

Explanatory Memorandum to the Meat Products (Wales) (Amendment) Regulations 2008

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

Description

These regulations implement European Commission Directive 2004/41/EC (Article 2) which repeals Directive 77/99/EEC. The amending Regulations implement changes to the Meat Products (Wales) Regulations 2004 (MPR) by removing labelling requirements relating to added starch and added protein from either animal (same species to the meat) or vegetable origin in certain meat products.

Matters of special interest to the Subordinate Legislation Committee

None.

Legislative Background

The powers enabling the Regulations to be made are contained in Sections 16(1) (e) and 48(1) of the Food Safety Act. These are exercisable by Welsh Ministers. The Regulations are subject to the Assembly's negative resolution procedure.

Purpose and Intended effect of the legislation

Objectives

There are two overall objectives:

- to bring labelling requirements for added starch and protein in certain meat products into line with European labelling requirements (and revocation of an equivalent national provision relating to meat preparations); and
- to issue new related UK guidance.

For the purposes of this explanatory memorandum (EM), protein means any protein of either vegetable or animal (where the animal is same species to the meat). The current name of the food requirements for the labelling of added ingredients of animal origin that is from a different species to the meat, including in so far as they relate to proteins, will remain. The guidance referred to relates to starch and protein only.

The objective of the proposed amendment to the Regulations is to bring labelling requirements for added starch and protein in certain meat products into line with European labelling requirements.

The main objectives of the related guidance are:

- to ensure clear information about the relevant meat products for consumers so that they can make informed choices;
- to give a guide on compliance with the legal requirements of the proposed amendment Regulations;
- to encourage a common understanding across industry and between enforcement authorities by:
 - giving a guide on compliance with the legislation; and
 - giving guidance on best practice; and
- to reduce administration burdens on industry by giving guidance on best practice as to when to indicate the presence of starch and protein in the name of the food.

The proposed legislative change involves removal of the name of the food labelling requirements related to added starch and protein from regulation 5 (and the corresponding exemptions from Schedule 3) of the MPR to bring them into line with amended European legislation. The general labelling provisions of the Food Labelling Regulations 1996 (as amended) (the FLR) will continue to apply, as will the Food Safety Act 1990.

The proposed new legislation will apply to Wales only. Parallel amending Regulations will apply in England, Scotland and Northern Ireland. The guidance is UK-wide and will be applicable to all four countries.

The aim of the Regulations and associated guidance is principally to provide the consumer with information concerning the name of the food for meat products that look like a cut, joint, slice, portion or carcass of meat or of cured meat.

The changes to the European legislation that necessitate the amendment Regulations have already been effected and came into force on 1 January 2006. To avoid any further delays and the possibility of infraction proceedings by the European Commission, it is proposed to directly implement the changes in the national legislation. Industry should already be labelling added starch and protein in line with regulation 8 of the FLR. Nevertheless, the consultation period was extended so enforcement and industry had enough time to prepare for implementation of the amending legislation. Commensurate with better regulation principles, it is proposed that the coming into force date coincide with the Common Commencement date of 6 April 2008.

A similar approach will be taken in England, Scotland and Northern Ireland.

Similarly, an extended consultation period on the related guidance, alongside the legislation, has allowed stakeholders to familiarise themselves with the content prior to the coming into force date of the Regulations.

Background

Starch and protein can be used in the meat products industry for a variety of products and for many different reasons. Very small amounts can be used to improve succulence by increasing moisture retention. Proteins can be used to bind added water. Added starch can make products easier to slice, helping to prevent sliced meats from falling apart (thickness of slice is an important factor for consumers¹).

Council Directive 77/99/EEC was revoked on 1 January 2006 when the consolidated EU food hygiene regulations came into force. This Directive had required that, amongst other things, added starch or proteins in meat products had to be mentioned in certain circumstances. The provision concerned stated:

“In addition The following information must be visibly and legibly displayed on the wrapping or on the label of meat products: where the legislation of a Member State authorises the use of starch or of proteins of animal or vegetable origin for other than technological purposes, a reference to such use in connection with the sales description.”

Directive 77/99/EEC defined “meat products” as being:

“products prepared from or with meat which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat”

This provision was implemented through regulation 5 of the MPR and its equivalents in the England, Scotland and Northern Ireland.

