

## **EXPLANATORY MEMORANDUM TO THE OFFICIAL FEED AND FOOD CONTROLS (WALES) REGULATIONS 2007**

This explanatory memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales.

### **1. Description**

This Statutory Instrument provides for the execution and enforcement of the feed and food elements of Regulation (EC) No 882/2004 on official feed and food, animal health and animal welfare controls. It designates the competent authorities and enforcement authorities and creates relevant offences and penalties. In particular, it provides for the enforcement of rules on official controls of feed and food of non-animal origin imported from outside the Community. Additionally, it provides for the recovery of certain expenses incurred by the competent authorities from feed and food businesses. It revokes and replaces the Official Feed and Food Controls (Wales) Regulations 2006 (SI 2006/590 (W 66)).

### **2. Matters of special interest to the Subordinate Legislative Committee**

None.

### **3. Legislative Background**

The powers enabling this Instrument to be made are contained in section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food and measures relating to feed produced for or fed to food-producing animals, the common agricultural policy of the European Community and measures in the veterinary field for the protection of public health. These powers are transferred to Welsh Ministers by virtue of the EC (Designation) (No 2) Order 2005 (which function has been transferred to them by virtue of paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006) in respect of measures relating to food (including drink) including the primary production of food.

### **4. Purpose and Intended Effect of the Legislation**

The SI revokes and replaces the Official Feed and Food Controls (Wales) Regulations 2006 (SI 2006/590 (W 66)) which, in turn, revoked and replaced the Official Feed and Food Controls (Wales) Regulations 2005 (SI 2005/3254 (W247)). These previous SIs gave effect, in Wales, to aspects of the feed and food elements of Regulation (EC) No 882/2004 on official controls<sup>1</sup> that applied from 1 January 2006. The principal purpose of replacing the current SI is to give effect to a provision in Regulation 882/2004 that applied from 1 January 2007. It will also give effect to a provision that applied from 1 January

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<sup>1</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules. Official Journal L191, 28.5.2004, 1-52.

2006 that was not covered by the preceding SIs. Some other minor amendments are also being made. The overall objective of the replacement SI remains the same, i.e. to contribute to delivering the anticipated benefits of a more effective and consistent enforcement system and, consequently, raise standards of food safety and consumer protection.

## **5. Implementation**

It is intended that these Regulations come into force on 14 December 2007. If the UK did not implement this Decision it would be in breach of a Community requirement. This Statutory Instrument applies only to Wales. Separate but parallel legislation will be made for Scotland, England and Northern Ireland.

## **6. Consultation**

A twelve week consultation was held, on the revisions to the 2006 Regulations, the supporting Regulatory Impact Assessment and the Guidance Notes on charges, between 2 July and 21 September 2007 in Wales.

## **7. Regulatory Impact Assessment**

### **a) Options**

A legal basis in domestic legislation is required to give effect in Wales to the particular elements of Regulation 882/2004 that this RIA covers. The policy options are, therefore, limited to the following:

- Option 1 - Do nothing. This would mean that it would not be possible to apply these particular elements of Regulation 882/2004 in Wales as the competent authorities would not have the necessary legal powers.
- Option 2 - Adopt the SI to ensure that the competent authorities for Wales may fulfil their obligations under Regulation 882/2004 and that provision is made for them to charge for: expenses arising from additional official controls; and, expenses associated with cases where co-ordinated assistance with the other Member States (MSs) and follow-up by the Commission has been necessary. As regards expenses arising from additional official controls, application of this must be linked to the UK's National Control Plan (NCP) which aims to describe the 'normal control activities' of the relevant authorities. Guidance on what constitutes these 'additional control activities' and on when Article 28 charges may apply has been developed by the FSA.

### **b) Benefits**

#### ***Sectors and Groups Affected***

#### ***Competent authorities***

The provisions that this RIA covers relate to charging by the competent authorities. These are the authorities that are responsible for organising and undertaking official feed and food controls. In the UK, this responsibility is held centrally but, in practice, day to day responsibility for official control functions is divided between central and local Government. The scope of the SI which is the subject of this RIA is restricted to those areas of feed and food law for

which the FSA is responsible at central level and to Wales only. The relevant competent authorities are: the FSA (including the Meat Hygiene Service, and other Government Agencies that undertake official control functions on behalf of the FSA), and feed and food law enforcement services of local and port health authorities.

