

**EXPLANATORY MEMORANDUM TO  
THE FOOD HYGIENE (WALES) (AMENDMENT) REGULATIONS 2014**

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

**Member's Declaration**

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

Mark Drakeford

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

14 July 2014

## **1. Description**

The Food Hygiene (Wales) (Amendment) Regulations 2014 (the Regulations) will implement EU regulations on

- Trichinella testing of pigs
- removal of the requirement for a special health mark for emergency slaughter and
- transport by seagoing vessel of liquid oils or fats which are intended for or likely to be used for human consumption.

## **2. Matters of Special Interest to the Constitutional and Legislative Affairs Committee**

None

## **3. Legislative Background**

The powers enabling these Regulations to be made are conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972.

The Welsh Ministers are designated for the purposes of section 2(2) of the 1972 Act in relation to measures relating to food (including drink) and to the veterinary and phytosanitary fields for the protection of public health. The relevant designation orders are the European Communities (Designation) (No. 2) Order 2005 and the European Communities (Designation) (No. 2) Order 2008. The 2005 Order conferred functions on the National Assembly for Wales. Those functions were transferred to the Welsh Ministers by section 162 of and paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006.

This instrument is subject to the negative procedure.

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

The objective of the Regulations is to:

1. introduce a risk-based programme for the testing of pigs at time of slaughter for Trichinella,
2. recognise the risk assessment carried out by the European Food Safety Authority (EFSA) for the Commission in relation to the meat from animals subject to emergency slaughter (subject to their passing post-mortem inspection) and remove restrictions on the sale of meat from those animals, and

3. reflect the EFSA view of the discussion in Codex Alimentarius which resulted in the adoption of criteria to be used to determine the acceptability of previous cargoes for bulk edible liquid oils and fats transported by sea.

## 5. Consultation

A separate public consultation exercise was held on each of the three measures in these amending Regulations in Wales. Different approaches were followed by other devolved administrations.

### Trichinella testing

In Wales, this measure was included in a wider consultation on a number of proposals from the EU on food hygiene relating to the slaughter of pigs. The consultation ran from 25 March to 6 May 2014.

One response was received from Farmers Union of Wales to the wider consultation, but this did not express any objection to the measure on Trichinella.

In England seven responses were received. The main issue raised in relation to the Trichinella testing measure was that no Trichinella had been detected in outside housed pigs in the UK for a number of years. Therefore, the proposed testing changes might be seen as disproportionate. However, the FSA has highlighted the benefit to the UK of becoming *officially* "Trichinella free" but has reminded stakeholders that three years' data from the coming into force of the EU Regulation on 1 June 2014 will be required for this benefit to be realised.

There was also a query over the distribution of the testing cost, with the opinion that this might end up being passed back to the farmer. The distribution of the costs of testing arrangements is addressed in the Impact Assessment that is appended to the Explanatory Memorandum to this Legislation Folder, but essentially, the setting of charges is a commercial decision for a slaughterhouse.

In Scotland six responses were received. Two industry responses questioned whether this measure was proportionate, given the absence of Trichinella in the UK. It was also considered that any costs may be distributed towards the smaller abattoirs, as these may be more likely to handle pigs from non-controlled housing. Further, given the specific geography in Scotland, it was thought possible that transport costs for samples to testing facilities are likely to be higher than in other parts of the UK.

In Northern Ireland, the Northern Ireland Food Advisory Committee highlighted an issue of the distribution of cost for testing of pigs coming for slaughter from another Member State (in their case the Republic of Ireland).

## **Emergency slaughter – Wales**

In Wales, the consultation on this measure ran from 13 May to 10 June 2014.

We received two responses, one from National Farmers' Union Wales and the other from Hybu Cig Cymru.

Both responses supported the proposal and agreed with our assumption that this would cause no increase in costs for the sector.

No written responses were received to the informal consultations carried out in Scotland and Northern Ireland. An informal response received from a stakeholder in Scotland was supportive of this measure.