Name of the food requirements in regulation 5 of the MPR takes the approach of requiring added ingredients to be included in the name of the food for meat products that look like cuts, joints, slices, portions or carcasses of raw or cooked meat or cured meat, unless the ingredient concerned is listed in Schedule 3. Therefore, rather than specifically requiring starch and protein used for non-technological purposes to be included in the name of the food (as set out in the Directive), regulation 5 takes a different approach by exempting starch and proteins from the name of the food where they are used for technological purposes. The overall effect is, however, the same.

Regulation 5 of the MPR applies to meat products as were defined in Directive 77/99, but also covers raw meat products (normally referred to as ‘meat preparations’). There was no basis in EU law to extend the provision to raw

¹ Consumer Survey: ‘Purchasing Ham’ Omnibus Research Report by COI for FSA, March 2007. www.food.gov.uk/multimedia/pdfs/hamreport.pdf

meat preparations, but the proposal to effect that extension was properly notified as a national provision to, and accepted by, the European Commission under the Technical Standards Directive, 98/34/EC.

It should be noted that the name of the food provisions in regulation 8 of the FLR also apply to meat products within the scope of regulation 5 of the MPR and will continue to do so. Regulation 8 of the FLR requires that, if there is no name of the food prescribed by law and if there is no customary name, or if the customary name is not used, then the name of the food has to be sufficiently precise to inform a purchaser of the true nature of the food and to enable the food to be distinguished from products with which it could be confused.

There are current difficulties with the application of regulation 5 of the MPR to added starch and protein. The first, and most significant, is in relation to interpretation of the term 'technological purpose'. The second is concerning the application of regulation 8 of the FLR.

Regulation 5 of the MPR exempts starch and proteins from being included in the name of the food if they are added for a 'technological purpose', but this term has never been defined in EU or UK law. In practice, the lack of a clear definition has resulted in:

- virtually all uses of starch and protein potentially being argued to be for technological purposes;
- not all food businesses take the same approach and so there is inconsistency of application of the provision;
- uncertainty as to the legal requirements in industry;
- enforcement authorities finding it difficult to take action; and,
- consumers could potentially be misled about the presence of added starch and protein, although they will be included in the ingredients list on pre-packaged meat products.

Other labelling requirements

It does not appear to have been generally understood that regulation 8 of the FLR applies as well as the requirements of regulation 5 of the MPR. Regulation 8 of the FLR could have overridden the exemption in respect of inclusion of added starch or protein for technological purposes in the name of the food. This is because the addition of starch or protein in some cases, even if it could be argued to be for a technological purpose, and hence exempt under the MPR, might still be misleading if not included in the name of the food. In such cases labelling in the name of the food would be required under regulation 8 of the FLR.

As stated above, labelling requirements under regulation 8 of the FLR may not have been a routine consideration. Because of this, although a significant number of changes are not expected, there may be a few cases where starch or proteins will now be included in the name of the food where they have not been previously. Meat products (falling within the scope of regulation 5)

where this may be the case are those where significant amounts of starch or protein are added. The amendment may therefore result in additional information to consumers and a small increase in burdens to business.

Guidance

There are current difficulties with the interpretation of regulation 8 of the FLR to added starch and protein, including uncertainty about what the FLR would require by way of the name of the food. The Agency, therefore, plans to issue new guidance which, amongst other things, explains the change in legislation and helps to interpret regulation 8 of the FLR. The guidance would be a purely voluntary measure (with no statutory force) relating to the labelling of meat products falling within the scope of regulation 5 of the MPR.

Implementation

European Commission Directive 77/99/EEC was repealed by Directive 2004/41/EC (Article 2) with effect from 1 January 2006. Consequently, an amendment to the MPR is required to bring the specific labelling requirements for added starch and protein (as outlined above) into line with European legislation.

It is intended that these regulations will come into force on 6 April 2008. Parallel legislation will also come into force simultaneously in England Scotland and Northern Ireland.

Consultation

Full details of the consultation undertaken are included in the Regulatory Impact Assessment below.

Regulatory Impact Assessment

Options

Three potential options have been identified for the UK Government following on from the changes to EC legislation.

Option 1 – Do nothing

This option would not achieve the intended objectives of amending national legislation to bring it into line with EC law; namely to standardise industry practice, remove the vague distinction between technological and non-technological uses.

In addition, the UK would be at risk of infraction proceedings by the European Commission for non-implementation of EC legislation and there would be no defence to any such proceedings.

