

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (BRIA)

Amendments to the Salmonella process hygiene criterion (PHC) for carcasses of pigs (as laid down in Regulation (EC) No 2073/2005) and the requirements for its verification by the competent authority (as laid down in Regulation (EC) No 854/2004)

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1. Title of Proposal

- 1.1 Commission Regulation (EU) No 217/2014¹ of 7 March 2014 amending Regulation (EC) No 2073/2005² as regards Salmonella in pig carcasses and also Commission Regulation (EU) No 218/2014³ of 7 March 2014 amending Regulation (EC) No 854/2004⁴ of the European Parliament and of the Council have subsequently been introduced at EU level to strengthen Salmonella control in slaughterhouses.

2. Purpose and Intended Effect

Objectives

- 2.1 The policy objectives are to reduce the risk to consumers from Salmonella contamination in pig carcasses by enhancing Salmonella controls in the slaughterhouse as a result of stricter parameters for the Salmonella Process Hygiene Criterion (PHC) and ensuring that the new competent authority (CA) verification and reporting requirements are fulfilled.

Rationale for Government Intervention

- 2.2 The FSA is the central competent authority in the UK responsible for carrying out official controls in slaughterhouses in Scotland, England and Wales. In Northern Ireland, the official controls are delivered by the Department for Agriculture and Rural Development (DARD) on behalf of the FSA.
- 2.3 Intervention is needed to implement Commission Regulation (EU) 217/2014 and Regulation (EU) 218/2014 to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004 respectively to improve consumer protection by reducing the presence of Salmonella on pig carcasses and improving official verification of food business operator (FBO) compliance. Adequate systems must be in place by 1 June 2014 for the UK to comply with the new sampling, verification and reporting requirements and to realise the benefits of a stricter Salmonella criterion and compliance verification system.
- 2.4 Salmonella is one of the commonest causes of food poisoning in the UK and can result in serious illness or death. Salmonella food poisoning has significant economic effects on society and industry through medical costs, loss of working time and consumer confidence in certain foods, and the costs of control.

Background

EU Hygiene Regulations

- 2.5 EU food hygiene rules for FBOs are set out in Regulation (EC) 852/2004 and Regulation (EC) 853/2004. Regulation (EC) 854/2004 lays down rules for CAs. These three Regulations, which came into force on 1 January 2006, govern the placing on the market of meat for human consumption and lay down, respectively, hygiene requirements for all food businesses, specific rules for foods of animal origin,

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:069:0093:0094:EN:PDF>

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2005R2073:20130701:EN:PDF>

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:069:0095:0098:EN:PDF>

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0854:20130701:EN:PDF>

and requirements for the organisation of official controls on products of animal origin for human consumption. The Regulations together are known as the Hygiene Package.

- 2.6 Official controls on meat are prescribed by directly applicable EU legislation. Their objective is to detect and prevent public health hazards such as foodborne pathogens or chemical contaminants. Meat inspection also plays an integral role in the overall monitoring system for certain animal diseases and the verification of compliance with animal welfare standards.

Revision of the Hygiene Package

- 2.7 In July 2009, the European Commission undertook a review of the experience gained from the implementation of the Hygiene Package since 2006. It concluded that, overall, the experience of the Hygiene Package was positive and that there was no need for a fundamental overhaul. However, the Council of the EU invited the Commission to prepare legislative proposals for the modernisation of sanitary inspection in slaughterhouses.
- 2.8 In May 2010, the Commission asked the European Food Safety Authority (EFSA) to carry out risk assessments on official meat controls and to recommend alternative approaches to inspection. EFSA's work was prioritised by species and its scientific advice (known as Scientific Opinion) on pig inspection was published in October 2011⁵.
- 2.9 The Opinion identified Salmonella as a priority target for the inspection of swine meat in abattoirs due to its prevalence and impact on human health. EFSA also concluded that the current meat inspection regime does not address current foodborne hazards, which are mostly microbiological in nature and cannot therefore be detected by the naked eye. Therefore, EFSA made a series of recommendations which included risk reduction measures in the abattoir, which focused on prevention of microbial contamination through robust process hygiene-based measures.
- 2.10 An EU-wide baseline survey on slaughtered pigs carried out in 2006-2007 informed the EFSA Opinion in relation to the estimated prevalence of Salmonella in slaughter pigs on carcasses across Europe. For the 2006-2007 study, in the UK, 660 pigs were sampled in total at 18 abattoirs. Samples were taken from carcass surfaces of randomly selected pigs in the participating slaughterhouses. The survey report was published by EFSA in June 2008⁶. The UK abattoir prevalence estimate was 13.5% for all Salmonella types compared to an EU average prevalence of 8.3%. A similar study was conducted in 2013 but results were not available at the time of publication of this business and regulatory impact assessment (BRIA).

