information legislation from fourteen pieces of legislation down to one Statutory Instrument. We have not monetised this benefit, as it is not clear the extent of the benefits that business may derive.

10.6. SI consolidation – Enforcers

10.6.1. Similarly to companies, enforcers may also benefit from SI consolidation through spending less time referring to several SI documents, which takes time. Instead, the relevant regulations will be contained within one SI, to which enforcers can refer. We have not monetised this benefit as the benefits to enforcers are also uncertain.

10.7. Health Benefits (consumers)

10.7.1. Although there is an increased cost of minced meat, consumers will derive a health benefit from a lower intake of higher fat food. The Department of Health (DH) has expressed concerns that if the derogation is allowed, products containing larger amounts of fat are likely to be marketed to more deprived areas, with the

attendant risk of exacerbating health inequalities, with corresponding costs to health services.

- 10.7.2. In order to quantify the benefits to consumers, we have assessed the reduction in saturated fat intake, and the resulting QALY⁹ impact. Mirroring the assumptions used to assess the increased cost to consumers, we estimate QALY benefits at £6.23m for each year in which the derogation is not taken. Assumptions behind this calculation (and the additional industry/consumer cost calculation) are included in Annex C.
- 10.7.3. It should be noted that there is significant uncertainty on these estimates. The estimate of health benefits above assumes that, following the introduction of the FIC without a 'derogation', consumers would stop consuming minced beef with greater than 20% fat, and would substitute to 20% fat mince rather than substituting instead to another product with the same or higher fat levels (for example a beef/pork blend up to 30%). The underlying modelling which has generated the estimate is not based upon in-depth health modelling of sub-sections of the population and their current levels of saturated fat intake. It is instead based on a generalised health impact of increased saturated fat intake – i.e. that the saturated fat does harm to all those who eat the relevant products. Bearing in mind these assumptions, and those in Annex C, estimated health benefits would be considerable, outstripping our estimated potential costs to businesses of implementing such a change.
- 10.7.4. If on the other hand consumers were to substitute the removed product with a higher fat product for reasons of cost, health benefits would be negated (and health outcomes could even be worsened). An implicit assumption in these health estimates is that consumers do not change their minced meat purchasing behaviour significantly in the 'do nothing' policy scenario, as a result of the improved information from FIC. Because FIC aims to improve information provision to consumers, it might be expected that consumers make some changes to purchases as a result (if they were previously lacking information).
- 10.7.5. Finally, in the analysis it is assumed that consumers are not already internalising the health costs of higher fat products when making their purchasing decisions. In other words, consumers might already understand what they are purchasing, and they make those decisions based on the price and attributes of the product in question. If this was the case, this would argue against government intervention as there would not be a market failure being addressed – any intervention would be distorting and would reduce consumer welfare. Whilst this is possible for some, it is unlikely that it applies to anything more than a subset of consumers.
- 10.7.6. In summary, this benefits estimate is fairly uncertain, and the health improvements may not actually be realised. In the extreme, health benefits could be close to zero. However, our best estimate is consistent with the reformulation cost estimates we have also estimated above. These costs of reformulation would only be incurred if the market reformulated products for consumers, and hence in a market which clears consumers would necessarily accrue the health benefits.¹⁰

⁹ Quality adjusted life years

¹⁰ If it turned out that consumers currently buying >20% fat mince were not willing to purchase <20% fat mince at the higher price, then firms would stop making such products and hence the ongoing reformulation cost would not be incurred.

Therefore whilst both the health benefits and compliance cost estimates are subject to uncertainty, that uncertainty would shift both estimates in the same direction – if the health benefits were instead near to zero, then that would also apply to reformulation cost. The estimates are therefore internally consistent.

10.8. Enforcement Benefits

10.8.1. More flexible enforcement procedures for enforcement officers

10.8.2. As with enforcement costs, these benefits are derived from implementation of EU FIC and are non-monetised. There is a potential benefit to Government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime. It is anticipated that the gains would originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing improvement notices, and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a court case. Therefore, as well as benefits for enforcers, magistrate court costs may also be reduced.

10.8.3. However, this benefit is likely to be relatively small given the number of cases associated with food labelling dealt with by enforcers is anticipated to be small and, in the case of the new approach, there will be appeals against improvement notices to deal with.