Option 2 – Implementation of the European changes

This option would have the desired effect in that national legislation would be brought into line with EC law. The name of the food requirements for meat products and meat preparations (including ‘technological purpose’ exemptions) for added starch and protein will be removed from regulation 5 of the Meat Products (Wales) Regulations 2004 with a coming into force date of 6 April 2008. The labelling rules in this respect would then fall solely under the horizontal labelling provisions, namely regulation 8 of the FLR. This option would partially achieve the intended objectives. The uncertainty surrounding ‘technological purpose’ will be removed. This is considered a positive step by most stakeholders and it would remove some of the burden on industry created by consideration of a regulatory process that was difficult to understand and comply with. However, a degree of uncertainty about the interpretation of the general labelling legislation i.e. what the FLR would require by way of the name of the food would remain.

A major enforcement stakeholder is concerned that costs will increase if the requirements fall to more general labelling legislation. These would stem from increases in activities associated with enforcement of compliance with the general labelling legislation i.e. monitoring, inspections and enquiries from industry.

Furthermore, differences of interpretation of the legislation between enforcement authorities could lead to unfair competition across industry. Equally, different interpretations by food businesses could have the same effect.

This option could benefit consumers as it may result in a small increase in the amount of products labelled as containing starch and protein in the name of the food (as the exemption might have been relied upon too heavily before).

The decision not to include transitional provisions in the amending legislation may lead to non-compliant products on the market after the coming into force of the Regulations. However, the extended consultation period and common commencement ‘coming into force’ date should give business enough time to use up existing labelling and stocks of the relevant products. Moreover, indications from stakeholders are that only a small proportion of existing product lines may potentially be affected.

Option 3 – Implementation of the European changes plus associated guidance

This option involves implementing the European provisions (as per Option 2) and, in addition, issuing associated guidance. The related guidance explains the change in legislation, and gives Agency advice on when to label added starch and/or protein in the name of the food. This would be a purely voluntary measure (with no statutory force) relating to the labelling of meat products falling within the scope of regulation 5 of the MPR.

This option, while retaining the benefits of Option 2, also partially addresses the main risks associated with that same option i.e. those arising out of compliance with the general labelling rules (regulation 8 of the FLR). The potential benefits might be:

Industry

- to reduce administration burdens created by the consideration of the legislation;
- to encourage standardisation of labelling practices and a level playing field in the marketplace;

Enforcement

- to reduce enforcement risks associated with compliance with the general labelling legislation;
- to reduce support needed for industry (i.e. dealing with enquiries);
- more consistent approach, by standardising enforcement practices between Local Authorities;

Consumers

- consistency of information about the relevant meat products that they are buying; and
- potential increase in information on the nature of the meat products they are purchasing (particularly where higher levels of starch and protein have been added).

The results of the extended consultation indicate that most of those consulted would welcome guidance on when to indicate the presence of starch and protein in the name of the food. These ingredients are typically used at very low levels (approximately 0.5%) for their intended technical effects such as improving the succulence of the meat and to aid sliceability. Generally higher levels are used for extending the meat and it is these products (where the presence of starch and protein should be indicated in the name of the food) the guidance seeks to differentiate.

Costs and Benefits

It is difficult to assess and quantify the potential costs and benefits of the proposal as the consultation process has not yielded substantive market share information for the whole sector. In addition, some of the potential costs and benefits may be non-monetary in their nature and thus very difficult to translate into financial terms i.e. the potential consumer benefits from more labelling information.

However, available information (such as ONS reports and results of stakeholder consultations) can give useful insights on the potential costs and benefits of each option.

Sectors and groups affected

It is estimated that 9,310² businesses in the UK trade in meat products falling within the scope of regulation 5 of the MPR (no breakdown for Wales is available). No particular cost effects are expected for the voluntary sector. The business sectors potentially affected by this proposal would be retailers (of which there are approximately 6,485), wholesale meat suppliers (of which there are approximately 2,190) and manufacturers of meat products and ingredient mixes (of which there are approximately 635). While large supermarkets and small butcher's shops³ share the bulk of the market, other players are becoming increasingly popular with consumers including farm shops and farmers' markets⁴. Removal of the national provisions will similarly affect importers.