Salmonellosis in humans

- 2.11 Salmonellosis is an infection of animals and man caused by a group of bacteria called Salmonella. These can live in the digestive tract of a wide range of mammals (including people), birds and reptiles and are present worldwide. Infection in humans may follow contact with infected animals or contaminated items or environment. Symptoms of human salmonellosis can include fever, diarrhoea and abdominal

⁵ <http://www.efsa.europa.eu/en/press/news/111003.htm>

⁶ <http://www.efsa.europa.eu/en/efsajournal/pub/135r.htm>

cramps. This is usually fairly short-lived and often does not cause any obvious disease. However, it can be life-threatening if it infects the bloodstream.

2.12 The epidemiology of salmonellosis in humans, which can be transmitted from pigs, is complex. There are many distinct types of Salmonella that can manifest themselves in different ways in pigs and humans, and the links between live pigs and human infection are not straightforward.

2.13 In 2012, 8,798 cases of laboratory confirmed salmonellosis in humans were reported in the UK. For every laboratory confirmed report of disease made to national surveillance schemes, there are estimated to be 4.7 unreported cases. This means the total number of cases in the UK in 2012 was approximately 50,000⁷.

2.14 In 2010, an analysis of the costs and benefits of setting a target for the reduction of Salmonella in slaughter pigs⁸ estimated that the total annual human health losses at EU level due to Salmonella in pigs to be approximately €90 million (£75m) and a total cost of €600 million (£500m) for Salmonella as a whole. This corresponds to €600 (£500) per human case.

Microbiological criteria for foodstuffs

2.15 Microbiological criteria for foodstuffs are set out in Regulation (EC) 2073/2005. The safety of foodstuffs is mainly ensured by a preventative approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in the validation and verification of HACCP procedures and are established at EU level, where their application provides additional public health benefits. These microbiological criteria are supported by risk assessment and scientific opinion from organisations such as EFSA and WHO/FAO (World Health Organization and the Food and Agriculture Organization of the United Nations).

2.16 The Regulation defines two types of microbiological criteria:

- process hygiene criteria (PHC): criteria to assess the hygiene of food production processes.
- food safety criteria: limits for certain microorganisms above which a foodstuff is deemed unacceptably contaminated.

2.17 Microbiological testing results support the validation and verification of HACCP procedures and other hygiene control measures which will be reviewed where results indicate contamination is occurring at unacceptable levels. Slaughter and dressing operations provide many opportunities for contamination of carcasses with bacteria that may be associated with animal infection or slaughterhouse environment. Testing against the PHC provides an indication of the operator's capability to manage contamination during slaughter, dressing and production processes.

2.18 The Regulation describes the requirements for the PHC for Salmonella in pig carcasses. The UK, making use of the flexibility within the Regulation, has adapted the testing requirements based on the slaughterhouse throughput level and risk:

⁷ <http://www.documents.hps.scot.nhs.uk/ewr/pdf2013/1337.pdf>

⁸ http://ec.europa.eu/food/food/biosafety/salmonella/docs/fattening_pigs_analysis_costs.pdf

- **Slaughterhouses with a throughput level above 100,000 animals per annum:** FBOs must sample and test five pig carcasses each week for Salmonella. In any 10-week period, the number of positive samples (or *c* value) must not exceed five (out of the 50 samples taken or *n* value), otherwise corrective action is required. If results are satisfactory over a period of 30 consecutive weeks, these slaughterhouses are eligible to move to a reduced testing frequency of five carcasses once every two weeks.
- **Slaughterhouses with a throughput level of 37,500 to 100,000 animals per annum:** FBOs must sample and test five pig carcasses once every four weeks. The same *c* and *n* value as for a higher throughput level apply, as well as the requirement of corrective action in response to unsatisfactory results. These slaughterhouses are however not eligible to move to a reduced testing frequency.
- **Slaughterhouses on a throughput level below 37,500 per annum:** FBOs are exempt from testing for Salmonella.

Table 1: Sampling regime in UK

Annual throughput	Sampling frequencies	
	Initial frequency	Reduced frequency if results are satisfactory
Over 100,000	5 carcasses once a week for 30 weeks (30x5=150 samples)	5 carcasses once every 2 weeks
100,000 - 37,500	5 carcasses once every 4 weeks	No reduction
Below 37,500	No testing required	

2.19 FBOs must test samples using the reference method or an alternative that has been validated according to the requirements in the Regulation.

2.20 The Regulation requires the FBO to analyse the trend of testing results and if the trend is towards unsatisfactory results, take action to prevent microbiological risk. This includes: improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin.