10.9. A more proportionate enforcement regime for business

10.9.1. There may be benefit to industry in terms of moving from the current criminal sanctions regime to the new regime (for most FIC contraventions) of improvement notices backed up with a criminal offence. Any savings would originate from reduced costs and time saved to businesses, as fewer contraventions would need to be escalated to a Magistrates Court. It is anticipated that the vast majority will be resolved through the issuing of improvement notices.

10.9.2. During consultation, some businesses expressed some concern that Improvement Notices represented an additional and unnecessary enforcement capability, which they feared would replace informal action in some cases. We intend to provide clear guidance that this is intended to replace lower-level criminal action and not informal action, and is therefore a 'de-criminalising' measure, commensurate with Government policy in reserving criminal sanctions for where they are appropriate. We have not monetised these benefits.

11. Option 2 (Recommended)

11.1. As noted in setting out the options, option 2 only differs to the baseline option in that it introduces the change in enforcement procedures from criminal to civil sanctions. The impact of the changes in enforcement, and retention of national measures on QUID and name of food for loose products will be the same as for Option 1, and are not reproduced here (see above).

11.2. There would remain familiarisation costs for local authorities. Although the minced meat measure will not apply in this option, there will remain a need to familiarise themselves with the new enforcement procedures, as well as the removal of measures on non-pre-packed food. The familiarisation cost for local authorities is estimated to be the same as for Option 1 - £6,700. There would be no familiarisation cost to industry, in addition to that for the directly applicable FIC.

11.3. One additional impact of taking the derogation on minced meat is that the UK market cannot exclude imports from the EU of minced beef products which do not meet the FIC stipulations. As most other countries in the EU are not expected to take up the derogation, there is a risk that mince manufacturers in other countries will see the UK market as an outlet for products with higher fat and collagen levels. We are presently unclear whether this is likely to be an issue, and it would need to be monitored.

11.4. Whilst the monetised cost here is very small, this is relative to the 'do minimum' option. The small monetised cost reflects the relatively small changes from the 'do minimum' option, and that some of these are non-monetised. However, any non-monetised benefits are also likely to be small.

12. Approach to small businesses

12.1. An exemption for small businesses was not included in FIC as a significant proportion of businesses in this sector in Europe are small to medium size enterprises (SMEs). To introduce an exemption would undermine the provisions and reduce the likelihood of achieving the identified benefits. Table 5 shows the significant presence of SMEs in the food and drink sector¹¹.

12.2. In 2010, 161,095 businesses were operating in the food and drink manufacturing, wholesaling, retailing or catering sectors in England, of which over 99 per cent were identified as having SME status. Only 1.5% of FBOs are medium and large companies.

Table 5: Food Business Operator numbers operating in England in 2010, by firm size

	Micro	Small	Medium	Large	Total
Manufacture	4,320	1,205	455	170	6,150
Retail	22,470	1,540	100	20	24,130
Catering	100,420	15,350	1,105	250	117,125
Wholesale	11,455	1,865	315	55	13,690
Total	138,665	19,960	1,975	495	161,095

12.3. A number of measures have been included in FIC to minimise burdens on SMEs where possible. Examples of these include exemptions from the mandatory nutrition declaration when manufacturers of small quantities of handcrafted food supply directly to the final consumer or to local retail establishments supplying directly to the consumer as well as minimal requirements for foods sold pre-packed for direct sale.

12.4. As noted, in this Impact Assessment we are assessing the impact only of the preferred national measures. For the Options considered here, only allergen information

¹¹ All figures refer to bespoke analysis from the 2011 ONS Business Demography publication. The analysis was taken from all businesses that are active within the specified year.

will be required for non-prepacked food, including food pre-packed for direct sale, and there is some flexibility in how this information should be given. Should FBOs choose to supply nutrition information on a voluntary basis, the Regulation sets out rules governing its content and presentation in order that consumers are not misled. FIC only applies to the activities of FBOs. The Regulation makes clear those charity events where private individuals are supplying food to, for example, a church fete, otherwise than in the course of a business would be exempt from labelling their food, although they might want to supply allergen information on a voluntary basis.

12.5. For the minced meat derogation, the business profile size for those organisations affected is less tilted towards the micro size band, given that caterers are not expected to be affected. However, the size profile is still overwhelmingly SME. As such, small businesses would have been affected had the derogation not been taken.