Businesses are already required to provide labelling information under the FLR and the MPR on all products at retail sale to the final consumer. In most cases the proposed changes will be for pre-packed products where a small number of labels may have to be re-printed. For products sold loose, including those pre-packed for direct sale (packed and sold on the same premises) the information required is often provided at point of sale which will be cheaper and easier to amend if necessary. Those businesses that simply sell on pre-packed produce, other than own-label, will not be affected because labelling would be the responsibility of the producer or packer. A major stakeholder representing the hospitality industry believes it is unlikely this measure will affect caterers.

Based on a targeted consultation with a major enforcement stakeholder, the measure will also have an impact on the work of enforcement bodies, for example trading standards departments, which would be responsible for the enforcement of the Meat Products Amendment Regulations.

Consumers will benefit from more consistent information on labels which in turn will enable them to distinguish between meat products and their fresh 'plain' meat counterparts. No other social impacts have been identified.

² Based on 'UK Inter Departmental Business Register 2006 (UK Business: Activity, Size and Location: Number of VAT-Based Enterprises) (UK Standard Industrial Classification of Economic Activities (SIC) 2003)'. Note: These figures list VAT-Based Enterprises only and do not take into account the number of individual premises affected; the total number of which may be somewhat higher than these estimates. Premises data (as obtained from the FSA Local Authority Monitoring Report) are not available at a sufficiently low level to allow for the identification of the specific businesses affected by this legislation.

³ For the purpose of SIC 2003 classification: "where the [meat] processing is minimal and does not lead to a real transformation (e.g. butchers) the unit is classified to wholesale and retail trade". Note: Relevant SIC (Standard Industry Classification) code data was used for sector based quantities where possible, although in practice the MPR was found to apply across sectors, or to groups of organisations that do not correspond directly to SIC codes.

⁴ Various sources including: Mintel Report: Red Meat - UK (November 2006), major trade association and internet research.

Regulation 5 only applies to meat products that look like a cut, joint, slice, portion or carcase of meat. It does not apply to fresh raw meat that contains no added ingredients or comminuted products such as canned corned beef, sausages, or burgers as they do not have the appearance of 'whole' meat. It follows that any impacts of the proposal will not include the sale of these meat products.

Benefits

Option 1 – Do Nothing

There do not appear to be any incremental benefits (economic, environmental or social) associated with this option.

Option 2 – Implementation of the European changes

The removal of the reference to 'technological purpose' would be welcomed by most stakeholders as the lack of a definition in UK and EU law created much uncertainty. Furthermore, the changes will mean that the labelling rules relating to the addition of starch and protein would be harmonised with EU law.

A potential benefit for consumers is that there maybe a small increase in the number of products labelled as containing added starch and protein in the name of the food (particularly where larger amounts are added).

Option 3 – Implementation of the European changes plus associated guidance

The introduction of guidance for starch and protein should create a number of benefits for all stakeholders (see page 7). Industry has identified regulation 5 of the MPR as one of the most burdensome Agency Regulations with much of the costs arising from 'familiarisation' with the legislation⁵. For the purpose of this RIA, it has been calculated that it costs approximately £876,000⁶ for the UK business population to familiarise themselves with the whole of regulation 5 legislation. If it is estimated that half⁷ of this cost (and time taken) arises from familiarisation with the labelling rules for added starch and protein, the present cost to industry is approximately £438,000⁸ (similar costs are anticipated if the requirements fall to general labelling legislation). It is further estimated that guidance would reduce the time taken and associated costs to £131,000⁹ representing a saving of £307,000 (or a 70% reduction). The specific cost savings associated with this option will be dependent on the

⁵ Administrative Burdens Measurement Exercise 'Final Report' by PricewaterhouseCoopers LLP, June 2006. www.food.gov.uk/multimedia/pdfs/abmefinrep.pdf

⁶ Based on 9,310 businesses and industry estimates of 6 hours and 40 minutes (ABME) for familiarisation with regulation 5 at an average hourly salary of £14.12 (£10.86 up-rated by 30% to account for overheads) calculated from Retail and Wholesale Managers as classified in the 'ONS Annual Survey of Hours and Earnings (2005): Mean Gross Hourly Pay'.

⁷ This estimate is based on it taking more time to understand the legislation relating to starch and protein due to uncertainty surrounding the term 'technological purpose'.

⁸ Based on time estimate of 3 hours 20 minutes i.e. half of the original ABME estimate.