Amendments to the Regulations

2.21 Following publication of the EFSA Opinion on pig inspection, the Commission developed legislative proposals to tackle the risk from Salmonella contamination in slaughterhouses and increase consumer protection.

2.22 The Commission presented initial proposals (to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004) at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) meeting on 21 September 2012. The proposals were subject to lengthy negotiations and considerable revision, ultimately achieving qualified majority vote of Member States in May 2013.

Amendments to the Salmonella PHC

2.23 The initial draft proposal amending criterion 2.1.4 (Salmonella in carcasses of pigs), as set out in Regulation (EC) 2073/2005, prescribed a five-fold increase in the sampling regime, whereby FBOs would be expected to sample 25 carcasses a week

without exceeding the maximum threshold of 25 Salmonella positive samples in any 10-week period. The UK opposed the draft proposal on the basis of it being disproportionate when compared to the potential positive effect on consumer protection. This proposal would have increased sampling and testing costs significantly but, as the ratio of acceptable number of positives to the total number of samples taken (1:10) had not changed, the UK had reservations about the positive impact on public health.

2.24 Following a number of proposals from the Commission and Member States and various suggested combinations of sample levels and acceptable limits, consensus was reached on a final proposal which maintained the current level of sampling⁹ (this is 50 samples over a 10-week period¹⁰) but lowered the tolerance for positives (c value) from five to three. Therefore, the new threshold for the Salmonella PHC is three positive samples over any 10-week period. Other provisions in the amending Regulation, such as sampling frequency flexibility, remain unchanged.

Amendments to official verification

2.25 Regulation (EC) 2073/2005 contains a general requirement for the CA to verify compliance with the rules and criteria laid down in the Regulation. The current procedures for official verification of FBO compliance with the Salmonella PHC are described in detail in the Manual for Official Controls¹¹. The Official Veterinarian (OV) is to monitor the sampling, transport of samples to the laboratory, laboratory methods used and provision of results at slaughterhouses. The interval between checks varies, depending on the sampling and audit frequency. The OV is also tasked with liaising with the FBO or representative at agreed intervals and reviewing the results.

2.26 The OV is responsible for verifying that where any further action by the FBO is required in regard to unsatisfactory testing results, this action is taken promptly and is documented within the HACCP based procedures. The OV is also responsible for taking appropriate enforcement action in the event of failure to take corrective action by the FBO, although anecdotal evidence indicates that enforcement action as a direct result of non-compliance with the Salmonella PHC is limited. Furthermore, failure to meet PHC does not result in withdrawal or recall of product.

2.27 Regulation (EU) 218/2014, which amends (EC) 854/2004, introduces a requirement that the CA collects testing data as part of the verification process. The approaches for a more robust official verification procedure are as follows:

- a) Official sampling; and/or
- b) Collection of FBO data on Salmonella PHC; and/or
- c) Collection of national control programme data on Salmonella.

Action on repeated failures to comply with the PHC

2.28 Regulation (EU) 218/2014 specifies that the CA must require FBOs to draw up an action plan if testing results against the Salmonella PHC are unsatisfactory on several occasions. While the need for corrective action by the FBO in the case of

⁹ The UK uses an adapted sampling regime based on risk – please refer to Table 1. The sampling regime (frequency of sampling) has not changed as a result of the amendment to the Salmonella PHC.

¹⁰ or 10 sampling events if sampling is not done weekly.

¹¹ <http://www.food.gov.uk/enforcement/monitoring/meat/manual/>

non-compliance with the PHC is not a new requirement, greater focus is now given to monitoring by the CA of the outcome of corrective actions. This is captured in the requirement that the CA must strictly supervise the outcome of the action plan.

Reporting of testing results

2.29 Furthermore, the text includes a requirement that the total number and the number of Salmonella positive samples, irrespective of the approach used for verification (a, b or c in paragraph 2.27 above), be reported by Member States to the Commission as part of the yearly report of zoonoses and zoonotic monitoring.

3. Consultation

Within Government

3.1 The FSA set up a Cross Government Group on Meat Official Controls (CGGMOC) in 2010. This group includes officials from the FSA in Scotland and also the Scottish Government Directorate for Agriculture, Food and Rural Communities. The group was instrumental in developing the high level UK negotiating principles and played a key role during the negotiations.

3.2 FSA officials with responsibility for operational delivery in pig slaughterhouses are also represented on both the CGGMOC and the Current and Future Meat Controls Group (CFMC), and were engaged throughout negotiations on the pig proposals and the development of the Future Meat Controls research.

3.3 FSA in Scotland have also worked closely with The Scottish Government's Better Regulation and Industry Engagement (BRIE) team on the development of the BRIA and with solicitors in Scottish Government Legal Directorate in the drafting of the Scottish Statutory Instrument (SSI) to give effect to these EU Regulations.

