

Explanatory Memorandum to the Food Information (Wales) Regulations 2014

This Explanatory Memorandum has been prepared by the Food Standards Agency (FSA) and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Member's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Food Information (Wales) Regulations 2014. I am satisfied that the benefits outweigh any costs.

Mark Drakeford, AM

Minister for Health and Social Services, one of the Welsh Ministers

27 August 2014

The Food Information (Wales) Regulations 2014

1. Description

The proposed Regulations provide for the domestic enforcement of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers ("FIC")¹ to be enforced in Wales. The new Regulations also consolidate and update existing general food and nutrition labelling Regulations in Wales. In addition, the Regulations take advantage of derogations contained in FIC and carrying forward some (EU permitted) national measures.

2. Matter of Special Interest to the Constitutional and Legislative Affairs Committee

None.

3. Legislative Background

The powers enabling this instrument to be made are as follows:

- section 2(2) of and paragraph (1A) of Schedule 2 to the European Communities Act 1972;
- sections 6(4), 16(1), 17, 18, 26, 45 and 48 of, and paragraphs 1 and 4(b) of Schedule 1 to, the Food Safety Act 1990; and
- sections 4(1), (2), (3), (4) and (8) and 10 of the Healthy Eating in Schools (Wales) Measure 2009.

There are no issues of regularity or propriety for the Welsh Government arising from the making of the 2014 Regulations.

4. Purpose and Intended Effect of the Legislation

EU FIC came into force in the EU on 13 December 2011 but the majority of provisions apply from 13 December 2014 however, the minced meat provisions have applied from 1 January 2014.

The EU FIC is a large piece of EU legislation regulating general food labelling requirements in Europe. This includes important mandatory particulars on food labels such as: name of food, ingredients list, quantitative ingredients listing (QUID), allergen information, nutrition information, country of origin, date marks, storage conditions.

¹ The full title is: Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ No L 304, 22.11.2011, p 18).

The policy aims are:


- (a) to meet the UK's legal obligations by including a proportionate, effective and risk based approach to the enforcement of the directly applicable EU FIC, and to remove any overlapping UK food labelling legislation;
- (b) to allow consumers to have the information they need to make informed and healthy food choices and to ensure they are not being misled; and
- (c) to protect allergic consumers by allowing them to have sufficient and clear information to make safe food choices.

The Regulations also take advantage of optional derogations and (as in the Food Labelling Regulations 1996) includes EU permitted national measures requiring the name of the food to be given in the case of non-prepacked etc. foods and a meat quantity indicator to be given for certain non-prepacked etc, e.g foods containing meat.

A change to the existing enforcement regime has also been taken forward with a move away from the across-the-board use of frontline criminal offences to a more proportionate and targeted regime using improvement notices. A backstop criminal offence will be in place where there is failure to comply with an improvement notice, with an offender being liable, on summary conviction, to a fine not exceeding level 5 (currently £5,000 but this will change when section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 is commenced). Criminal offences will continue for the contravention of certain provisions, namely mislabelling of foods containing allergenic ingredients because a failure to comply with the allergen provisions may result in a risk to consumer health and safety. Businesses will have the opportunity to appeal against an improvement notice to the Magistrates Court

Some of the main aspects of interest are:

(a) Derogations

- Inclusion of a derogation of not requiring all the mandatory particulars for milk and milk products presented in glass bottles intended for re-use. This is because it avoids unnecessary additional burdens and enables an effective re-use of materials.
- Inclusion of a derogation for minced meat that does not comply with the fat and/or collagen compositional requirements of EU FIC. Such products will have to be labelled with a national mark e.g.  'For UK Market only' indicating that these products are for the UK market only.

(b) National Measures (permitted by EU FIC)

- A national provision that the 'name of food' should be provided for loose foods. This is similar to the national measure that already exists in the Food Labelling Regulations 1996.
- A national provision requiring a 'quantitative ingredient declaration' (QUID) of the meat content of loose meat products. This is similar to the national measures that already exist in the Food Labelling Regulations 1996.

- A national provision allowing information on allergens for non-prepacked to be provided in any manner, including orally. Where oral communication is used, there must be a clear indication via a label attached to the food, or on a notice/menu/ticket/label that the allergen information can be obtained from a member of staff. Unlike the national provisions relating to the name of the food and the quantity indicator for products containing meat, this national provision applies in the case of loose foods sold by mass caterers to a final consumer and provision is therefore made allowing for the necessary information to be given on a menu.

(c) Other National Measures

- National composition rules on ice cream will be revoked on 13 December 2014.
- National composition and labelling rules on cheese, cream and alcohol-related claims will be revoked on 13 December 2018. During the four years from the coming into force date of the FIC, with consumers, industry and enforcement authorities to consider what, if anything, might be appropriate in terms of the future control and protection of these products.
- All other National Measures contained within the Food Labelling Regulations will be revoked when these Regulations come into force.