⁹ Based on it taking 1 hour with guidance for familiarisation with relevant legislation.

nature of individual businesses; small businesses in particular might benefit as they often do not have staff dedicated to monitoring the legislation.

The guidance should encourage standardisation of labelling across industry; a level playing field in this respect has been identified as an important factor by stakeholders during formal and informal consultations.

Enforcement stakeholders will benefit from this option, as guidance will promote a common understanding in the marketplace thus reducing the uncertainty related to compliance with regulation 8 of the FLR. This should lead to a reduction in the enforcement costs as outlined at Option 2. It will also encourage a common understanding of the requirements between enforcement authorities.

Consumers should ultimately benefit from more consistent labelling and further confidence in the products they are buying.

No significant environmental benefits have been identified for the options but an extended consultation period should lead to less need to dispose of labels and packaging.

Costs

Option 1 – Do Nothing

No significant incremental social, environmental or economic costs have been identified for this option.

However, the UK Government may face costs resulting from infraction proceedings by the European Commission for non-implementation of EU legislation.

Option 2 – Implementation of the European changes

Indications from informal one-to-one consultations with industry (including retailers, wholesalers and manufacturers) are that this measure would not incur any significant costs to any of the relevant industry sectors.

One effect of this option could be a small increase in the number of products labelled as containing starch and protein in the name of the food. It is difficult to estimate the costs to the whole sector, although informal consultation with stakeholders has yielded some useful information relating to butchers' shops and large supermarkets, who share the bulk of the market. The following estimates give a useful indication of the costs of this measure to the industry sectors affected.

The average cost of re-labelling a product line is estimated by butchers to be approximately £43 (mid-point of the range £33 – £53¹⁰) (the exact amounts will depend on volume, packaging and size of each business). Given that an

¹⁰ . Based on cost estimates from shop proprietors to set up software templates, print and label a product line (includes labour costs).

estimated 7,500 butchers each stock an average of 12 product lines that contain starch and protein, and an estimated 2% of the total number of these products throughout all businesses will be affected by this legislation, the estimated cost will be £77,400 to this sector.

Current and previous consultations indicate one-off costs incurred by larger retailers to re-label a product line are approximately £1,250 (mid-point of the range £1,000 - £1,500¹¹). Based on information gathered, it is estimated that large supermarkets¹² stock an average of 135 own-brand product lines that contain starch and protein, and an estimated 4% potentially affected by this legislation at an approximate cost of £47,250 to this sector.

It has not been possible to estimate costs to predominantly wholesale businesses, large meat manufacturers or medium sized retailers from the information gathered. Of those contacted, however, none believed re-labelling costs would be significant. (For products sold loose, i.e. at butchers' and deli-counters, labelling information is often provided by point of sale displays that need only be replaced once, so re-labelling of loose products would be cheaper.) Re-labelling costs will depend on the nature and size of individual businesses, however overall estimates are low, even for large supermarkets, and support the view of those contacted that incremental costs would not be significant.

Industry may incur one-off costs reflecting expenditure for the disposal of labels. According to the meat industry (including small businesses) 6-12 months is necessary to use up stocks of packaging for major nutrition labelling changes¹³. This measure is significantly smaller, therefore it is anticipated that there will be enough time (including an extended consultation period) for industry to make the necessary arrangements, within their normal commercial labelling cycles.

Businesses may incur additional administration costs arising out of uncertainty about interpretation of regulation 8 of the FLR. Initial consultations have indicated that there will be no significant incremental costs to industry as a similar level of uncertainty existed before on what constituted 'technological purpose'. However, an enforcement stakeholder has indicated that there might be a rise in inspections of premises which will potentially raise costs to industry. These costs are estimated to be approximately £35,300¹⁴ per year.

No other on-going costs to businesses have been identified.

There is a risk that uncertainty surrounding the labelling requirements of the FLR will impact adversely on public sector bodies responsible for enforcing

¹¹ Based upon previous and present stakeholder estimates of having to re-label 50,000 products in one line at a cost of 2-3p each (including labour costs).

¹² Top 7 according to market share: Tesco, Asda, Sainsbury's, Morrisons, Somerfield, Waitrose and Iceland (<http://news.bbc.co.uk/1/hi/business/4694974.stm>).