Public Consultation

3.4 A series of nationwide citizen's forums¹² were conducted between June and July 2010 to explore consumer attitudes to meat hygiene and views on potential changes to meat official controls. Participants indicated that they would favour any changes to meat inspection that were based on robust science, with proportionate managed communications to the public about the implications, and a robust monitoring system for animal diseases.

3.5 Consumer perspectives were also sought through the FSA Consumer Advisory Panel (CAP), whose role is to provide consumer insights into the FSA's work by supplementing consumers' views and opinions obtained from direct engagement. CAP's preference was that an Official Veterinarian (OV) should continue to have oversight of the slaughter process, and advised on communication handling.

3.6 The CFMC was consulted throughout negotiations and included consumer representation.

¹² <http://food.gov.uk/multimedia/pdfs/publication/cfsummreportmeathygiene.pdf>

3.7 In addition, the FSA in Scotland issued a full public consultation on the new pig rules from 25 March to 28 April 2014.¹³ The purpose of this consultation was to seek stakeholder views on the practical application of the changes and to determine whether the FSA's assumptions were a fair reflection of costs, benefits and wider impacts for stakeholders. We received three responses to this consultation from a Local Authority, slaughterhouse and farming union which provided detailed comments on the estimated costs and benefits and likely impacts.

Business

3.8 The FSA has worked in collaboration with industry groups throughout the development of the Future Meat Controls programme, and more recently during the negotiations on the pig proposals. Individual slaughterhouses have assisted the development of the evidence base through contributing to the FSA's research programme.

3.9 On a policy level, the CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers. The Group meets three times a year and contributes to discussions on strategy and planning, both in respect to research and future negotiations.

3.10 In 2011 the FSA established a specific Task Group of the CFMC in relation to pigs to provide comments and feedback on the Commission's proposals and help inform the UK negotiating position. Input from the Task Group was sought throughout negotiations. This collaborative approach was a success, and a similar approach will be taken when the FSA begins negotiations on other species.

3.11 Face-to-face visits with operators of pig meat slaughterhouses were also conducted as part of the consultation process – see section 5 below. Individual slaughterhouses have also assisted the development of the evidence base through contributing to the FSA's supporting research programme.

4. Options

4.1 The options considered are:

Option 1: Do nothing. In practical terms this would mean:

- not implementing a lower *c* value for the Salmonella PHC
- not implementing a more robust procedure for official verification of FBO compliance with the Salmonella PHC
- not reporting on Salmonella PHC sampling results to the Commission

Option 2: Implementation of Regulation (EU) 217/2014 and Regulation (EU) 218/2014 to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004.

Sectors and groups affected

Industry – pig slaughterhouses

¹³ <http://www.food.gov.uk/news-updates/consultations/consultations-scotland/2014/pigmeat-inspect-consult-scot>

4.2 Only approved slaughterhouses with a throughput of over 37,500 pigs per annum will be affected by the changes, since slaughterhouses with a lower throughput level are exempt from testing for Salmonella (see Table 1 and also paragraph 2.18). In 2013, there were 17 approved pig slaughterhouses in Scotland – two of which are specialist pig slaughterhouses (i.e. pigs only) and the remaining 15 are multi species slaughterhouses. Table 2 below shows these slaughterhouses by throughput level.

Table 2: Number of approved pig slaughterhouses in Scotland by 2013 throughput

Throughput Band	Number of slaughterhouses
Above 100,000	1
100,000 – 37,500	1
Below 37,500	15
Total	17

4.3 No changes have been introduced to the current sampling regime. This means that high throughput abattoirs (i.e. slaughtering over 100,000 pigs per year) will continue to have the option to move to reduced testing frequency as long as their sampling results remain satisfactory. This fortnightly testing frequency is subject to obtaining satisfactory sampling results for 30 weeks. ‘Satisfactory results’ has to date been defined as five or fewer positive results in any 10-week period.

4.4 However, as previously stated, from 1 June 2014 the threshold for the acceptable number of positive samples will be lowered from five to three. As the tolerance for the number of positive results is redefined downwards, this means that slaughterhouses could be more likely to obtain unsatisfactory results, which may have an effect on:

- For slaughterhouses with an annual throughput of above 37,500 pigs, the frequency of corrective action may increase.
- For slaughterhouses with an annual throughput of above 100,000 pigs, their ability to move to a reduced sampling frequency may be affected.