## **Transport of oils and fats**

The consultation ran from 9-23 June 2014

We received one response from the chair of the All Wales Port Health Expert Panel, part of the Wales Heads of Environmental Health Group, confirming that there was no known trade of this nature through sea ports in Wales.

This measure is to be included in forthcoming Statutory Instruments in the rest of the UK, so no public consultation has yet occurred outside Wales.

## **6. Regulatory Impact Assessment**

**NOTE:** This impact assessment refers only to the measure on Trichinella testing. It has been established through public consultation that no financial impacts are expected in Wales as a consequence of the other measures.

### **Sectors and Groups Affected**

#### **Slaughterhouses**

Breeding sows and boars will continue to be tested as they are at present within the core testing programme that has been in place for some years. This fulfils the first component of the testing requirements. To fulfil the second part of the testing requirements, slaughterhouses will need to test all pigs from non-controlled housing

conditions. The FSA pig plant data for 2013 shows that there are a total of 130 slaughterhouses in England and Wales which slaughter pigs. Of these, 56 slaughterhouses slaughter pigs only and 74 are multi-species slaughterhouses, which slaughter pigs as well as other species.

A total of 8.12m pigs were slaughtered in these 130 plants. There is a significant amount of consolidation in the pig industry. For example, the 11 largest pig-only plants account for 6.8m of the 8.12m pigs slaughtered. The 9 largest multi-species plants account for a further 743,000 pigs, which means that combined together the 20 largest plants account for 7.54m (93%) out of 8.12m pigs slaughtered in England and Wales. The remaining 580k pigs are slaughtered in 110 small, medium and micro plants.

All 130 of these plants could be affected, as they could potentially slaughter pigs from non-controlled housing conditions, and could therefore incur increased costs of additional testing. The calculations below reflect this possibility. However, given that almost 93% of pigs are processed in the largest 20 plants, it is not unreasonable to expect that a significant proportion of pigs not in controlled housing will be processed at these 20 plants, a number of which already test all of their pigs for *Trichinella*.

**Table A:** Number of Slaughterhouses Potentially Affected by Size (England and Wales)

	Micro	Small	Medium	Large	Total
England	57	41	4	13	115
Wales	12	3	0	0	15
Total	69	44	4	13	130

*Source: FSA pig plant data (2013); Micro: slaughterhouses killing less than 5,000 pigs per annum; Small: 5,000 to 37,500 pigs per annum; Medium: 37,500 to 100,000 pigs per annum; Large: over 100,000 pigs per annum.*

### **Farmers**

We anticipate that the effect on farmers will be minimal. The only impact on farmers is that they need to ensure that information about housing conditions is included in the FCI accompanying the pigs to the slaughterhouse. As mentioned above, this will be captured by one single, additional box on the Food Chain Information (FCI) form, which farmers will need to tick if pigs have been reared under non-controlled housing conditions.

**Table B:** Number of Holdings Affected (England and Wales)

	England	Wales	Total
Total no. of holdings	<b>7900<sup>1</sup></b>	<b>1407<sup>2</sup></b>	<b>9307</b>

*Source: 2012 Census data*

<sup>1</sup> Some holdings will have both breeding and fattening pigs.

<sup>2</sup> The Welsh figures include non-commercial holdings, so the actual figure of holdings with pigs going for slaughter will be significantly lower.

## **Food Standards Agency**

The FSA will incur costs arising from the mapping of controlled housing and compartments. The Agency will also have the cost of providing support and advice on setting up new in-house laboratories. There will be also be a cost to the FSA with regard to training for Official Veterinarians (OVs) in slaughterhouses as Trichinella testing is done under their supervision and they will need to be familiar with the testing requirements to provide appropriate verification that testing is being carried out correctly.

## **Enforcement**

There will be a cost to OVs in terms of familiarising themselves with the new requirements regarding the definition of controlled housing and integrating such verification into existing audit processes, although we are exploring how far this can be supported by third party accredited schemes.

## **Consumers**

The main direct impact of this proposal is increased testing for Trichinella by slaughterhouses, which could potentially generate health benefits to consumers, although, as mentioned above, the risk of Trichinella in the UK has been assessed as low. As the number of additional pigs to be tested is estimated to be around 3% of the England and Wales pig populations, many of which may well already be tested given the consolidation within the industry, the impact of this measure on consumers in terms of price changes is expected to be negligible.