¹³ FSA Survey: Evaluating the impact on business of changes to nutrition labelling requirements in the UK, December 2006. www.food.gov.uk/multimedia/pdfs/ffinutritionlabellingreport.pdf

¹⁴ Based on 5,000 businesses (enforcement stakeholder estimate) undergoing enforcement inspections for 30 minutes at an average hourly rate of £14.12.

the changes in the legislation. A major enforcement stakeholder has indicated that enforcement costs could rise from an increase in enquiries and monitoring activities (in particular inspections of premises, sampling and analysis).

To quantify these costs, it is estimated that the amount of time taken to provide advice would increase by an average of 2 hours per Local Authority per year at a cost of £19¹⁵ per hour. This would amount to an incremental cost of approximately £18,800 for 494 Local Authorities undertaking enforcement activities. This would equate to approximately £836 for Wales.

Informal consultation with stakeholders, including the Association of Public Analysts, show that monitoring activities (i.e. sampling and analyses) related to added starch and added protein are low and relatively cheap at an average of £66¹⁶ per sample. Based on these estimates, it is anticipated that on-going monitoring costs for a maximum of 100 samples per year would amount to approximately £6,600 for the whole of the UK.

Inspections of premises may also increase leading to a maximum incremental cost of £125,000¹⁷ for the whole of the UK.

The on-going yearly rise in enforcement costs is therefore estimated at approximately £150,000 for the whole of the UK.

Option 3 – Implementation of the European changes plus associated guidance

There are economic costs associated with this option. It is estimated that it will cost the UK industry £65,700¹⁸ with respect to the time taken to become familiar with the guidance on the legislation although this cost would be offset by longer-term benefits once the guidance has been read. In addition there may be increased costs to industry from labelling (see Option 2) however these are not thought to be significant.

It is estimated that the cost for 494 Local Authorities to read and familiarise themselves with the guidance would be approximately £4,700¹⁹. This would equate to approximately £209 for Wales.

No significant environmental costs have been identified for this option although there might be a small increase in environmental costs from disposal of labelling and packaging. No significant social costs have been identified.

¹⁵ ONS Annual Survey of Hours and Earnings 2005: 'Inspectors of factories, utilities and trading standards' £16.52/hour up-rated by 30% to account for overheads, equates to £18.99/hour

¹⁶ Based on personal communications with stakeholders (May 2007).

¹⁷ Based on LACORS' estimate of it taking 30 minutes to inspect a maximum of 5,000 businesses at an hourly rate of £50.

¹⁸ Based on 9,310 businesses taking 30 minutes to read the guidance at an average hourly salary of £14.12 (£10.86 up-rated by 30% to account for overheads) calculated from Retail and Wholesale Managers as classified in the 'ONS Annual Survey of Hours and Earnings (2005): Mean Gross Hourly Pay'.

¹⁹ Based on the assumption it will take Local Authorities 30 minutes to read the guidance. ONS Annual Survey of Hours and Earnings 2005: 'Inspectors of factories, utilities and trading standards' £16.52/hour up-rated by 30% to account for overheads, equates to £18.99/hour

Administrative Burdens Assessment

The administrative burdens and associated costs and benefits of the three options were all considered. The costs and savings are outlined in the Summary section (see pages 17 and 18).

Option 1 – Do nothing

There would be no changes to the level of administration burdens on industry arising from compliance with the existing legislation (regulation 5 of the MPR).

Option 2 – Implementation of the European changes

This option would reduce the administration burden on industry from consideration of a regulatory process (relating to 'technological purpose') that was difficult to understand. However, it would not fully address the administration burdens faced by industry on whether to label added starch and protein in the name of the food as there will still be a degree of uncertainty under the general labelling legislation (i.e. regulation 8 of the FLR). There may be some re-labelling costs although these would not be significant. There may be a rise in costs relating to enforcement of compliance which will lead to increased costs to industry.

Option 3 – Implementation of the European changes plus associated guidance

This option would also reduce burdens on industry resulting from revocation of the existing legislation. However, there are administrative costs associated with this option. Industry and enforcement will need time to become familiar with the guidance. However, these costs will be partially offset by the anticipated savings resulting from the longer-term benefits of having clear guidance relating to the general labelling requirements.

Sustainability Assessment

The economic, social and environmental costs and benefits associated with the three options were all considered.

Option 1 – Do nothing

This option is not sustainable as it would leave the UK open to infraction proceedings by the EU.