Industry – primary producers

4.5 The amended tolerance level for the number of Salmonella positive samples may have an indirect effect on pig farmers. Following unsatisfactory results, slaughterhouses are expected to implement corrective action which may include a review of on-farm biosecurity. While it is envisaged that slaughterhouses will first review their slaughter hygiene and process controls, it is possible that a lower threshold may require more extensive corrective action, which may trigger reviews of on-farm biosecurity and implementation of additional controls for Salmonella. Anecdotal evidence is that such on-farm reviews are very rare. However, as a result of greater attention to on-farm Salmonella control plans by slaughterhouses, farmers may be under increased pressure to control Salmonella. Most farmers have Salmonella control plans in place, particularly if they belong to an assurance scheme (as it is often a requirement), but farmers may be under pressure to reduce Salmonella prevalence in their holdings if this is identified as the reason for high Salmonella contamination in the slaughterhouse. The actions that farmers take to control Salmonella will be specific to each holding and will vary depending on the source of contamination. As the impact on farmers is indirect we do not envisage any familiarisation costs to this group (there are no new requirements on farmers outlined in the amendments to the Regulations).

Enforcement

- 4.6 The FSA verifies compliance with the microbiological testing requirements for Salmonella testing in approved slaughterhouses in Scotland. The introduction of the requirements to carry out official sampling for verification purposes and/or to collect FBO sampling data by the CA, and to report on official verification data will have an impact on official resources. Procedures and resources will need to be in place in order to give effect to these requirements and to supervise action plans as a consequence of repeatedly failing to meet the PHC. Enforcement officers will also incur familiarisation costs as they will need to be aware of the changes.

Consumers

- 4.7 As indicated by EFSA in its Opinion, Salmonella is a priority target in pig inspection due to its prevalence and impact on human health. The purpose of microbiological testing (against PHC) is to ensure that process controls are reviewed where results indicate contamination is occurring. By lowering the number of Salmonella positive results deemed acceptable, tolerance for Salmonella contamination in the slaughterhouse is reduced. The objective of this measure is to increase process hygiene in abattoirs which is expected to have an effect on food safety and bring about public health benefits to consumers.

Benefits

Option 1: Do nothing.

- 4.8 Slaughterhouses are a key point in the pig meat production chain where stricter controls may have a significant effect on Salmonella contamination. Doing nothing would mean that the public health benefits from implementing more robust Salmonella control and compliance measures would not be accrued, and that measures that may reduce the cost of Salmonellosis to society are not implemented.
- 4.9 Doing nothing would not prevent the new regulations from coming into force as they are directly applicable across the EU. The UK would therefore be in non-compliance with its legal obligations.

Option 2: Implementation of Regulation (EU) 217/2014 and Regulation (EU) 218/2014 to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004.

- 4.10 Putting the mechanisms in place to apply and give effect to the amending Regulations is the preferred option.

Requirement for corrective action and action plans

- 4.11 Under Option 2, FBOs will be required to draw up an action plan if the Salmonella PHC is not complied with on several occasions. There is currently a general requirement for FBOs to implement corrective action when PHC are not met. This requires improvements in slaughter hygiene with review of process controls and animal origin¹⁴. The new Regulations introduce a specific requirement for an action

¹⁴ Actions currently required in the abattoir may include: investigation of the hygiene of slaughter and dressing; improvement of the clarity of instructions issued to staff and increased staff training; improved cleaning of process equipment and the lairage; scheduling animals from farms with a history of Salmonella last in the day; undertaking special conditions during slaughter of animals with a history of Salmonella; and undertaking serotyping of Salmonella positive isolates to help identify the source. In addition, it may be

plan from the FBO which has the benefit of increasing attention to Salmonella control at all stages of the chain, including on farm.

Official verification of compliance with the Salmonella PHC requirements

4.12 Option 2 provides the added benefit of greater focus on CA monitoring of the outcome of corrective actions. Three alternatives are provided for data collection:

- a) Official sampling (in addition to FBO sampling). At least 49 random samples to be taken by the CA in each slaughterhouse each year. The number of samples may be reduced in small slaughterhouses based on a risk evaluation; and/or
- b) Collection of all information on the total number and the number of Salmonella positive samples taken by FBOs in accordance with the PHC requirements set out in Regulation 2073/2005; and/or
- c) Collection of all information on the total number and the number of Salmonella positive samples taken within the frame of national control programmes.

4.13 It must be noted that these implementation options are not mutually exclusive. Each MS's CA may implement one of the above or a combination of the above in their territory as appropriate. These three approaches (a), (b), and (c) are further described below.

