

Explanatory Memorandum to the Food Hygiene (Wales) (Amendment) Regulations 2010

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

Member's Declaration

In my view this explanatory memorandum gives a fair and reasonable view of the expected impact of the Food Hygiene (Wales) (Amendment) Regulations 2010. I am satisfied that any benefits outweigh any costs.

Gwenda Thomas AM

Deputy Minister for Social Services
Assembly Member in charge of the Proposed Measure

18 March 2010

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1. Description

This Statutory Instrument (SI) will provide for the execution and enforcement of several implementing and transitional measures in respect of EU Food Hygiene Regulations. This will be achieved by substituting a revised Schedule 1 to the Food Hygiene (Wales) Regulations 2006 (S.I. 2006/31 (W.5)) as amended by S.I. 2007/373 (W. 33)).

The S.I will also provide for the application of two national measures that exempt former low throughput slaughterhouses from certain hygiene requirements. . This will be achieved by substituting a revised regulation 17 and by inserting new Schedules 3A, 3B, 3C and 3D into the Food Hygiene (Wales) Regulations 2006.

2. Matters of special interest to the Constitutional Affairs Committee

There are further amendments to the EU Food Hygiene Regulations which are subsequent to the amendments which are the subject of the Food Hygiene (Wales) (Amendment) Regulations 2010. The SI which will provide for the execution and enforcement of those further amendments is the subject of a separate consultation exercise.

3. Legislative Background

The powers enabling this instrument to be made are contained in section 2(2) of the European Communities Act 1972. The Welsh Ministers are designated for the purposes of section 2(2) in respect of measures relating to food (including drink) including the primary production of food by virtue of the European Communities (Designation) (No.2) Order 2005 (SI 2005/1971) (which function has been transferred to them by virtue of paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006).

The EU Food Hygiene Regulations, which applied from 1 January 2006, had as their primary objective the optimisation of public health protection through consolidation and modernisation of the previous sector specific EU legislation. The EU Food Hygiene Regulations are directly applicable in EU Member States. The necessary powers of entry, penalties and offences required to execute and enforce the EU Regulations are provided through national legislation in the form of an SI in Wales. Since 1 January 2006, the European Commission has adopted a number of implementing and transitional Regulations for which provision must also be made in national legislation.

4. Purpose and Intended Effect of the Legislation

The EU Food Hygiene Regulations which are the subject matter of this SI amend or, in some cases, apply transitional measures to the following policy areas:

Regulation (EC) 1243/2007

The Regulations provides:

- A derogation for small coastal fishing vessels from some record keeping, thus reducing administrative burdens for food business operators in that sector;
- For the addition of two further sources of raw material for the production of gelatine, changes in requirements for wrapping and packaging, and other minor changes to the legislation that provide clarity of interpretation in order that gelatine manufacturers can make use of all available technologies, where it is established that there is no negative impact on public health.

Regulation (EC) 1244/2007

It is necessary to allow competent authorities alternative ways of carrying out their duties, which may bring benefits as long as public health protection is maintained or improved.

The Commission Regulation sets the criteria for:

- Competent authorities to apply when determining official veterinarian (OV) attendance during post-mortem inspection; and
- For the 'visual-only' post-mortem inspection of young animals, with the public health benefit of removing the necessity, in some cases, of cutting into the meat and possibly spreading infection.

The measure also permits Member States competent authorities the use of an alternative screening method for the detection of Amnesic Shellfish Poisoning (ASP) toxins, which may bring high capacity at low cost without lowering the standards of public health protection.

Regulation (EC) 1241/2007

Following opinions given by EU scientific bodies, the Commission Regulation:

- Revises microbiological criteria for infant formula;
- Imposes new criteria for infant and follow-on formula;
- Harmonises testing of carcasses; and
- Updates the standard test method for Staphylococcal enterotoxins.