## **Costs**

### **Costs to Slaughterhouses**

#### ***Familiarisation Costs (One-Off Costs)***

There will be costs to slaughterhouses from the need to familiarise themselves with the new Regulation. Although not all slaughterhouses will be affected by the requirement of additional testing we envisage that most slaughterhouses will want to familiarise themselves with the new requirements to ensure that they meet legal requirements. Familiarisation costs can be monetised as a time cost, multiplying the time required for familiarisation by the wage rate of the employee carrying out the familiarisation. We envisage that it will be business managers (wage rate of £25.80<sup>3</sup>) who will need to familiarise themselves with the new requirements and that this will take approximately one hour per business. Multiplying the wage rate by the number of hours required and the number of slaughterhouses (see Table **A**) generates a total cost to England and Wales slaughterhouses of £3,354.

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<sup>3</sup> Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-280149>. Median hourly wage rate of a 'production managers and directors' was used, £19.83, plus 30% overheads, totalling £25.8.

Table C: Familiarisation costs to slaughterhouses in England and Wales (£)

	England	Wales	Total
Familiarisation	2,967	387	3,354

In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor.<sup>4</sup> The total one-off familiarisation cost under this proposal is £3,354, which generates a total EAC of £390.

Table D: Familiarisation Equivalent Annual Costs (£)

	England	Wales	Total
EAC	345	45	390

Costs from Additional Testing (Ongoing Cost)

There will be costs to slaughterhouses that slaughter pigs from non-controlled housing conditions. FSA pig plant data suggest that there are around 8.12m pigs that go for slaughter in England and Wales each year, out of which approximately 3% (243,600) are from what would be considered as holdings not operating controlled housing conditions (also known as ‘outdoor pigs’) and therefore would have to be tested under the proposal. This therefore amounts to an additional 243,600 samples per annum. However, as noted earlier, given the consolidation of the industry and the fact that almost 93% of pigs are processed in the 20 largest plants, it is not unreasonable to expect that a significant proportion of these pigs may already be subject to testing, as the 20 largest plants include those that test for export and some businesses which already have an in-house laboratory for Trichinella testing.

Based on existing structures within industry which sees the vast majority (c. 95%) of Trichinella testing being conducted through the in-house laboratory route (which is much cheaper and which means that carcasses can be moved through more quickly), we anticipate that 95% (231,420) of the pigs not from controlled housing will go through ‘in-house’ labs at 60p per test; and that the remaining five percent (12,180) would go through the private accredited laboratory route which means an estimated cost of £4.09 per pig tested<sup>5</sup>.

Based on these assumptions, we can calculate that the cost of additional tests carried out in in-house laboratories is £138,852<sup>6</sup> and the cost of additional tests carried out privately is £49,816. As the cost of in-house testing is borne entirely by the FSA (with the exception of those FBOs that test for export), the total cost to the

<sup>4</sup> The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. For a policy with a life span of 10 years and a discount rate of 3.5% the annuity factor is approximately 8.6.

<sup>5</sup> This estimated figure for cost per animal tested through private accredited laboratories is based on current testing costs.

<sup>6</sup>  $0.95 * 243,600 * £0.6 = £138,852$

slaughterhouse sector under this proposal is £49,816<sup>7</sup>. This cost could be an overestimate as a proportion of slaughterhouses already carry out tests for Trichinella on all pigs they slaughter. Currently the distribution of these costs across slaughterhouses by country and size is unclear. Table E below shows these costs.

It should also be noted that the assessment of the costs of any additional testing required to meet the requirements of the Regulation are based on the current framework for Trichinella charging and the existing distribution of costs between FSA and industry (i.e. FSA bearing the cost of testing for all sows and boars and all outdoor pigs tested in in-house laboratories). As such, this does not represent a commitment for the structure of any future charging framework

Table E: Total cost of additional of additional testing (£)

	No. tests	Cost per test	Total cost
In-house tests (borne by FSA)	231,420	£0.6	£138,852
Private tests (borne by industry)	12,180	£4.09	£49,816
<b>Total cost to industry</b>	£49,816		

It should be noted that if the testing requirements are properly implemented for three years and there are no positive results for Trichinella in the pig population, then the UK will be in a position to apply for derogations from the testing requirements which may help to reduce costs.