### ***Feed and food businesses***

The charges will be levied against feed and food businesses. There are approximately 91,000 feed business establishments in the UK (breakdown figures for each country of the UK are not available). This includes producers of feed materials, manufacturers of additives and premixtures, manufacturers of compound feedingstuffs, importers, distributors, retailers and farms. With regard to food, there are approximately 32,000 establishments in Wales which include slaughterhouses, cutting plants, manufacturers, processors, packers, importers, distributors and wholesalers, retailers, and restaurants and caterers. There are also approximately 25,000 holdings making up the primary food production sector in Wales.

### ***Consumers***

The proposed measures will contribute towards the overall expected benefits of application of Regulation 882/2004, i.e. a reduction in food-borne disease, a reduction in contamination incidents, and to increased consumer protection. In addition, relevant costs that, indirectly, currently fall to the taxpayer will fall in future to the feed and food industry.

### ***Social and environmental impacts***

The Agency believes that the SI will have no impact on racial equality or on social or environmental sustainability issues.

### ***Administrative burdens***

This SI does not include any new information obligations on businesses and the Agency considers that there are no new administrative costs arising from it which are over and above those that a business would incur commercially.

- **Option 1** - This option will maintain the *status quo* and so will not generate any incremental benefit.
- **Option 2** - ***Expenses arising from 'additional official control activities'***

Costs arising from additional controls currently fall to the tax payer but will, in future, fall to businesses. There will, therefore, be an indirect saving to taxpayers (this is estimated at £10 million - an explanation is provided under "Costs for Competent Authorities" below). This follows the 'polluter pays' principle thereby creating an additional incentive for complying with legal requirements. Although it is not possible to quantify the effect, and albeit that this is not likely to be significant, this in turn may contribute towards a reduction in contamination incidents and food-borne disease and the costs associated in dealing with these.

**- Co-ordinated assistance and follow-up by the Commission**

This relates to administrative costs of informing the other MSs and of travel and subsistence costs associated with the Commission sending an inspection team to investigate cases where repeated non-compliance has been found. Businesses will only be subject to charges where they have not complied with feed/food law such that this too follows the 'polluter pays' principle.

**c)Costs**

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

- **Option 1** - As there would be no change to current arrangements for financing of official controls, there would be no compliance costs for the competent authorities or for businesses. However, to do nothing would leave the UK in breach of an EU obligation to apply Regulation 882/2004. There is also a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK enforcement arrangements and their compliance with the requirements of Regulation 882/2004. In view of this, the FSA considers that Option 1 is not viable.

- **Option 2 - Costs for the competent authorities**  
In relation to both expenses arising from additional official control activities and co-ordinated assistance and follow-up by the Commission, there may be new administrative costs for the competent authorities in terms of collection of monies, including: (a) invoicing and general administrative costs; and (b) costs for pursuing unpaid monies through the courts. As regards (a), such costs should not be significant as competent authorities will already have procedures in place and the number of cases per year is expected to be small. Similarly, in relation to (b), overall costs are not anticipated to be significant given the number of cases per year is expected to be small.

**- Costs for other Government bodies**

In cases where expenses arising from additional official controls may apply it is possible that some additional public expenditure may arise as a consequence of an increased recourse to the use of referee samples to resolve disputes between food business operators and enforcement authorities relating to results of chemical analysis or microbiological examination. The Government Chemist acts as the referee laboratory and the cost of the service, with the exception of a nominal administration fee, is borne by the Department for Innovation, Universities and Skills (DIUS).<sup>2</sup> In the case of samples submitted to the referee analyst, typical costs range from £5,000 for a simple case to £30,000 for a complex investigation. It is, however, not possible to estimate the number of additional referee samples that may be

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<sup>2</sup> More information on DIUS is available at: <http://www.dius.gov.uk/>.

submitted annually or the complexity of any associated investigations. However, given the small number of anticipated incidents to which expenses arising from additional official controls will apply, it is not likely that any costs associated with additional referee sample analysis will be significant.

**- Costs for businesses - expenses arising from additional official controls**

Where feed/food businesses have operated in compliance with feed/food law, the proposed measures have no implications.