13. Recommended Option

13.1. Table 6 below illustrates the costs and benefits of the two options compared to the 'do minimum'. The 'do minimum' and Option 2 are very similar, whilst Option 1 has the key difference of not allowing the minced meat derogation after 2 years. While it shows a net benefit from removing the derogation after two years, this is based on an assumption that businesses and consumers, especially, will respond in a particular way, for example, not substituting the 'withdrawn' higher fat minced beef with an equally or even higher fat product (for example beef and pork blend up to 30% fat). There are significant risks that the modelled outcome may not materialise. This is outlined in more detail above, and in Annex C.

13.2. Therefore, whilst the table below represents our central estimate of the costs and benefits, the risk that they will not respond in this way could negate the positive effect of not allowing the derogation. There is a significant risk that the benefits are lower, and, in particular there is a risk that the costs of addressing the collagen issue are significantly higher. For this reason the policy option (Option 2) that is recommended is to allow current practice to continue on composition but with the attendant improvements in nutritional and compositional information for consumers.

Table 6: Net present value of options

Option 1		Present Value (£m)
Costs	Familiarisation cost (enforcers)	0.007
	Familiarisation cost (business)	0.99
	Re-labelling cost (business)	0.04
	Reformulation cost (business/consumers)	32.26
Benefits	Health benefits	41.37
Net Present Value		8.07
Option 2		
Costs	Familiarisation cost (enforcers)	0.007
Benefits	N/A	0
Net Present Value		-0.007

13.3. The preferred option (option 2) is summarised below:

- Providing enforcement provisions in the form of an SI, revoking 14 existing SIs and minimising the additional burdens to business by taking advantage, where appropriate of available derogations and national measures.
- Through this option an SI will be produced putting into place offences and enforcement provisions, and setting out in English law those areas of Member State flexibility which are in UK businesses' and consumers' best interests. EU obligations would be fully met.
- Inconsistent domestic legislation – affecting the transitional arrangements under FIC - will be amended. This will clear the way for industry to take advantage of the transition period relating to the format of nutrition declarations whilst complying with domestic legislation. It will give businesses sufficient time to introduce any necessary label changes and familiarisation training for workers, incorporating these into ongoing and scheduled activity.
- The following derogations taken forward as national measures are;
 1. Use of Article 40 national measure for milk or milk products presented in glass bottles intended for reuse – ability to derogate from the mandatory requirements, to provide nutrition information, in Article 9(1).
 2. Use of Article 44 (1) power to impose a national measure to retain requirements to provide QUID declarations on the meat content of meat products sold non-prepacked.
 3. Use of Article 44 (1) power to impose a national measure requiring the provision of the name of non-prepacked food.

13.4. A derogation allowing minced meat to be marketed in England that does not meet the requirements of Annex VI Part B will be allowed.

13.5. Existing national measures setting composition standards for some ice-cream designations will be revoked. Existing national measures setting composition standards for some cheeses and creams will be revoked in 4 years.

Annex A

Council Directive 89/396/EEC which regulated food lot marking had been substantially amended several times. Because of this it needed replacing with a codified version of the amended Directive in the interests of clarity and was replaced by Directive 2011/91/EU. There were no changes of substance. Our domestic Food (Lot Marking) Regulations 1996 include a reference to Directive 89/396/EEC (reference is in the definition of the expression ‘first seller established within the European Union’). The reference to Directive 89/396/EEC in our domestic Regulations needs to be updated so that it refers to Directive 2011/91/EU instead. The consequential amendment (in paragraph 2 of Part 1 of Schedule 6 to the draft Regulations) effects this simple amendment.

The revocation of the Food Labelling Regulations 1996 and repeal of Directive 2000/13/EC as part of the FIC exercise will result in the need for other amendments to be made to the Food (Lot Marking) Regulations 1996 as from 13th December 2014. These amendments are contained in paragraph 1 of Part 2 of Schedule 6 to the draft UK Food Information Regulations.

The amendments that are being made, mainly to definitions, should have minimal if any impact on businesses.