Option 2 – Implementation of the European changes

Social costs are not significant. There is a small risk of environmental impact from the disposal of labels and packaging however an extended consultation period will mitigate this risk. There will be economic costs falling on industry and enforcers.

Option 3 – Implementation of the European changes plus associated guidance

Costs are as outlined for Option 2, but are offset against benefits from having guidance. This is the most sustainable option.

Enforcement, Sanctions and Monitoring

Enforcement of the Regulations will be the responsibility of Local Authority Trading Standards or Environmental Health Departments. Port Health Authorities are responsible for enforcing the Regulations in respect of imports.

In the absence of guidance future enforcement costs are estimated to be £150,000 for the UK (as per Option 2). If the Agency's recommended option (Option 3) is applied the enforcement costs would be similar, however these can be partially offset by the benefits of having guidance.

The associated guidance has been written in part to explain the amending legislation but also to give further advice (which has no statutory force) on the labelling of the addition of starch and protein to the relevant meat products. Guidance should help enforcers give advice on improving the information given on labels in this area, without resorting to enforcement action. This may eventually reduce enforcement costs.

Small Firms Impact Test

Approximately 9,255²⁰ of the 9,310 companies affected claim small business status (defined as having less than 250 employees). Butchers represent a large proportion and, according to a major trade association, there are about 7,500 in the UK. Estimates of business totals broken down by size are as follows (No breakdown is available for Wales):

- Micro (less than 10 employees) 85.8%
- Small (less than 49 employees) 11.6%
- Medium (less than 249 employees) 2.0%
- Large (greater than 250 employees) 0.6%.

The Agency has conducted a "Small Firms Impact Test" the results of which indicate that this measure would not have a major impact on small businesses. Small businesses (retail and wholesale) and a major trade association representing butchers were consulted.

²⁰ Based on 'UK Inter Departmental Business Register 2006 (UK Business: Activity, Size and Location: Number of VAT-Based Enterprises) (UK Standard Industrial Classification of Economic Activities (SIC) 2003)'. Note: These figures list VAT-Based Enterprises only and do not take into account the number of individual premises affected; the total number of which may be somewhat higher than these estimates. Premises data (as obtained from the FSA Local Authority Monitoring Report) are not available at a sufficiently low level to allow for the identification of the specific businesses affected by this legislation.

None of those contacted thought that the proposed changes would have a significant impact on their business. Information provided suggests that butchers tend to stock 10-15 'regulation 5' meat product lines, some of which are manufactured in-house and others bought in from suppliers. The establishments contacted prided themselves on selling traditional 'premium' products. Most said they did not add starch or proteins to their meat and none used starch and/or proteins to bulk out their products.

All of those contacted re-programme and print their labels in-house at a relatively low cost to their business (see page 11). None thought any potential re-labelling of product lines or label disposal costs would be significant to their business. No on-going costs were identified.

The Agency's preferred option (Option 3) would not impose any new administration burdens on small businesses. One stakeholder bought in a proportion of his products from suppliers with labelling information already provided while others believed that none of their products would be affected. Smaller wholesalers might face potential costs, particularly if they have to re-label their own-brand products, however a smaller wholesaler contacted did not think this would be significant.

Competition Assessment

The results of the Competition Assessment²¹ indicate that the proposed changes in legislation are unlikely to have any significant effects on competition in the UK marketplace. Smaller businesses generally have a reduced ability to absorb costs, for example those incurred by re-labelling, however consultations with smaller businesses have revealed that the costs would not be high enough to affect their ability to compete in the wider market. It is unlikely that the legislation or proposed guidance will have any adverse effect on barriers to entry or international trade as the proposed changes in the legislation will bring the UK into line with EU law.

Consultation

Public Consultation

Over the 18 months prior to the formal consultation on these amendment Regulations and associated guidance, stakeholders were kept informed via letters and stakeholder meetings.

The Food Standards Agency Wales carried out an extended formal 18 week consultation on the draft amending regulations between 26 July to 30 November 2007. Parallel consultations were conducted in England, Scotland and Northern Ireland.

Stakeholders, including industry, enforcement and consumer representatives were invited to comment on the draft Regulations, the draft Regulatory

²¹ . Further information on this process can be found in "Guidelines to Competition Assessment – A Guide to Policy Makers Completing Regulatory Impact Assessment" on the OFT website at www.of.gov.uk.