4.14 **Approach (a) (official sampling).** The requirement is for the CA to undertake sampling using the same method and sampling area as FBOs in order to verify compliance with the Salmonella PHC. As the purpose of this task is to verify that approved pig slaughterhouses comply with EU Food Hygiene Regulations, the cost of carrying out the sampling would be statutory work for which FBOs are charged. However, informal consultation with stakeholders during negotiations on the legislative amendments highlighted that this option was not seen as proportionate by the UK abattoir sector as it would increase the burden on FBOs, who already carry out extensive testing, and focused only on slaughterhouses. The Regulation already includes provisions for the CA to carry out additional testing, as necessary, to verify FBO testing against the PHC. Therefore, this option is not considered further.

4.15 **Approach (b) (collection of FBO sampling data).** This is the **preferred approach**. Since 2006, FBOs have been required to sample and test pig carcasses for Salmonella. Under this option FBOs would make their sampling result available to the CA. As with approach (a), the cost of collecting the data would be considered statutory tasks and therefore chargeable to FBOs. This is consistent with the current UK approach for risk-based CA sampling where the majority of sampling should be carried out by FBOs and further official sampling is only carried out if there are concerns with the FBO or the sampling and testing carried out. Approach (b) requires data transfer between FBOs and the CA. Some FBOs currently have mechanisms in place to allow for the exchange of data, such as inspection results. At present, this is done through an automatic download of data or via manual FBO input on an FSA electronic interface. Alternatively, officials in slaughterhouses could input the data provided by the FBO (five sampling results per week) on the FSA system.

required that suppliers of the animals carry out an investigation of the biosecurity and hygiene on the farm and transport to the abattoir.

4.16 **Approach (c) (national control plan data).** There is currently no national control plan for Salmonella in pigs in the UK, therefore this option cannot be considered in the short or medium term.

Reporting on Salmonella PHC verification data

4.17 The total number and the number of Salmonella positive samples must be reported to the Commission, via EFSA, in accordance with Article 9(1) of Directive 2003/99/EC. The report must differentiate between samples taken under approach (a), (b) and (c). Reports, and any summaries of them, must be made publicly available. Although it is an existing requirement that each year MS send to the Commission a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance, the amendment effectively modifies the list of zoonoses that MSs must report on, adding Salmonella PHC results to the list.

Benefits to Consumers

4.18 There are multiple factors that can contribute to the presence of Salmonella contamination on pig carcasses, from carcass dressing practices and slaughterhouse process controls to Salmonella levels on the farm and transport conditions. However, a stricter Salmonella PHC may mean that action may be required more regularly to identify and address sources of contamination. As a result, levels of Salmonella in pig meat are likely to decrease. The effect of this on cases of human Salmonellosis is difficult to assess; however, it can be expected that lower levels of Salmonella may lead to fewer cases of food poisoning due to improper cooking or cross-contamination with other foods. Based on estimates of the cost of Salmonella to society¹⁵, each human case prevented will mean a saving of €600.

Costs

Option 1: Do nothing.

4.19 This option would involve taking no action to update UK operational procedures but this would not prevent the new regulations from coming into force as they are directly applicable across the EU. Under this option, the public health benefits from implementing the new Salmonella control and compliance measures would not be accrued. Also, consumer confidence in food safety controls could be reduced if action is not taken to improve official controls on pig meat in response to the EFSA Opinion highlighting Salmonella as the key zoonotic risk.

4.20 This option also entails not being in compliance with EU legislation which could lead to infraction proceedings. The maximum fine that could be imposed on the UK is some €703,000 per day or £256 million per year¹⁶.

Option 2: Implementation of Regulations (EU) 217/2014 and Regulation (EU) 218/2014 to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004.

Industry – pig slaughterhouses

¹⁵ http://ec.europa.eu/food/food/biosafety/salmonella/docs/fattening_pigs_analysis_costs.pdf

¹⁶ <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

Familiarisation Costs (One-off Cost)

4.21 There will be a one-off cost to slaughterhouses from reading and familiarising themselves with the new requirements. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the person carrying it out. It is our assumption that it will be the slaughterhouse manager (wage rate of £25.80¹⁷) that is responsible for familiarisation and that it will on average take one manager per slaughterhouse one hour to familiarise themselves and disseminate the information to other key staff. Multiplying the wage rate by the number of slaughterhouses that will be affected by the changes (there are two with a throughput of over 37,500 pigs per annum) and hours required (1) generates a total familiarisation cost to the two slaughterhouses in Scotland of £52.

Inability to move to a reduced testing frequency (Ongoing Cost)

4.22 As described in paragraph 2.18, only slaughterhouses that slaughter more than 100,000 pigs per year are eligible for reduced sampling. Slaughterhouses producing 100,000 or fewer pigs per year are either ineligible for reduced frequency or not required to test. Therefore, a change in the threshold will potentially affect 1 plant in Scotland currently slaughtering more than 100,000 pigs a year. A consequence of lowering the threshold for the number of Salmonella positive samples from five to three is that slaughterhouses may not be able to meet the eligibility criteria for reduced testing as frequently. This is dependent on achieving satisfactory results for 30 weeks; from June 2014, this will mean not having more than three positive results every 10 weeks over a period of 30 weeks (a total maximum of nine positive results).