(d) Other Labelling Requirements

- There is a requirement that the words “irradiated” or “treated with ionising radiation” must be provided when irradiated food products or food products containing an irradiated ingredient are sold in bulk and when irradiated ingredients are used in certain pre-packed foods. This implements certain provisions of Article 6 of Directive 1999/2/EC and replaces a similar provision in the Food Labelling Regulations 1996.

5. Regulatory Impact Assessment.

Costs and Benefits

1. The IA considers the impact of those provisions over which there is a choice available.

Baseline (Do Nothing)

2. 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 directly applicable regulation, rather than as a part of the cost and benefit assessment)². 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.

² <http://www.food.gov.uk/news-updates/consultations/consultations-wales/2012/fir-wales-2013>

3. This 'Do nothing' option as described above is the reference option against which all other options as assessed.

Option 1A

Costs

Industry

Implementation of Member State Flexibility, FIC point 3 of Part B of Annex VI – Implementation of a national mark for minced meat

4. Under the conditions laid down in the Food information to Consumers Regulation (EU 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 of 2011/1169, Annex VI part B);

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%

5. In addition, the following expression must appear on the labelling; *'percentage of fat content under ...' and 'collagen/meat protein ratio under ...'* (point 2 of 2011/1169, Annex VI part B).

Point 3 of Annex VI 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. The UK takes '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.

7. 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.
8. Minced beef currently on sale in UK supermarkets 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
9. These correspond to the practical implementation of previous guidance and industry practice on labelling of minced beef.
10. There are therefore two assumed costs associated with this measure, either:
 - Relabeling costs to include the national mark on packaging
 - Reformulation costs to bring minced meat products below the required fat and collagen proportions. (N.B. This cost would not apply should affected businesses choose to take advantage of the derogation).
11. The UK has made an estimate of the costs for the minced beef industry in the following paragraphs.
12. In order to assess **re-labelling costs**, we estimate from engagement with the food industry 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 advantage of the derogation in 2014-15, and re-label their products.
13. The UK estimates that there are 20 beef mince products which do not meet the requirements (out of a total number of beef mince SKUs of around 150³). Although economy mince makes up approximately only 5% (by value) of the market, we have assumed that there are disproportionately more SKUs (compared to market value) as it is a cheaper product. Assuming a labelling cost of £1,800 per product⁴, this equates to a one-off re-labelling cost of £36,000.
14. 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

³ Source: Kantar Worldpanel, 2013

⁴ See Annex B on estimating costs of label changes

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).

15. We have estimated the reformulation costs as £174k 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 market 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.
16. 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.
17. 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 -0.6%⁵, 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 £174k per annum cost above, estimated at £204k per annum without the demand adjustment).

⁵ Family Food Survey 2011

Enforcement

18. 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.

Consumers

Removal of Member State flexibility, power to impose a national measure to retain requirement to provide Quantitative Ingredient Declarations (QUID) declarations on the meat content of meat products sold non-prepacked

19. The removal of this measure means the potential loss of information consumers are used to seeing on their food, although information is likely to be caught under the Unfair Commercial Practices Directive, this removed the direct requirement to provide the information.

Removal of Member State flexibility, requirement to provide name of food on products sold non-prepacked

20. The removal of this measure means the potential loss of information consumers are used to seeing on their food, although information is likely to be caught under the Unfair Commercial Practices Directive this removed the requirement to provide the information.

Familiarisation Costs

Government

21. 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.
22. Based on the number of enforcement authorities (22) with responsibility for food in Wales this is estimated to **cost around £415 per hour**. Following a period of familiarisation, the burden of work will remain largely as before.

Industry

23. 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 £53,802, 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	410	£ 10,917
Wholesale and Retailers	2,980	£ 42,885
Total cost		£ 53,802

Benefits

SI consolidation

Industry

24. 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.

25. 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.

Enforcers

26. 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.

Enforcement

More flexible enforcement procedures for enforcement officers

27. 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.
28. 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.

A more proportionate enforcement regime for business

29. 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.

30. 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 in respect of this matter for enforcers and food business operators

Consumers

30. There are no significant benefits for consumers.

Option 1B (Preferred Option)

Costs

Industry

31. Costs are the same as for option 1A except those set out below:

Continuation of Member State flexibility, Article 44 (1) power to impose a national measure to retain requirement to provide Quantitative Ingredient Declarations (QUID) declarations on the meat content of meat products sold non-prepacked.

32. There are no additional costs for this measure as businesses are already required to provide this information.

Continuation of Member State flexibility, Article 44 (1) power to impose a national measure to retain the requirement to provide the name of the food on products sold non-prepacked packs.

33. There are no additional costs for this measure as businesses are already required to provide this information.

Member State flexibility, Article 44 (1) (a) allowing information on allergens for loose foods to be provided in any manner including orally. Where oral communication is used, there must be clear indication via a label attached to the food, or on a notice/menu/ticket/label that the allergen information can be obtained from a member of staff. Unlike the national provisions relating to the name of the food and the quantity indicator for products containing meat, this national provision applies in the case of loose foods sold by mass caterers to a final consumer and provision is therefore made allowing for the necessary information to be given on a menu.