Impact Assessment and associated guidance. The consultation package was also posted on the Agency's website.

In total 17 responses were received UK wide to the formal consultation. Fourteen responses were received to the England consultation, including from representatives of enforcement, industry and consumers. There were 2 responses to the Welsh consultation, 2 responses to the Scottish consultation and no responses to the Northern Ireland consultation.

Nearly all of the stakeholders that responded to this consultation acknowledged that it is necessary to amend the legislation and were in favour of removing the reference to technological purpose from the MPR. However, although most stakeholders were generally in favour of guidance (particularly relating to FLR (regulation 8), most were not in favour of including threshold levels²² for added starch and protein.

All the responses to the consultation were taken into consideration by the Agency when preparing this full version of the RIA submitted for ministerial signature. The Agency will amend the legislation as planned and issue associated guidance. The Agency will not, however, pursue the concept of having threshold levels in the guidance for including added starch and protein in the name of the food. Consequently, references to threshold levels will be deleted from the guidance. A full Agency response to the consultation has been published on the Agency's website.

No policy changes to the draft Regulations were identified as a consequence of the public consultation.

Within government

The National Assembly for Wales, the Department for Environment, Food and Rural Affairs (Defra) and the devolved administrations in Scotland and Northern Ireland have been consulted and kept informed of progress with respect to the revocation of Council Directive 77/99/EEC (on 1 January 2006) and new developments as they have arisen. Further views were sought as part of the consultation exercise.

Post-implementation Review

The Agency will consider whether the amending legislation and the associated guidance met the policy objectives. In particular, it will take into account the outcome of relying solely on regulation 8 of the FLR for declaring added starch and protein in the name of the food. The Agency will also take into consideration further communications from consumer, industry and enforcement stakeholders (e.g. during stakeholder meetings or from general enquiries).

²² The Agency originally proposed to have a threshold level of 1%, to apply independently to added starch and protein, over which their presence would be indicated in the name of the food for 'regulation 5' meat products.

Summary

The Meat Products (Wales) (Amendment) Regulations 2008 will bring national legislation into line with EU law. In addition, it will dispel the uncertainty relating to the term 'technological purpose' which will benefit consumers, enforcement and industry.

Publication of the associated guidance on declaration of added starch and protein will go some way to addressing the new uncertainty arising out of sole reliance on regulation 8 of the FLR.

Option 3, will introduce these benefits by amending the legislation and issuing associated guidance and therefore it is the Agency's recommended option.

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1. Do Nothing	No benefits have been identified.	Risks infraction proceedings imposed by the European Commission against the UK.
2. Implement European changes	<p>No significant benefits although the removal of the reference to 'technological purpose' is welcomed by most stakeholders.</p> <p>Small possibility of an increase in labelling information for consumers.</p>	<p>Possible increase in industry costs due to a slight increase in labelling; total cost cannot be quantified but may not be significant. (Estimated so far to be £77,400 for all butchers and £47,250 for the top 7 supermarkets with the largest market share). A rise in costs might result from inspections of premises of up to £35,300.</p> <p>Small possibility of increase in industry costs due to disposal of labelling, however probably not significant.</p> <p>Increase in enforcement costs of up to £150,000 arising out of activities relating to enforcement</p>

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
		of compliance with regulation 8 of the FLR.
3. Implementation of the European changes plus associated guidance	<p>Possible industry administration cost savings of up to £307,000.</p> <p>Encourage standardisation of application of the legislation (by both industry and enforcement) leading to a more level playing field in the market place.</p> <p>Increased consistency of labelling for consumers.</p> <p>Small possibility of increased labelling information for consumers.</p>	<p>Possible increase in industry costs due to a slight increase in labelling; total cost cannot be quantified but may not be significant. (Estimated so far to be £77,400 for all butchers and £47,250 for the top 7 supermarkets with the largest market share). A rise in costs might result from inspections of premises of up to £35,300.</p> <p>Small possibility of increase in industry costs due to disposal of labelling, however probably not significant.</p> <p>Industry costs of up to £65,700 for familiarisation with the guidance.</p> <p>Enforcement costs of up to £4,700 for familiarisation with the guidance.</p> <p>Increase in enforcement costs of up to £150,000 arising out of activities relating to enforcement of compliance with regulation 8 of the FLR.</p>