Potential Costs from Moving to In-House Testing (One-Off Cost)

The new testing requirements will result in an increase in the number of Trichinella tests that slaughterhouses need to carry out. Testing must be carried out using the methods set out in the regulation at a designated laboratory and many slaughterhouses may therefore consider setting up their own in-house lab, rather than using a private accredited laboratory. Although this cost would not technically be a direct cost, as setting up an in-house lab is not a direct requirement of the new Regulation, initial discussions with stakeholders suggest that in practice this would be the most likely outcome of the policy.

Engagement with stakeholders and information from current practice suggests that the cost of setting up an in-house laboratory is around £3-5k (this covers the capital investment in kit and materials, it does not include staff costs); however, this figure can vary depending on the scale of the operation. Based on current information about testing practices, we would expect that micro plants will either seek to make an arrangement to use the in-house laboratory of a nearby food business operator

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<sup>7</sup> 0.05 \* 243,600 \* £4.09 = £49,816



(FBO) or send samples to a private accredited laboratory nearby. The recent increased interest from small plants in setting up their own in-house testing indicates that most in this sector would seek to set up their own laboratory, as would the medium and larger businesses, mainly because this facilitates faster turnaround of carcasses. We currently do not know how many slaughterhouses there are that already have in-house labs, but if we assume a high-impact scenario where all small, medium and large slaughterhouses would need to set up an in-house laboratory, the total one-off cost to industry would be between £183,000 and £305,000 (using the cost range of £3-5k above), with a best guess estimate of £244,000 (based on the average of the range). Table F below show the central (best guess) scenario. However, given that some of these slaughterhouses may already have in-house labs, this is likely to be an overestimate.

Table F: Costs to slaughterhouses from setting up an in-house lab (£)

	Micro	Small	Medium	Large	Total	EAC
England	0	164,000	16,000	52,000	232,000	26,953
Wales	0	12,000	0	0	12,000	1,394
Total	0	176,000	16,000	52,000	244,000	28,347

## Costs to Farmers

### *Familiarisation (One-Off Cost)*

The main direct impact on farmers from the new Regulation is that the food chain information that needs to accompany pigs from the farm to the slaughterhouse will need to include information on whether the pigs are from non-controlled housing or not. To farmers this essentially means ticking a box if the pigs they supply are from non-controlled housing. We envisage that this will involve some familiarisation costs to farmers. Familiarisation costs can be monetised by multiplying the wage rate of the person carrying out familiarisation by the time required. We envisage that it will be the farm manager (wage rate of £17.20<sup>8</sup>) that will familiarise themselves with the changes, and that half an hour per farm would be sufficient; as only a proportion of the new requirements apply to farmers. Multiplying the wage rate by the time required, and again by the number of farms (see Table B) generates a total one-off cost of familiarisation to farmers of £80,040. Table G below shows the familiarisation costs to farmers and the associated equivalent annual costs.

Table G: Familiarisation Costs to Farmers (£)

	England	Wales	Total
Familiarisation	67,940	12,100	80,040
EAC	7,893	1,406	9,299

<sup>8</sup> Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of 'Managers and proprietors in agriculture and horticulture' was used, £13.26, plus 30% overheads, totalling £17.2.

### Changes to Requirements on Provision of Food Chain Information (Ongoing Cost)

As outlined above, the new Regulation requires that FCI includes information on whether pigs are from non-controlled housing or not. The amendment to the FCI form will consist of one additional box, which the farmer will need to tick to indicate whether or not the farm has controlled housing conditions, and therefore whether or not the pigs need to be tested for Trichinella. We envisage that this requirement will result in a negligible cost to farmers, as they already need to fill in the rest of the form, and the additional tick will require negligible time.