Annex B – Estimating costs of label changes for FIC requirements

Label costs

Information from the 2010 Campden BRI study “Developing a framework for assessing the costs of labelling changes in the UK” looks at the total cost of all stages of the label cycle, from familiarisation of new legal requirements, re-design and auditing through to printing. The study concluded that the following costs would be incurred by businesses making minor or major label changes:

Extent of change	Average cost (£/SKU)	Trimmed Mean (£/SKU)
Minor change	£1,810	£1,800
Major change	£3,800	£3,330

Source: Developing a framework for assessing the costs of labelling changes in the UK

There are a number of variables which affect the costs of relabeling including size of firm, printing methods, type of market and type of product. In distinguishing between major and minor label changes the following descriptions are used:

Minor label change: only the text has been changed on a single face of the label and no packaging size modification was required to accommodate this.

Major label change: the text but also the layout and/or colours and/or format were changed and/or multiple faces of the package were affected. The change is also considered as major in each case when the process entailed packaging size modification.

We consider that the label changes consequent to the FIC and enabling SI are, by these descriptions, minor

Annex C: Assumptions for calculating costs and benefits of not taking the available derogation on high-fat/collagen minced meat

Costs of placing an upper limit of 20% fat and 15% collagen/meat protein ratio on minced beef

Fat.

To estimate the cost of bringing currently non-compliant minced beef into compliance we have made the following assumptions;

1. The vast majority of non-compliant minced beef is that sold as 'value' or 'economy' or similar marketing terms. In total, approximately 13,300 tonnes of this product is sold.
2. 8.3% of minced beef has a fat percentage in excess of 20%.¹²
3. The average fat content of this non-compliant minced meat is 25.7%, i.e. 5.7% above the limit set in FIC.¹³
4. Therefore approximately 9,800 tonnes of minced meat at 25.7% fat content must be replaced by the same quantity at 20%

We have used data provided by industry to estimate what the cost would be of re-formulating this non-compliant section of the minced meat market so that it comes down to 20%, using a simple method of substituting high-fat economy mince for more expensive 'lean' meat to bring overall fat levels down. This could be a more expensive method than would be used in practice, and may therefore be conservative. In effect, the reformulation is assumed to blend 6,900 tonnes of 25.7% 'economy' meat is blended with 2,800 tonnes of 'lean' (6%) minced meat to make 9,800¹⁴ tonnes of 20% minced meat.

Given the information from industry on volumes and values, this entails:

- An addition of 2,800 tonnes of 'lean' mince @ £3,600/t (=£10.30m)
- A decrease of 2,800 tonnes of economy mince @ £2,00/t (=£5.63m)
- And therefore a net cost of £4.67m
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Given that the value figures are in 2008 prices, these are up-rated to 2013 prices (21.5% increase). The net cost in 2013 prices is £5.67m++.

We then adjust this cost estimate for a demand reduction which originates from the price increase. Assuming a price elasticity of demand of -0.6¹⁵, the elasticity adjusted final cost is £4.86m.

Collagen

There are conflicting accounts of the levels of connective tissue in minced meat sold in England. A survey in 2010 carried out on behalf of Local Authorities in England showed that the large majority of minced beef was within the collagen/meat protein ratio limits in FIC (15%). The limits

¹² Kantar WorldPanel data 2011 (sourced from Department of Health)

¹³ Kantar WorldPanel data 2011 (sourced from Department of Health)

¹⁴ NB: These figures are rounded to the nearest hundred tonnes – the rounded figures may not add up.

¹⁵ Family Food Survey 2011

themselves are specified to be calculated on the basis of a 'daily average' meaning that, given reasonable estimates of tolerance levels, much of the remaining sample that was outside the limits would have been from daily batches that met the requirements overall.

On the other hand the British Meat Processors Association (BMPA) and a major producer have countered this data with the contention that most of their current production would fall outside the FIC limits to such a degree that if they were to be forced to meet the composition limits on collagen, the effect on the industry would be very significant.

Having considered survey data on collagen content of minced beef, it seems likely that the solution set out above to bring fat levels into line with FIC limits, i.e. the substitution of some 'economy' mince with 'lean', will also have the effect of bringing collagen levels into compliance. However the data is incomplete and the costs of refusing the derogation could, for collagen rather than fat reasons, be considerably higher.