34. The costs of this measure are subsumed into the familiarisation cost for businesses and compliance with the directly applicable EU Regulations. There is no additional cost for businesses.

Enforcement Costs

35. Costs are the same as option 1A

Consumers Costs

36. There are no significant costs to consumers

Familiarisation Cost

Government

37. Costs are the same as option 1A

Industry

38. Costs are the same as option 1A

Benefits

SI Consolidation

Industry

39. Costs are the same as option 1A

Enforcers

40. Costs are the same as option 1A

Enforcement

More flexible enforcement procedures for enforcement officers

41. Costs are the same as option 1A

A more proportionate enforcement regime for business

42. Costs are the same as option 1A

Consumer

43. This is a non monetised benefit. The retention of National Measures on Quid and Name of food means the continuation of valuable consumer information.

Option 2

Costs

Industry

44. Costs are the same as option 1B except those set out below:

Member State Flexibility on use of Article 44 (1) power to impose national measures requiring some or all of the mandatory particulars detailed in Articles 9(1) other than the name of the food, (separately addressed in point 2 above) e.g. list of ingredients, storage conditions and/or conditions of use, the name or business name and address of the food business operator, etc. and 10(1) to be provided in relation to non-prepacked food .

Member State Flexibility on use of Article 43 power to impose a national measure on the voluntary indication of reference intakes for specific population groups. For example, the provision of guideline daily amounts (GDAs) reference intakes for children, in addition to the current requirement to provide GDAs for an average adult. As provision of reference intakes for specific groups would remain voluntary, this national measure would not itself impose costs on business. However, there would be a cost to FBOs that chose to adopt them.

Member State Flexibility on use of Article 35(3) power to require FBOs to notify any Additional Forms of Expression (AFE's) used for front of pack nutrition labelling and to provide justification regarding fulfilment of the AFE criteria. As AFEs are voluntary, this national measure would not itself impose costs on business. However, there would be a cost to FBOs that chose to adopt them.

45. These costs are all non-monetised.

Enforcement

46. Costs are the same as option 1A & 1B

Consumers

47. There are no significant costs to consumers

Familiarisation Cost

Government

48. Costs are the same as option 1A & 1B

Industry

49. Costs are the same as option 1A & 1B

Benefits

SI Consolidation

Industry

50. Costs are the same as option 1A & 1B

Enforcers

51. Costs are the same as option 1A & 1B

Enforcement

More flexible enforcement procedures for enforcement officers

52. Costs are the same as option 1A & 1B

A more proportionate enforcement regime for business

53. Costs are the same as option 1A & 1B

Consumers

54. This is a non monetised benefit. The retention of additional three National Measures on This will increase consumer information and choice.

Approach to small businesses

55. 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 sector⁶.

56. In 2012, 9,580 businesses were operating in the food and drink manufacturing, wholesaling, retailing or catering sectors in Wales, of which over 99 per cent were identified as having SME status. Only 1% of FBOs are medium and large companies.

Table 5: Food Business Operator numbers operating in Wales in 2012, by firm size

	Micro	Small	Medium	Large	Total
Manufacture	346	57	6	1	410
Retail	2,113	349	35	8	2,505
Catering	5,221	861	87	21	6,190
Wholesale	401	66	7	2	475
Total	8,081	1,333	134	32	9,580

57. 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.

58. 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 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.

59. 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

⁶ All figures refer to bespoke analysis from the 2012 ONS Business Demography publication. The analysis was taken from all businesses that are active within the specified year.

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.

Preferred option

60. The preferred option (option 1B) 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 Wales 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 arrangement 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.

61. The following derogation taken forward as national measures are:

- 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)
- 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.
- Use of Article 44 (1) power to impose a national measure requiring the provision of the name of non-prepacked food.
- Use of Article 44 (1) (a) power to impose a national measure allowing information on allergens for loose food to be provided in any manner including orally. Where oral communication is used, there must be clear indication via a label attached to the food, or on a notice/menu/ticket/label that the allergen information can be obtained from a member of staff.

62. A derogation allowing minced meat to be marked in Wales that does not meet the requirements of Annex VI Part B will be allowed.

63. Existing national measures setting compositional standards for some ice-cream designations will be revoked. Existing national measures setting compositional standards for some chesses 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 I 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 13 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

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-prepacked⁷.
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 FIC⁸. The nature of the

⁷ 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.

⁸ 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

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 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 Northern Ireland due to EU legal requirements and to take advantage of derogations and any additional permitted national measures which serve Northern Ireland's interests.

13. As noted above, the 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

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;

Food Labelling Regulations (Northern Ireland) 1996, as amended, and no substantive changes are being introduced.

- (b) Update the Food (Lot Marking) Regulations (Northern Ireland) 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.