4.23 We currently have limited data to monetise the impact of this change. We have, however, carried out some indicative analysis based on the EU baseline survey from 2006/07¹⁸. This survey showed a UK abattoir prevalence of 13.5% for all Salmonella types. Based on this prevalence, analysis suggests that a lowering of the *c* value from 5 to 3 would reduce the probability of an average plant to achieve satisfactory results, after a 10 week period, from 32% to 8%. Due to data limitations we have, however, been unable to calculate any robust estimates of this potential cost.

Increased corrective action (Ongoing Cost)

4.24 Unsatisfactory results require corrective action by the slaughterhouse which includes improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures¹⁹ in the farms from which pigs are sourced. This requirement is already in place, however, implementing a lower *c* value means that corrective action may be required more often. The magnitude of this cost will depend on the prevalence of Salmonella in the animals and the slaughterhouse's ability to control contamination. The new Regulations also specify that, if the PHC is not complied with on several occasions, the CA must require an action plan from the FBO and strictly supervise its outcome. We have at this stage been unable to monetise the implication of these requirements.

¹⁷ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/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.

¹⁹ Biosecurity measures encompass good hygiene practices on farm including precautions taken when entering or leaving any premises with farm animals to prevent the spread of animal diseases.

Official verification (Negligible Cost)

4.25 Under the preferred approach for verification (Approach (b) CA collection of FBO sampling data) the slaughterhouse will make their sampling data available to the CA. There are various possibilities for data exchange: (i) automatic electronic data transfer; (ii) electronic interface for FBO manual input of data; and (iii) the FBO makes the data available to the CA in hard form so it can enter the data on the system. Under all these approaches we envisage that the cost to the FBO would be minimal. Some FBOs already have systems in place for the automatic transfer of data, and for those FBOs, costs will be minimal. For FBOs which choose to input results manually, we also envisage costs to be minimal (inputting results into the system is estimated to take less than half a minute per week, hence in total less than 30 minutes per annum). For FBOs which choose to provide sample results in hard form for the CA to input them into the system, this work would be considered 'statutory work' and is therefore chargeable to the FBO. However, as noted above, the processing costs have been considered negligible and would therefore be absorbed by the FSA as part of the discharge of official duties. It is our working assumption that the third approach is the most likely approach to go ahead. We therefore envisage that the cost to slaughterhouses associated with this requirement would be minimal.

Industry – primary producers

Increased Number of On-Farm Investigations (Non-Monetised Cost)

4.26 Farmers that send animals to those slaughterhouses which process more than 37,500 pigs a year may potentially be affected by the new Regulations. In order to address unsatisfactory results, slaughterhouses are expected to take corrective action which may include a review of on-farm biosecurity and Salmonella control measures in place at farms from which animals are sourced. The revised *c* value may have an effect on the frequency at which corrective actions are taken in the slaughterhouse, which may result in an increased number of investigations of the biosecurity and hygiene on the farm and transport to the abattoir. Farmers may be under pressure from slaughterhouses to reduce Salmonella prevalence in their holdings if this is identified as the reason for high Salmonella contamination in the slaughterhouse. However, the actions that farmers take to control Salmonella will be specific to each holding and will vary depending on the source of contamination. We have at this stage been unable to monetise the implication of this requirement.

Enforcement

Familiarisation Costs (One-off Cost)

4.27 There will be a one-off cost to enforcement from reading and familiarising themselves with the new requirements. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the official carrying it out. It is OVs that are responsible for the monitoring of Salmonella controls. There are currently 2 full-time employed OVs that will be affected by the Regulations and therefore will need to familiarise themselves with the Regulations. It is our assumption that it will take approximately one hour per OV to familiarise themselves and disseminate the information to other key staff. Multiplying the hourly wage rate on an OV (£36.8) by

the number of affected slaughterhouses (2) and hours required (1) generates a total familiarisation cost to enforcement of £73.

Increased corrective action (Ongoing Cost)

4.28 The lowering of the threshold for the number of acceptable positive samples may result in FBO corrective action and action plans after repeated failure being required more frequently. This could have an effect on OV resources as OVs are required to monitor that corrective action is taken and to supervise the outcome of action plans. We have been unable to monetise the associated costs as we currently do not have sufficient information to be able to do so.