Public Health Benefits of a 20% limit on the fat content of minced beef

The health benefits assessment assumes:

- Saturated fat intake per 100g of mince is reduced from 11.0g/100g¹⁶ to 8.5g/100g as a result of the reduced fat content of minced meat.
- A QALY has a monetary value of £60,000¹⁷
- 52g of beef mince is eaten per person per week¹⁸
- Approximately 8.3% of this consumption is of affected mince.¹⁹
- The average person eats 175g per week of saturated fat²⁰
- Saturated fat represents 13.1% of overall energy intake²¹
- The effect of reducing the fat content of mince to is to reduce overall saturated fat intake by 0.065%, and saturated fat intake as a percentage of overall energy intake by 0.0085%.
- A reduction of saturated fat, as a percentage of overall energy intake, of 0.5% equates to 7176 QALYs across the population.
- Therefore the reduction in saturated fat from this measure equates to 121 QALYs $(=(0.0085\%/0.5\%)*7176)$.
- The total, monetised, QALY benefit is £7.28m per annum. The elasticity assumptions used to calculate the costs are mirrored here to leave a net benefit of £6.23m per annum.

¹⁶ McCance and Widdowson database

¹⁷ DH guidance.

¹⁸ Family Food Survey 2011

¹⁹ Kantar WorldPanel, 2011 (sourced from DH)

