

## REGULATORY APPRAISAL

### FOOD, WALES

#### THE FOOD HYGIENE (WALES) (AMENDMENT) REGULATIONS 2007

##### Background

1. This Regulatory Appraisal primarily describes the impact of the European Commission implementing Regulations that amend the EU Hygiene Regulations or previous implementing measures, which are directly applicable in Member States. It does not describe the impact of the national legislation (The Food Hygiene (Wales) (Amendment) Regulations 2007), which gives effect to the Commission Regulations as it has no impact itself.
2. A package of EU food hygiene Regulations<sup>1</sup> was adopted in Spring 2004 and applied from 1 January 2006, its foremost objective being the optimisation of public health protection through consolidation and up-dating of the previous EU legislation. The new Regulations introduced 'horizontal' legislation across the food chain from 'farm to fork'<sup>2</sup>. A previous suite of implementing measures and transitional arrangements<sup>3</sup> amending the food hygiene legislation was issued by the Commission and applied from 11 January 2006.
3. The most recent Commission implementing Regulations, which are the concern of this Regulatory Appraisal, were first presented (in draft form) to Member States at a meeting of the Standing Committee for the Food Chain and Animal Health (SCOFCAH) on 19/20 June 2006<sup>4</sup>. They were adopted at SCOFCAH on 18 July 2006<sup>5</sup> and were published in the EU Official Journal on 18 November 2006.

##### Purpose and intended effect of the measure

4. These Regulations amend the Food Hygiene (Wales) Regulations 2006 by updating the definitions of certain Community Instruments that are referred to in those Regulations. This provides enforcement powers in respect of the EU Food Hygiene Regulations and associated pieces of implementing and transitional legislation.

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<sup>1</sup> Regulation (EC) 852/2004 on the hygiene of foodstuffs; Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin and Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Also part of the package were:

Directive 2004/41 repealing the previous EU legislation or, in some cases, amending still existing legislation and

Directive 2002/99 that lays down the animal health rules on products of animal origin for human consumption and came into force from 1 January 2005. (Defra policy responsibility.)

<sup>2</sup> Background to the legislation, including links to pdf copies of the Regulations can be found on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>

<sup>3</sup> An explanation of the role of the implementing and transitional measures as well as copies of the measures in pdf format can be found at <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg>

<sup>4</sup> A report on this meeting was made available to stakeholders on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/scofcah060619>

<sup>5</sup> A report on this meeting was made available to stakeholders on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/scofcah06071819>

5. The key amendments are:

- Adding to the definition of 'the Community Regulations' references to the Commission legislation listed in paragraph 6 below;
- Substituting a revised Schedule 1 including these references.

6. A list of the Commission Regulations setting out the implementing and transitional measures is given below:

- Commission Regulation (EC) No 1662/2006 of 6 November 2006 amending Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin;
- Commission Regulation (EC) No 1663/2006 of 6 November 2006 amending Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;
- Commission Regulation (EC) No. 1664/2006 amending Regulation (EC) No. 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures;
- Commission Regulation (EC) No 1665/2006 of 6 November 2006 amending Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* (ringworms) in meat; and
- Commission Regulation (EC) No. 1666/2006 amending Regulation (EC) No. 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council.

## **Risk Assessment**

### Fish and Shellfish Industry

7. There are implications for shellfish harvesting. Until 31 December 2005, legislation required that 90% of samples of live bivalve molluscs (LBMs) (e.g. clams, cockles, mussels etc.) harvested from a 'Class B area'<sup>6</sup> used for the classification of that shellfish bed should meet the specified E.coli level; this 90% requirement was removed by the EU Commission and has not been in operation since 1 January 2006. The Commission had sought to replace this

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<sup>6</sup> 'Class B area' – molluscs from these areas can be marketed for human consumption only after purification in an approved plant, or after relaying in an approved Class A relaying area, or after being subjected to an EC approved process. Additionally, the end product standards, including microbiological (*E. coli*) criteria, laid down in Section VII, Chapter V of Annex III to Regulation (EC) 853/2004, must be met.

tolerance level with scientific and risk based criteria. This was not forthcoming in the required time and the UK and other EU Member States were concerned about the absence of this and the possible implications of 100% of samples needing to meet the Class B classification criteria. However, the draft requirement effectively re-establishes the 90% figure. There is, therefore, no change to current practice resulting from this.