Revision of the microbiological criteria to reflect updated scientific understanding will reduce the risks of illness caused by certain pathogenic micro-organisms in food and improve public health protection.

Regulation (EC) 1245/2007

The Regulation provides for the use of liquid pepsin for the detection of Trichinella in meat. This provides a choice of form of the reagent pepsin for laboratory staff undertaking official controls to use, with the potential of benefitting their health, and with no consequent lowering of the protection of public health.

There are a number of policy areas where the EU regulations allow Member States to adopt certain provisions in their national legislation. These are the basis for national measures that will exempt (former) low throughput slaughterhouses for the need for:

- cleansing and disinfection facilities; and
- detention facilities for meat.

Exemption for cleansing and disinfection facilities for livestock vehicles

The measure will ensure that certain small (and often rural) slaughterhouses without cleansing and disinfection facilities can be approved as meeting the legal requirements relating to equipment and structure, and can therefore continue to operate.

Exemption requirements for detained meat facilities in low throughput slaughterhouses

The measure will ensure that certain small (and often rural) slaughterhouses without detained meat facilities can continue to operate.

It is proposed to achieve this -

- as regards the EU transitional and implementing measures by substituting a revised Schedule 1 to the Food Hygiene (Wales) Regulations 2006 (S.I. 2006/31 (W.5)) as amended by S.I. 2007/373 (W. 33)); and
- as regards the national measures by substituting a revised regulation 17 and by inserting new Schedules 3A,3B, 3C and 3D into the Food Hygiene (Wales) Regulations 2006.

5. Consultation

The Food Standards Agency consulted stakeholders for 12 weeks on the draft Food Hygiene (Wales) (Amendment) Regulations 2008 (as they were then titled) and the RIAs for both the Commission measures and the national measures – this consultation closed on 4 January 2008. Ninety-nine Welsh stakeholders, including industry representatives and farming unions, were invited to comment. 5 responses were received in Wales. No significant concerns arose from the stakeholders' comments and the proposed national measures were welcomed as they would reduce the regulatory burden on the small abattoir sector, particularly in rural areas.

Following discussions with the European Commission, the national measures have been revised from those proposed in the stakeholder consultation. The Commission's own periods of scrutiny of the draft national legislation have contributed to the gap between the original date when the EU measures were adopted and the making of this SI.

Originally another national measure was included in the consultation. This measure set out the form for a national mark applying to red meat from animals slaughtered in emergency circumstances (i.e. outside of an approved slaughterhouse). This has since been separated from these EU measures and the two national measures and requires further consideration and will be subject to further consultation during 2010.

6. Regulatory Impact Assessment

6.1 Regulation (EC) 1243/2007

The measure revises Regulation (EC) 853/2004 to:

- i. Include a derogation from record keeping requirements set out in one of the European Food Hygiene Regulations, currently applying to small-scale coastal fishing vessels carrying out their activities for periods under twenty-four hours; and
- ii. Increases the range of raw materials permitted in the manufacture of gelatine and collagen for human consumption, and changes the requirements for the wrapping and packaging to indicate the date of preparation of the gelatine in favour of an indication of the date of minimum durability.

6.1.1 Options

Doing nothing maintains the current position and so has no incremental cost or benefits. It would mean that certain fishing vessels might continue to have to keep records where it was not justifiable on public health grounds with possible long-term unnecessary costs.

Doing nothing would also mean that manufacturers of gelatine could not take advantage of alternative methods of production and other flexibilities provided.

It is recommended to support the Regulation's application and provide for its enforcement in Welsh law through an amendment to the Food Hygiene (Wales) Regulations 2006. This is the preferred option because there is a strong likelihood that the measures will lower the administrative burden on the small business sector, and will provide greater flexibilities in the manufacture of gelatine.