²⁰ National Diet and Nutrition Survey

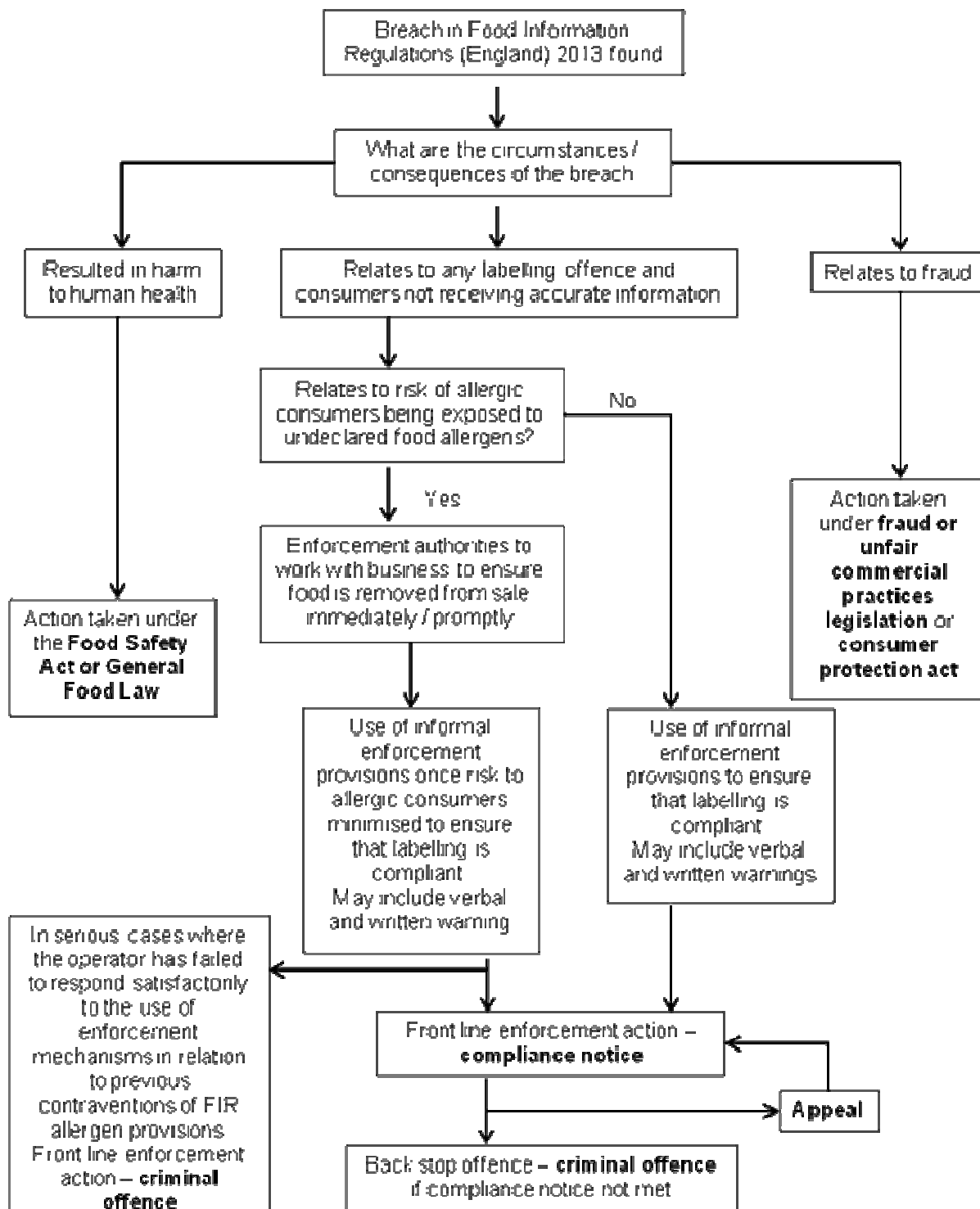
²¹ National Diet and Nutrition Survey

Public health benefits; Risks in assumptions

1. **Health benefits may not fully materialise.** The public health benefits calculation assumes that as minced beef containing more than 20% fat is withdrawn from the market, and that consumers will switch to a product with 20% fat content. However, given that minced meat containing pig-meat with up to 30% fat will be able to remain on the market, it is also possible that producers will market a beef/pork mince blend of 20%-30% and that some consumers will switch to this for cost reasons. At the same time, reformulation costs mirror the health benefits – if consumers switch to other products then there is no need for industry to reformulate.
2. **Improved information may deliver health benefits.** FIC requires additional information to be given to consumers than is currently provided. In particular a declaration 'percentage of fat content under...' must appear on the labelling and, for minced meat where fat or collagen levels exceed those in FIC a 'national mark' should be included. There is mixed data on consumer responses to nutritional labelling, but if consumers are intending to reduce their intake of harmful fat, their ability to do so will be improved by these provisions, in which case the full extent of the benefits estimated above would not materialise.

The main evidence contains a discussion of the public health benefits, and risks to them being realised.

Annex D



Annex E

Main changes effected by EU FIC

1. European requirements on food information and labelling have been in place since 1978 and been subject to a significant number of amendments. The rationale for Commission intervention and these Regulations was the need to update and consolidate regulation in this area, with the intention that review and simplification would be beneficial to consumers and businesses. The Regulation brings together both general and nutrition labelling provisions in a single directly applicable regulation. There is also a recognition that while a number of horizontal directives are already in place, for example foods containing quinine and caffeine, the area would benefit from review and consolidation of all such requirements into a single Regulation. A further objective was to ensure consistency of labelling requirements across Europe by replacing the current Directives with a single Regulation, ensuring a 'level playing field' and a competitive market for all businesses operating within the EU.
2. There was also a need to ensure that labelling information is in line with consumer needs and reflects changes in eating habits and consumer lifestyles. Provisions that reflect this include:-
 - Distance selling. With the increase in sales of food online it was recognised that measures were needed in order to ensure consumers were receiving similar amounts of information when purchasing using distance communication such as catalogues and the internet as they would when shopping in store
 - Mandatory nutrition labelling for most pre-packed foods
 - Easy to access voluntary nutrition information. FIC provides a common basis for easy to access voluntary front of pack labelling. This makes it easier for consumers to understand the information when provided and helps ensure that where additional forms of expression are used that it can be demonstrated that they are understood by consumers.
 - Easier to access food allergy information. Highlighting the allergens in the ingredients list in pre-packed foods will allow allergic consumers to access the information quickly so that they can make safe food choices.
 - Extension of provisions for allergen information for non-pre-packed foods, including in cafes and restaurants.
3. The FIC contributes to the healthy eating and obesity challenge through improved information for consumers on the nutrients present in their food. This is due not only to the requirement for a mandatory nutrition declaration, but also to the provision of a framework for voluntary nutrition information, ensuring that where information is provided on a voluntary basis, it does not undermine the benefits to consumers of the mandatory requirements. Through this framework, labelling schemes developed in the UK can continue and will be used across Europe, ensuring that there is a level playing field for industry and that consumers are not confused or misled by the information they receive
4. For minced meat, the requirement that it should bear a statement of both fat percentage and collagen/meat protein ratio are important consumer benefits. These are essential indicators of the nutritional value and quality of the product and provide consumers with consistent information with which to make purchasing decisions.