In terms of total potential costs where non-compliance is detected and 'additional controls' are necessary, annual costs may be estimated on the basis of the typical amount that businesses would be charged per incident and the expected annual number of incidents to occur. However, as highlighted previously, this is extremely difficult to do as it is not possible to predict the number, nature or extent of serious or significant incidents that may occur and where charges will be appropriate. It is also important to recognise that the cost of an incident may vary widely from case to case depending on the type of additional control activities undertaken and the volume of such controls that are required. The variations include costs for:

- Enforcement or inspection visits: costs vary depending on the degree and nature of activity that the enforcement officer must undertake.
- Sampling activities - the average cost lies between £25 and £100 per sample depending on the type of product being sampled.<sup>3</sup>
- Chemical analysis or microbiological examination – costs range between £50 and £400 per sample.<sup>4</sup> Exceptionally the costs of particularly complex analysis, as in the case of dioxin, may start at £700 per sample.<sup>5</sup>

Notwithstanding these points, an indication of annual costs to all competent authorities has been estimated as described below.

With regard to labour costs (officer time) associated with feed/food incidents, it can be estimated that in the order of 20 officer days per year may be allocated to dealing with incidents by each of the 22 local authorities in Wales.<sup>6</sup> This suggests a total annual cost of £80,000 to local authorities handling incidents in Wales.

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<sup>3</sup> Source: Data provided to the FSA in relation to its imported food sampling programme.

<sup>4</sup> Source: Data provided to the FSA in relation to its imported food sampling programme.

<sup>5</sup> Source: Data provided to the FSA by LGC independent chemical analysis laboratory. More information on LGC is available at: <http://www.lgc.co.uk/>

<sup>6</sup> Source: Estimate of resource allocated in a cross section of local authority service plans.

In 2006, the total number of UK incidents reported to the Agency by local authorities (under the provisions of the Food Law Code of Practice) was 1352, of which 10 were classified as 'high' in accordance with the Agency's Incident Response Protocol,<sup>7</sup> giving an average labour cost of around £1,000 per incident. Taking into account that a serious or significant incident may require a much greater allocation of officer time it may be concluded that such incidents represent a labour cost of £10,000 across the UK.

In addition to labour costs, however, there will be costs for sampling and analysis, and depending on the nature of the incident, these may represent a significant proportion of the total charges made. It may be suggested that in dealing with a serious or significant incident, the competent authority may need to take an additional 2,000 samples at a cost of £100 each and have these analysed at a typical cost of £400 per sample. Based on the frequency of 10 serious incidents occurring annually (this was the number that occurred in 2006), this would represent an upper bound estimate of the annual cost in the UK of £10.1 million.

The incidents that were classified as 'high' are described in the FSA Annual Report of Incidents 2006.<sup>8</sup> It should be noted that the application of expenses arising from additional official controls was not considered in these cases as Article 28 has only applied since 1 January 2007. These incidents are provided only as examples of the type of incident where charges for additional official controls *may* be applied and in identifying them no judgement has been made as to whether such charges would have been appropriate. They are being used for indicative purposes only in the absence of real situations where Article 28 has been used. The post-implementation review of the measures will be important in re-considering the costs to businesses.

***- Costs for businesses - expenses associated with co-ordinated assistance with the other MSs and follow-up by the Commission***

The costs incurred here are likely to be insignificant. As regards informing the other MSs and the Commission of a problem where there is repeated non-compliance, this would be achieved via a single email. As regards follow-up by the Commission, costs relate to travel and subsistence expenses associated with a visit to a MS to investigate issues where repeated non-compliance is found. Such visits are expected to take place only very infrequently.

Annual total costs for this are estimated at approximately £10,000. This is based on the assumption that there would be two visits of four

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<sup>7</sup> Classification 'high' describes severe incidents that are complex and widespread. More information on the Incident Response Protocol is at: <http://www.food.gov.uk/consultations/ukwideconsults/2006/prevrespfood>.