### **Costs to Enforcement**

#### Familiarisation (One-Off Cost)

There will be costs to enforcement from the need to familiarise themselves with the new Regulation. We envisage that the main impact will be on OV's as they are responsible for monitoring Trichinella testing. We envisage that familiarisation would require one OV per slaughterhouse and that familiarisation would take approximately one hour. As mentioned above, familiarisation costs can be monetised as a time cost, multiplying the time required for familiarisation by the wage rate of the employee carrying out the familiarisation. Multiplying the wage rate of an OV (£36.80, FSA internal data) by the number of hours required and the number of slaughterhouses (see Table A) generates a total cost to enforcement of £4,784. Table E below shows the familiarisation costs to enforcement as well as the associated Equivalent Annual Costs.

Table H: Familiarisation Costs to OV's (£)

	England	Wales	Total
Familiarisation OV's	4,232	552	4,784
EAC	492	64	556

#### Training (One-Off Cost)

We anticipate that enforcement officers will incur training costs as a result of the Regulation, as they are responsible for the supervision of Trichinella testing. These costs will be borne by the FSA and costs have therefore been presented in the section on costs to the Food Standards Agency.

#### Audit and Verification On-Farm (Ongoing)

With regard to the costs of auditing and verification, in line with the recommendations of the Farming Regulation Task Force, this will be integrated as far as possible within existing AHVLA inspections and visits, as a number of the criteria for determining whether a holding has controlled housing relate to core issues such as biosecurity and compliance with animal by-products regulations. These factors are also assessed in audits by accredited third party assurance schemes and we anticipate

that the on-farm verification can be supported by such third party schemes. The final costs associated with this aspect of enforcement, including related issues such as communication, have still to be determined.

## **Costs to Food Standards Agency**

### Cost of mapping controlled housing (One-Off)

The new Regulation requires that all pigs from non-controlled housing conditions are tested for Trichinella. The FSA is currently undertaking an exercise to map controlled housing holdings, supported by evidence from historic testing data and wildlife surveillance. The estimated cost to the FSA associated with this mapping exercise is £10k.

### Cost of Additional Testing for Trichinella (Ongoing)

The new Regulation requires that all pigs from non-controlled housing conditions are tested for Trichinella. As outlined above, this will generate costs both to slaughterhouses and to the FSA. Currently all costs of in-house testing are borne entirely by the FSA, and as this will continue under the new proposal, the total additional costs to the FSA from this Regulation are £138,852.

### Costs of Training OV's (Borne by the FSA) (One-Off Costs)

We anticipate that the Regulation will result in training costs to OV's. These costs will be borne by the FSA. We envisage that training will take one OV per slaughterhouse approximately one hour and consist of an on-line course. Just as familiarisation costs, training costs can be monetised as a time cost. Multiplying the wage rate of an OV (£36.8, FSA internal data) by the number of hours required and the number of slaughterhouses (see Table A) generates a total cost to enforcement of £4,784. Table I below shows the familiarisation costs to enforcement.

Table I: Costs of Training OV's (Borne by the FSA) (£)

	England	Wales	Total
Costs of Training OV's	4,232	552	4,784

## **Benefits**

### **Benefits to Consumers**

#### Benefits to Consumers from more Stringent Trichinella Controls (Non-Monetised)

Although UK evidence from testing indicates that the risk from Trichinella is low in the UK, the parasite can cause serious illness in humans. The aim of the new EU Regulation is to minimise this risk and can therefore have public health benefits.

### **Benefits to Industry**

#### Potential to Secure Derogations from Trichinella Testing (Non-Monetised)

The UK has a long-term objective to secure derogations from Trichinella testing. The new Regulation provides a clear path to securing that new recognition, which applies if no infections have been detected in pigs reared in controlled housing conditions for a period of three years. UK evidence from testing indicates that the risk from Trichinella is low and it is the FSA's view that this is a realistic prospect for the UK. Compliance with the European requirements, which are in turn aligned with those governing trade and animal health and are in development at international level (Codex and OIE), will also help support further trade in the medium and long term.