8. The 'Lawrence Method'<sup>7</sup> (non-animal testing) is permitted as an alternative method of detecting paralytic shellfish poisoning (PSP) in live bivalve molluscs in particular cases. However, this will have no impact at the moment, as the UK does not intend to consider the use of this method until all the technical issues identified with this method have been resolved by the Commission and the Community Reference Laboratory.
9. The Commission Regulations now identify that fish oil manufacture for human consumption is subject to the food hygiene legislation under the fishery products criteria. This has implications for the UK fish oil processing industry, as establishments will now have to be approved to manufacture fish oil, or products from fish oil.
10. The Commission Regulations provide model health certificates for the import of LBMs and fishery products, thus removing the need for a large number of Commission Decisions concerning import conditions for particular countries.

#### Red meat industry

11. In the red meat sector, the draft legislation introduces one new issue, which is allowing the muzzle and lips of adult cattle to enter the food chain, provided they are handled hygienically. Other amendments, such as the requirement to remove tonsils from pig carcasses or changes to health certificates simply correct or clarify the current statutory requirements.

#### Dairy industry

12. In the dairy sector, specific provisions for colostrum (fluid secreted by the mammary glands of milk producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk) are introduced in the food hygiene Regulations for the first time. A new reference method has been introduced for the determination of alkaline phosphatase activity (a measure of whether pasteurisation has been undertaken successfully).

#### **Options**

13. In respect of this legislation, the 'Do Nothing' option is not as option, as it would ultimately lead to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the 'Make the

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<sup>7</sup> The Lawrence method is an analytical method for the detection of Paralytic Shellfish Poisoning (PSP) toxins. It is a High Performance Liquid Chromatography (HPLC) method with fluorescent detection and pre-column oxidation. It has recently been accepted as an Association of Official Analytical Chemists' international official first action method for the detection of some PSP toxins in certain shellfish species such as mussels, clams, oysters and scallops.

Legislation' option, to implement the changes required to comply with European legislation, is being proposed. Furthermore, it would also mean a failure to give effect to the Commission Regulations where they might have benefits (e.g. by simplifying procedures) and hamper developments that would lead to greater long-term public health protection.

#### Make the legislation

14. Although EU Regulations are directly applicable in law, giving full effect to the Regulations in UK national law should ensure that the UK fulfils its Treaty obligations obviating the need for action against the UK being taken by the Commission. It would also mean that benefits provided by the amendments to legislation are given effect by national legislation and appropriately enforced.

### **Benefits**

#### Fish oil industry

15. The clarification of the position of fish oil under hygiene legislation as a fishery product should help to ensure that protection of public health is extended and that the manufacture of fish oil for human consumption is consistent with the manufacture of other products of animal origin for food. The Agency considers that this development will bring a public health benefit.

#### Red meat industry

16. The Agency sees a benefit arising from food businesses being permitted to supply muzzle and lips of adult cattle ('pomos') for human consumption. The Agency believes that there might be a niche market for these products, which will extend consumer choice. The Agency is aware of some trade related to 'pomos' from calves. This amendment will remove the distinction between adult and young cattle, which can be difficult to enforce.

17. The revised model health certificates remove the need for reference to numerous Commission Decisions and by improving layout and references, they should be simpler to enforce.

#### Imports of fish/shellfish

18. The introduction of a generic model health certificate will remove the need for reference to numerous Commission Decisions and should be simpler to enforce. The Agency considers that cost benefits might arise from the simplification of these certificates, although it is not possible to quantify these savings.

### **Costs**

19. There are no additional financial implications for the Assembly arising from the making of these Regulations.

20. The Commission Regulations concern the fish/shellfish, red meat and dairy food sectors. There may also be cost benefits for imports and official

controls following the introduction of a generic model health certificate. However, it is not possible to quantify these cost benefits.

#### Fish oil industry

21. The Agency anticipates that there may be costs to the fish oil processing industry as establishments manufacturing fish oil for human consumption will now have to be approved by the competent authority and this might result in the need for structural and/or work behavioural changes. However, the Agency is not aware of any UK manufacturers in this sector.

#### Red meat industry

22. The amendment requiring removal of tonsils from pig carcasses corrects an accidental omission from the hygiene regulation to carry forward requirements. The Agency's understanding is that operators are continuing previous practice and that this will not introduce new procedures or costs.

#### Dairy industry

23. It is not anticipated that there will be any costs associated with the measures regarding colostrum. As far as the Agency is aware, colostrum or colostrum products are not produced in the UK for human consumption.

#### Enforcement of legislation applying to fish oil manufactured for human consumption.

24. The Agency considered there may be an increase in costs for competent authorities due to an increase in inspections of establishments manufacturing fish oil. However, the Agency is not aware of any UK manufacturers. Additionally the Local Authority Co-ordinators of Regulatory Services (LACORS), the co-ordinating body for local authorities in England and Wales, did not identify any additional potential costs during the consultation exercise.

### **Competition Assessment**

25. The markets that may be affected are the fish, red meat and dairy food sectors. Importers of animal origin products will also be affected.