Official verification (Negligible Cost)

4.29 Under the preferred approach for verification (Approach (b) CA collection of FBO sampling data) the slaughterhouse will make their sampling data available to the CA. There are various methods for data exchange: (i) automatic electronic data transfer; (ii) electronic interface for FBO manual input of data; and (iii) the FBO makes the data available to the CA in hard form so it can enter the data on the system. Under all three methods, the CA may incur a one-off cost for setting up a data capture/exchange system. Currently we are uncertain about which of the three methods above will be used for the exchange of data, but we are likely to start with (iii) which carries negligible costs to slaughterhouses. We anticipate the cost to the FSA of setting up this system will be negligible (as described above) and we have therefore not monetised this cost.

Costs of reporting on Salmonella PHC official verification data (Negligible Cost)

4.30 Although the requirement to report on the total number and the number of Salmonella positive samples taken as part of the official verification is new, the UK already reports yearly on information on monitoring of zoonoses in accordance with Directive 2003/99/EC. Therefore, the costs associated with adding this dataset to the report have been assessed as minimal. We envisage that it should not require more than one official spending two hours per annum interrogating the system and producing a report. This would generate a cost to the CA of approximately £28²⁰ per annum.

5. Scottish Firms Impact Test

5.1 As part of the public consultation the FSA in Scotland held face-to-face meetings with FBOs of the three largest pig slaughterhouses in Scotland, which account for 85% of all pigs slaughtered in Scotland, as well as a number of FBOs from smaller plants, to discuss their views and comments in more detail.

5.2 In general, businesses were supportive of the strengthened *Salmonella* controls. Comments were also received on the move towards visual inspection and the new *Trichinella* rules and are summarised in the respective BRIAs on these matters. Both FBOs of the two slaughterhouses, that currently test against Salmonella PHC, confirmed that they had no concerns with the lowering of the *c* value from five to three - this would not cause any change in terms of number of per annum tests taken and no increase in their sampling costs and corrective action.

²⁰ 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 'Administrative occupations: Government and related organisations' was used, £10.61, plus 30% overheads, totalling £13.8.

Competition Assessment

- 5.3 The incoming Regulations are not expected to have any impact either directly or indirectly on competition. In light of responses following the consultation exercise we will revisit our position.
- 5.4 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 2) will neither directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.

Test Run of Business Forms

- 5.5 The updated national operational procedures for officials working in slaughterhouses does not introduce any new or additional forms to business.

6. Legal Aid Impact Test

- 6.1 The new EU Regulations will not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund.

7. Enforcement, Sanctions, and Monitoring

- 7.1 Enforcement will be the responsibility of the FSA, as the competent authority – this will be drawn from powers written within the Food Hygiene (Scotland) Regulations 2006.

Sanctions

- 7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in the Food Hygiene (Scotland) Regulations 2006.

Monitoring

- 7.3 The effectiveness and impact of these EU Regulations will be monitored via feedback from stakeholders, including the CFMC Task Group, as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries.

8. Implementation and Delivery Plan

- 8.1 The publication of the Food Hygiene (Scotland) Amendment Regulations 2014 will be communicated to stakeholders by email, letter and via the FSA website. This will be done shortly after the SSI has been published on legislation.gov.uk website.

9. Post-implementation Review

9.1 A review to establish the actual costs and benefits, and the achievement of the desired effects of the Regulation, is expected to take place in five years.

10. Summary and Recommendation

10.1 The Agency recommends Option 2 to provide for the execution and enforcement of the EU Regulations and provide the legislative framework for the requirements to be enforced under UK law.

10.2 Taking this option allows the Government to fulfil its obligations to implement EU law.

11. Summary Costs and Benefits Table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social policy & administrative
1 Do Nothing	No familiarisation costs would be incurred.	This option entails not being in compliance with EU legislation which could lead to infraction proceedings. The maximum fine that could be imposed on the UK is some €703,000 per day or £256 million per year.
2 Implementation of Regulation (EU) 217/2014 and Regulation (EU) 218/2014 to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004	This option would ensure that adequate systems would be in place for the UK to comply with the new sampling, verification and reporting requirements and to realise the benefits of a stricter Salmonella criterion and compliance verification system. Public health benefits from implementing more robust Salmonella control and compliance measures would be accrued. As a result, levels of Salmonella in pig meat are likely to decrease.	Both affected businesses have stated that sampling costs would not change in terms of per annum pounds spent on sampling. The lowering of the threshold from 5 to 3 would not impact on costs. The costs from official collection of sampling data would not incur costs. There should be no increase in on-farm investigations, therefore no additional costs will be incurred. There should be no additional costs from a potential increase in the frequency of corrective action.

Declaration and publication

I have read the final Business and Regulatory Impact Assessment (BRIA) and I am satisfied that, (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister’s signature

Minister’s title

Date

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