6.1.2 Costs and Benefits

The derogation for small coastal fishing vessels is likely to reduce administrative burdens for the operators of these vessels and may result in some small cost savings, however, consultation responses suggest that legislation already allows vessels proportionate record-keeping and vessels supplying small quantities to local markets are exempt anyway. Therefore comments received suggest that the impact of the derogation is unlikely to be significant. There may also be some benefits to Enforcement Officers, who no longer have to check the appropriate records.

The introduction of additional permitted raw materials for the production of gelatine would not result in any cost to industry, as any affected manufacturers could continue with their current practices if they so chose. Manufacturers that choose to move to a new production method would do so in pursuit of commercial benefit.

6.2 Regulation (EC) 1244/2007

The Regulation amends Regulation (EC) 2074/2005. The intended effect is to amend the legislation to ensure official controls are proportionate and allow alternative ways of carrying out controls where there are benefits without any lowering of the protection of public health. Specifically to:

- i. Sets out criteria for competent authorities to apply when determining official veterinarian (OV) attendance during post-mortem inspection in establishments carrying out 'discontinuous slaughter'; and
- ii. Sets criteria for the 'visual only' post-mortem inspection of young animals - with the public health benefit of removing the necessity, in some cases, of cutting into the meat and possibly spreading infection;
- iii. Set criteria for the visual inspection of fattening pigs; and
- iv. Places an additional requirement for the post-mortem examination of solipeds (horses and mules) from countries not free of glanders.

6.2.1 Options

Doing nothing would provide no incremental costs or benefits. It is recommended to support the Regulation's application and provide for its enforcement in Welsh law through an amendment to the Food Hygiene (Wales) Regulations 2006.

6.2.2 Costs and Benefits

It remains uncertain regarding the number of plants affected and the number of hours saved which are foregone, however, it has been estimated that around 10% of slaughterhouses in Wales will be affected by the changes to official controls, as they will now no longer be able to make use of flexibilities on OV time. Each plant would forego savings of 10% of daily OV hours¹. It has been estimated that 10% of the 29 slaughterhouses in Wales in 2007 will be affected. Therefore, potential costs to the three plants have been estimated at a total of £26,340². No comments were received regarding this issue during the public consultation.

Despite there being a potential significant cost associated to this Regulation, it enables the benefits to improvements in the proportionality of enforcement activity in certain animal product sectors, with no danger to public health. The Agency will continue to monitor the impact of this Regulation in order to minimise any negative effects in liaison with the industry.

There are unlikely to be any benefits from reducing incisions at post-mortem inspection, as the time saved is likely to be invested in increased visual inspection.

The measure (Regulation (EC) 1244/2007) also permits competent authorities the use of an alternative screening method for the detection of Amnesic Shellfish Poisoning (ASP) toxins, which may bring high capacity at low cost without lowering the standards of public health protection.

¹ 0.8 hours per day, 5 days per week, 50 weeks a year = 200 hours

² 3 plants charged at £43.90 per hour ((estimated hourly OV full cost rate) for 200 hours

6.2.3 Options

Doing nothing would provide no incremental costs or benefits. It is recommended to support the Regulation's application and provide for its enforcement in Welsh law through an amendment to the Food Hygiene (Wales) Regulations 2006. This is the preferred option because it allows the use of an alternative screening method, providing a choice and the potential for lower cost monitoring, while maintaining public health protection.

6.2.4 Costs and Benefits

The measure proposes a potential alternative for the Food Standards Agency to consider for testing for official control samples, which is potentially both cheaper and faster. The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use and any potential saving.

6.3 Regulation (EC) 1441/2007

Following opinions given by EU scientific bodies, the Regulation:

- i. revises microbiological criteria for infant formula;
- ii. imposes new criteria for infant and follow-on formula;
- iii. harmonises testing requirements for carcasses; and
- iv. updates the standard test method for staphylococcal enterotoxins.

6.3.1 Options

Doing nothing would provide no incremental costs or benefits. It is recommended to support the Regulation's application and provide for its enforcement in Welsh law through an amendment to the Food Hygiene (Wales) Regulations 2006. This is the preferred option as the UK supports the changes contained in Commission Regulation (EC) 1441/2007, because the amendments will allow microbiological criteria to reflect current scientific understanding and improve public health protection.