26. The Agency has little concrete information on the fish oil industry at present, as this industry has not previously been subject to food hygiene legislation and no substantive information came from the formal consultation.

27. In the UK, the slaughter of cattle is an important industry carried out by businesses of all sizes. The Agency expects the change to allow the supply of muzzle and lips of adult cattle will have a limited impact on the market as a whole, but will provide an outlet for these specialist products. Statistics indicate, that in the cattle slaughtering sector, the largest of more than 300 plants in the UK accounts for less than 5% of total cattle throughput. Currently, there is no legitimate international trade in these products.

28. The Agency does not expect that any part of the pig slaughter industry will be unduly affected by the new measure, which merely corrects an omission in the legislation. Businesses involved in the industry will carry on unaffected.
29. The dairy manufacturing industry is a large UK wide industry, with a range of size of businesses. Regarding the introduction of the new reference method phosphatase (indicative enzyme) testing to this sector, it has been noted by an industry representative organisation that smaller firms might feel compelled commercially to use the phosphatase test, although it will not be a legal obligation only a reference method. The Agency is aware from informal contact with the industry that larger dairy firms are working to go beyond the methods minimum requirement.

## **Consultation**

### With Stakeholders

30. The Food Standards Agency carried out a UK-wide public consultation on these Regulations on 18 September 2006 to 11 December 2006. 152 stakeholders in Wales, including consumer and industry representative bodies and farming unions, were invited to comment on the draft Regulations and the draft Regulatory Appraisal. (A list of Welsh consultees is attached at Annex A). Two responses were received to the consultation exercise in Wales, neither offering any comment on the consultation package. Ten responses were received UK-wide, eight of which offered no specific comments on the draft Regulations. One respondent offered their agreement to a proposed amendment, whilst one raised issues, which were not covered by the draft Regulations.
31. None of the comments received gave rise to the need to amend the proposed Regulations.

### With Subject Committee

32. These Regulations were notified to the Health and Social Services Committee, via the list of forthcoming legislation on 28 September 2006 (HSS(2)-13-06-(p.2b) item no: FSA 21 (06)) and have remained on the list ever since. The Regulations were not identified for detailed scrutiny.
33. In addition, the Regulations were notified to the Environment, Planning and Countryside Committee and the Local Government and Public Services Committee, via their lists of forthcoming legislation, on 15 November 2006 (EPC(2)-15-06 (p.4) item no: 39) and 23 November 2006 (LGPS(2)-16-06(p.2), respectively. The Regulations were not identified for detailed scrutiny.

## **Enforcement, Sanctions, and Monitoring**

34. Enforcement responsibilities are essentially the same as the original Food Hygiene Regulations. There appears to be little or no substantial additional burdens.

## **Review**

35. The Commission Regulations that are the subject of this Regulatory Appraisal cannot be seen in isolation, but as amendments or additions to the food hygiene legislation as a whole introduced from 1 January 2006. There would be little or no benefit, therefore, in looking solely at these measures at some point in the future.
36. The European Commission is at the beginning of a review of the food hygiene legislation with the current intention of making any proposals for change at the end of 2008. Indications at this stage are that the scope of the review is unlikely to be wide-ranging; however, this might impact on the nature of any review of the legislation in a UK context. The UK is of the opinion that the legislation does not need a major overhaul, but will anyway need to consider the issue of legislative review generally. Clearly, consultation with stakeholders, such as those representing industry and enforcement, would need to be part of such a review. The Agency will regularly update stakeholders with reports of the progress of the Commission review on its web site.
37. The Food Standards Agency, as 'owner' of the policy remit for the whole of the food hygiene legislation will keep the legislation under review as part of its on-going work. This includes regular informal contact with stakeholder groups, and formal consultations when new legislation or any substantial changes (e.g. to national legislation) are proposed. Stakeholders are always likely to bring to the Agency's attention any areas of the legislation, which are problematic for them and the Agency will work with stakeholders to seek improvements to, or resolution of, those problems.

## **Summary**

38. These Regulations will amend The Food Hygiene (Wales) Regulations 2006 by updating the definitions of certain Community instruments that are referred to in those Regulations. They will give full effect to our Community obligations and will contribute to delivering the anticipated benefits of enhanced public health protection through more risk based and proportionate EU Food Hygiene legislation.