5. For meat products, meat preparations and fishery products containing added proteins such as hydrolysed proteins, of a different animal origin, the name of the food shall bear an indication of the presence of those proteins and of their origin. This will benefit consumers who for cultural or religious reasons choose not to eat certain species of meat.
6. For meat and fish products and preparations which have the appearance of a cut, joint, slice, fillet or whole fish where added water makes up more than 5% of the weight of the finished product the name of the food shall include an indication of the presence of added water. .
7. Meat products, meat preparations and fishery products which may give the impression that they are made of a whole piece of meat or fish, but actually consist of different pieces combined together by other ingredients, including food additives and food enzymes or by other means, shall show 'formed meat' or 'formed fish' as appropriate.
8. The FIC also contributes to managing public health issues such as the presence of liquorice or phytosterols in food, which particular groups need to be aware of in order to ensure that products containing these ingredients are not over-consumed to avoid adverse health effects.
9. The FIC extends the mandatory requirement for allergy information to non-prepacked food but allows the FBO some flexibility in how this is provided. This has previously been a sector where the greatest proportion of severe/fatal food allergic reactions has occurred, with some 75% of reactions occurring after eating food sold non-prepacked²².
10. The impacts of the provisions on country of origin labelling and net quantity requirements are not included in this IA. Some country of origin requirements come into force without the need for further EU action, i.e. those in Article 26(2)(a) of FIC²³. The nature of the information to be given when country of origin information becomes mandatory remains under discussion in the EU. [Defra has established a negotiating position on this based around principles of minimising burdens to business while providing consumers with the information they need to make safe and informed choices.] Once agreed, enforcement provisions to support these areas will be needed and the impact of these provisions will be assessed at that time.
11. The net quantity provisions are being considered as part of a separate simplification exercise on weights and measures requirements and legislation for food being undertaken by the National Measurement Office (NMO). The cost and benefits of those provisions will therefore be assessed in that exercise and are not outlined here.
12. At present the requirements for general labelling of food are set out in Directive 2000/13/EC of the European Parliament and of the Council and requirements relating to nutrition labelling are set out in Council Directive 90/496/EEC. Both are implemented in the GB (with

²² Pumphrey, RS. 2000. Lessons for the management of anaphylaxis from a study of fatal reaction. *Clinical and Experimental Allergy*. Vol 30, pages 1144-1150. Pumphrey, RS and Gowland, MH. 2007. Further fatal allergic reactions to food in the United Kingdom 1992-2006. *J Allergy and Clinical Immunology*. Vol 119, pages 1018-9.

²³ Indication of the country of origin or place of provenance shall be mandatory [...] where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance;

separate regulations in Northern Ireland) by the Food Labelling Regulations 1996 (as amended) (FLR). These cover much of the same areas as the new EU FIC Regulation although as a result of the consolidation and review in Europe some of the requirements have changed or been extended. FIC repeals both 2000/13 and 90/496/EEC, as well as other EU legislation. We need to revoke the FLR as the domestic legislation implementing the requirements of 2000/13/EC and 90/496/EEC. We also need to introduce provisions to enforce the FIC in England due to EU legal requirements and to take advantage of derogations and any additional permitted national measures which serve England's interests.

13. As noted above, this Impact Assessment is concerned with those measures over which the UK has a choice, including derogations and national measures. Some national measures permitted by FIC already exist in current UK legislation. These include the following:

- mandatory requirement to provide a Quantitative Ingredient Declaration ('QUID') indication of meat content in meat products sold loose; and
- mandatory requirement to indicate the 'name of food' for foods sold loose.

14. In addition, the Regulations will;

- (a) Implement the relevant irradiated food provisions in Article 6 (1) of 1999/2/EC. No food is currently irradiated in the UK and very little, if any, irradiated food is sold in the UK, so this is simply for legal completeness. These provisions were previously implemented by the Food Labelling Regulations 1996, as amended, and no substantive changes are being introduced.
- (b) Update the Food (Lot Marking) Regulations 1996 to take account of the recast of 89/396/EEC. Most of the amendments that are being made, mainly to definitions, should have minimal if any impact on businesses.