6.3.2 Costs and Benefits

There will be some adjustment costs for some businesses as a result of the Regulations, but these are not expected to be a significant additional burden.

The revised criteria provide business operators with tools that are based on available science to help validate and verify their food safety management systems, reducing the risk of food borne illness from certain pathogenic organisms. This will improve public health protection in respect of those particular pathogenic organisms for which criteria have been revised and clarify requirements for businesses and enforcement authorities.

6.4 Regulation 1245/2007

The Regulation provides for the use of liquid pepsin for the detection of *Trichinella* in meat. This provides a choice of form of the reagent pepsin for laboratory staff undertaking official controls to use, with the potential of benefitting their health, and with no consequent lowering of the protection of public health.

6.4.1 Options

The 'do nothing' option would mean that the only prescribed form of detection of Trichinella in meat in EU law would be the pepsin powder reagent. This might lead to allergic reactions in those handling the pepsin powder where it could have been avoided by use of the liquid form. There are no incremental costs and benefits from this option. It is recommended to support the Regulation's application and provide for its enforcement in Welsh law through an amendment to the Food Hygiene (Wales) Regulations 2006. This is the preferred option because it increases flexibility and is beneficial to the health of some staff, without affecting the level of public protection.

6.4.2 Costs and Benefits

The Regulations will enhance flexibility for the Competent Authority and will reduce the possibility of allergic reactions amongst laboratory staff who handle pepsin for the purposes of official controls. Should laboratories choose to use it, liquid pepsin may be more expensive than powdered pepsin, however, any additional cost is likely to be insignificant.

6.5 Exemption for Cleansing and Disinfection Facilities for Livestock Vehicles

The measure will ensure that certain small (an often rural) slaughterhouses without cleansing and disinfection facilities can be approved as meeting the legal requirements relating to equipment and structures, and can therefore continue to operate.

6.5.1 Options

Doing nothing would provide no incremental costs or benefits. The preferred option is to adopt a national measure to adapt requirements of Regulation (EC) 853/2004 on facilities for cleansing and disinfection of livestock vehicles in slaughterhouses with a low throughput to exempt certain slaughterhouses from the need to have these facilities. This is the preferred option because it will allow certain small slaughterhouses to continue to trade with no lowering of the protection of public health.

6.5.2 Costs and Benefits

There are no low throughput slaughterhouses in Wales awaiting approval under Regulation (EC) 853/2007, therefore currently there are no costs or benefits to industry associated with these Regulations. In Wales, all former low throughput slaughterhouses met the new legal requirements concerning cleansing and disinfection facilities and were fully approved by December 2008. However, the national measure will allow them to make use of this national flexibility in the future and continue to operate as an approved establishment.

6.6 Exemption Requirements for Detained Meat Facilities in Low Throughput Slaughterhouses

This measure will ensure that certain small (often rural) slaughterhouses that were not previously required to have detained meat facilities can continue to operate without such facilities.

6.6.1 Options

Doing nothing would provide no incremental costs or benefits. The preferred option is to adopt a national measure to adapt requirements of Regulations (EC) 853/2004 on having refrigerated detention facilities in slaughterhouses with a low throughput. This is the preferred option as low throughput slaughterhouses without a detained meat facility do not pose an increased risk to public health if certain conditions are met.

6.6.2 Costs and Benefits

There are no low throughput slaughterhouses in Wales awaiting approval under Regulation (EC) 853/2007, therefore currently there are no costs or benefits to industry associated with these Regulations. In Wales, all former low throughput slaughterhouses met the new legal requirements concerning cleansing and disinfection facilities and were fully approved by December 2008. However, the national measure will allow them to make use of this national flexibility in the future and continue to operate as an approved establishment.