## ANNEX A

<b>Organisation</b>
ADAS Wales
Agricultural Industries Confederation (AIC)
Association of Muslim Professionals
British Retail Consortium
Carmarthenshire College
CBS Technologies Ltd
Chartered Institute of Environmental Health in Wales
Coleg Llysfasi Ruthin
Communicable Disease Surveillance Centre Wales
Country Land and Business Association
Eppyut Hill and Beulah Face Sheep Society
Eurofins Scientific
Farm Assured Welsh Livestock
Farm Assured Welsh Livestock
Farmers For Action
Farmers' Union of Wales
Federation of Small Businesses (South Wales)
Food Consultancy
Guild of Welsh Lamb and Beef Suppliers
Hybu Cig Cymru / Meat Promotion Wales
Iceland Frozen Foods
Institute of Grassland and Environmental Research
Institute of Rural Health
Llanwenog Sheep Society
Lleyn Sheep Society
National Farmers Union (Wales)
National Federation of Meat and Food Traders
National Federation of Womens Institutes
National Sheep Association (Wales)
NPHS in Wales
Organic Strategy Group
Pencoed College
Plas Gwyn
Public Analyst's Laboratory
Royal Welsh Agricultural Society
Royal Welsh Agricultural Society
State Veterinary Service
Stork MPS (Meat Processing Systems)



The Western Mail
Trading Standards Institute (Wales)
Wales Centre For Health
Wales Young Farmers' Club
Welsh Assembly Government
Welsh Assembly Government
Welsh Assembly Government
Welsh Assembly Government – Animal Health Divisional Office
Welsh Assembly Government - Public Health Protection
Welsh Black Cattle Society
Welsh Consumer Council
Welsh Food Alliance
Welsh Food Microbiological Forum
Welsh Highland Shepherds
Welsh Institute of Rural Studies
Welsh Lamb and Beef Promotions
Welsh Local Government Association
Welsh Local Government Association
Womens Farming Union
Womens Farming Union
Wales Council for Voluntary Action
Abergavenny Fine Foods Ltd
Dairy Strategy Group
TILLERY VALLEY FOODS LTD
Woodward Food Service
Zorba Foods
Department of Food Science & Technology
Public Health Alliance Wales
SEVERN TRENT LABORATORIES
National Public Health Service For Wales
Association of Public Analysts
RHM Frozen Foods Ltd
G C Hahn & Co Ltd
Headland Foods
DEE DAIRY SERVICES
Organic Working Group
WDA Agri-Food Development
PB Gelatins UK Ltd
WDA Food Directorate
Countryside Council for Wales
CO-OPERATIVE GROUP
Peters Food Service Ltd
Halo Foods Ltd
Tovali Ltd

Countryside Council for Wales
CARDIFF SCIENTIFIC SERVICES
Chartered Institute of Environmental Health Wales
Welsh Local Government Association
Rhondda Cynon Taff CBC
MERIDIAN FOODS
Federation of Bakers
South Caernarfon Creameries
T/A Source Foods
B Sidoli & Sons Ltd
Clark's Original Pies
Mid Wales Manufacturing Group
Wales Tourist Board
WDA Food Directorate
FOOD SAFETY MICROBIOLOGY LABORATORY
Brookfield Foods Limited
Rachel's Dairy
Chartered Institute of Environmental Health
Conwy County Borough Council
Rhondda Cynon Taff CBC
Denbighshire CC
Blaenau Gwent CBC
Conwy County Borough Council
Monmouthshire County Council
Newport CBC
Powys CC
CAERPHILLY COUNTY BOROUGH COUNCIL
City and County of Swansea
Welsh Fishermen's Association
Cardigan Bay Fisherman's Association
WREXHAM COUNTY BOROUGH COUNCIL
Wales & West Coast Fish Producers Organisation
South West Wales Shellfish Liaison Group
CEREDIGION COUNTY COUNCIL
Denbighshire CC
Gwynedd CC
CITY & COUNTY OF SWANSEA
Institute of Consumer Sciences
Port Health Services
Neath & Port Talbot County Borough Council

Pembrokeshire County Council
Vale of Glamorgan Council
DENBIGHSHIRE COUNTY COUNCIL
Isle of Anglesey County Council
TORFAEN COUNTY BOROUGH COUNCIL
Welsh Food Microbiological Forum
University of Wales Aberystwyth
Bridgend CBC
Flintshire County Council
Vale of Glamorgan Council
Centre for Research into Environment & Health
Welsh Local Government Association
Isle of Anglesey County Council
GWYNEDD COUNCIL
Conwy Mussel Fishermen's Association
North Wales and Deeside Shellfish Liaison Group
Welsh Fishermen's Association - Northern Section
Neath Port Talbot County Borough Council
Merthyr Tydfil County Borough Council
Rhondda Cynon Taff CBC
International Federation for Home Economics
CARDIFF COUNTY COUNCIL
Conwy Mussel Company
Pembrokeshire County Council
CARMARTHENSHIRE COUNTY COUNCIL
Flintshire County Council
GWYNEDD COUNCIL
SWANSEA BAY PORT HEALTH AUTHORITY
Welsh Assembly Government