<sup>8</sup> Report is available at: <http://www.food.gov.uk/multimedia/pdfs/incidentsar.pdf>

days duration, and with a Team of three inspectors. Costs are based on travel and subsistence costs for officials of the Commission's Inspection Services (the Food and Veterinary Office).<sup>9</sup>

#### **d) Competition Assessment**

On the basis of a Competition Filter Test, the provisions in the SI that affect businesses are unlikely to have a negative impact on competition. These provisions apply to all new and existing feed/food businesses but are expected to affect only a very small number of businesses annually. In view of this, any effect on competition will be negligible.

#### **e) Consultation**

Thirty nine stakeholders were consulted in Wales with two respondents. Across the UK some 1000 stakeholders were consulted. The majority of the comments related to the “additional official controls”. In general the principle that charges should be imposed was accepted but concerns were expressed as to how these may be applied in a fair and consistent manner.

The Guidance Notes have been revised to take account of these concerns and to clarify as much as possible when and how charges should be applied. The Guidance will also be kept under review and revised in the light of experience and the establishment of case law, and to reflect any developments at EU level. There was also concern that there was no formal right of appeal. As regards this point, it is considered that the civil courts will provide the most appropriate forum for dealing with grievances in respect of these charges as determination of the issue will be quicker and less cumbersome than a formal appeal to the Magistrates Court, or an appointed person.

#### **f) Post Implementation Review**

The SI and associated guidance will be kept under review and any feedback received from stakeholders will be considered. In particular, the Guidance Notes on applying the provision in the SI on expenses arising from additional official controls will be kept under review and revised in the light of any developments at Community level and to reflect experience of the competent authorities in applying Article 28 charges and the establishment of relevant case law.

Regulation 882/2004 empowers the Commission to develop detailed implementing rules regarding the provision on charges for expenses arising from additional official controls with a view to ensuring uniform application. Such rules are unlikely to impact on the legal measure included in the SI for England but they may impact on the associated guidance. The SI and

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<sup>9</sup> Staff Regulations of Officials of the European Communities (Annex VII: Remuneration and reimbursement of expenses (European Community website at: [http://ec.europa.eu/civil\\_service/docs/toc100\\_en.pdf](http://ec.europa.eu/civil_service/docs/toc100_en.pdf)).

Guidance will be reviewed if and when the Commission introduces implementing rules.

In addition, the European Commission is required under the provisions of Regulation 882/2004 to undertake a review of its application. The focus of the review will be the provisions on financing of official controls. The review should have been undertaken in 2007 but was delayed as the new framework on financing had only just come into operation. The Commission is now expected to initiate a review of the impact of the framework in 2008. The UK will feed into this and will review the SI and any other application measures as part of that.

The annual reports on implementation of the UK National Control Plan will also provide the basis to review the effectiveness of the application measures put in place in Wales (and throughout the UK).

### **g)Summary**

The proposed SI will ensure that the provisions on charges for expenses arising from additional official controls and expenses associated with cases where co-ordinated assistance with the other MSs and follow-up by the Commission has been necessary are applied in Wales. The cost to feed/food businesses will be off-set by savings for the competent authorities (and indirectly to the taxpayer). The provisions will apply only where there is non-compliance with feed/food law. The charges may, therefore, provide an incentive to businesses to comply with legal requirements. This may contribute to a reduction in food-borne disease and in contamination incidents and to increased consumer protection. In view of the above, it is considered appropriate to adopt option 2 and introduce the SI into Welsh law is.

### **Summary costs and benefits table**



<b><i>Option</i></b>	<b><i>Total cost per year</i></b>	<b><i>Total benefit per year</i></b>
1. Do nothing	<p>None.</p> <p>This option will leave the UK in breach of an EU obligation to apply Regulation 882/2004 and open to challenge from the European Commission.</p>	None.
2. Adopt the SI to ensure that competent authorities in Wales and may fulfil their obligations under Regulation 882/2004	<p>Feed/food businesses not in compliance with feed/food law, an upper bound estimate of the annual cost in the UK of £10.1 million.</p> <p>Total annual expenses of £10,000 associated with co-ordinated assistance with other MSs and follow-up by the Commission.</p> <p>Additional public expenditure that may arise as a consequence of an increased recourse to the use of referee samples. It is not possible to quantify these costs.</p>	<p>Reduced cost to taxpayers of an estimated £10.1 million</p> <p>The additional incentive for businesses to comply with feed and food law may contribute to a reduction in contamination incidents and food-borne disease and the costs associated with these.</p>