

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (BRIA)

IMPLEMENTATION OF THE REVISED EU TRICHINELLA REQUIREMENTS

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1. TITLE OF PROPOSAL

- 1.1 Commission Regulation (EU) No 216/2014 of 7 March 2014 amending Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* in meat.¹

2. PURPOSE AND INTENDED EFFECT

Objectives

- 2.1 Commission Regulation (EU) No 216/2014, which comes into force on 1 June 2014, forms part of a package of revised pig meat inspection rules covering visual inspection of carcases, strengthened *Salmonella* controls, and more proportionate and risk based *Trichinella* controls. This is part of a wider European legislative framework which is intended to ensure that food is safe to eat.
- 2.2 The Regulation amends EU rules on official controls for *Trichinella* in meat and moves away from requiring all pigs to be tested for *Trichinella* to a more risk-based testing regime. This represents a significantly reduced *Trichinella* testing requirement for industry as a whole, compared to the previous requirements – it is far more proportionate and more accurately reflects the level of risk associated with the various pig housing systems used in Scotland and across Great Britain. This proportionate, risk-based approach is one that the UK has long advocated in discussions with the European Commission and at international fora such as Codex and World Organisation for Animal Health (OIE).
- 2.3 The revised *Trichinella* rules also provide a clear pathway for securing derogations from the testing requirements (which would formerly have been captured within ‘negligible risk recognition’). This has been a long standing aim of the UK to help support further trade in the medium and long term, and is fully in line with the Scottish Government’s trade and growth agenda.

Rationale for Government Intervention

- 2.4 Although evidence from UK testing indicates that the risk from *Trichinella* is low in all UK countries, the parasite can cause serious illness in humans. Consumers generally do not have sufficient information or knowledge to understand the risks associated with *Trichinella*, and government intervention is therefore necessary to ensure that there are safeguards in place to protect consumer health.
- 2.5 The previous EU requirements on *Trichinella*, requiring all pigs to be tested for this parasite, are currently under-implemented in the UK as the view was taken that these requirements were neither risk-based, nor proportionate. However, this new EU *Trichinella* regulation will move away from requiring all pigs to be tested for this parasite to a more risk-based regime. The Food Standards Agency (FSA) as the Competent Authority is required to ensure that these testing requirements are implemented.
- 2.6 Failure to implement the new EU Regulation would result in a high risk of infraction proceedings being taken against the UK, given the long-standing UK policy of under-

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:069:0085:0092:EN:PDF>

implementation of the previous requirements which has been regularly highlighted by the Commission's Food and Veterinary Office (FVO). This would have wider ramifications for government and industry, including the potential to jeopardise recently established UK trade with third countries, markets which Scottish pork processors are actively looking to develop.

- 2.7 Full implementation of these requirements is a necessary step towards building a strong evidence base for attaining the derogations available in the Regulation. It also provides a platform to support current UK trade and possible expansion, particularly if the criteria for the relevant derogation can be met, which will enhance potential trade opportunities for Scottish pork processors.

Background

- 2.8 Trichinella is parasitic worm which infects pigs, horses, wildlife such as foxes and rats, as well as humans. It is transmitted by eating infected muscle tissue and can be transmissible to humans through undercooked food. It can cause serious illness, from vomiting, fever and severe muscular pain up to cardiac problems, but can also be treated effectively if caught within 10 days of infection. The existing evidence we have from our testing indicates that there is a very low risk to public health in the UK from Trichinella. The last case from meat produced in GB was in 1977 and the most recent human cases were a cluster of 8 in North London in 2000, which was traced to the personal import of pork salami from Serbia. The FSA also provides extensive advice to consumers on the safe and hygienic preparation and cooking of pork.

Current regulatory regime

- 2.9 Under current EU law (EC Regulation 2075/2005), every pig slaughtered for human consumption should be tested for Trichinella. The UK considers that this is not proportionate or risk based, failing to take into account the different levels of risk for pigs raised indoors, in controlled housing, compared to the risk for pigs which spend varying periods of their life outdoors. As such, this requirement has been under-implemented in the UK. We have maintained a core testing programme with all sows, boars, horses and wild boar tested in approved slaughter premises and a number of slaughterhouses test in their own on-site labs, although only some of the testing data from these laboratories is available to the Central Competent Authority.
- 2.10 The UK applied unsuccessfully in June 2006 to the Commission for recognition as a region of negligible Trichinella risk; the response from the Commission and Member States focussed on the need for testing more outdoor pigs and presenting GB and NI data separately, as they have different epidemiological profiles. Applications for recognition were put on hold as the Commission developed the revised proposals, which include clear criteria for derogations from testing (along the lines of negligible risk recognition), but achieving derogations from testing requirements remains a long-term objective for the UK – the new Regulation has clear criteria for securing derogations from testing after three years, provided testing is carried out in accordance with the legislation and no positives are found.

New EU Regulation

Testing requirements for pigs

2.11 The new, directly applicable, EU Regulation comes into force in June 2014 and is significantly more risk-based and proportionate than Regulation 2075/2005. It recognises the different risks of different housing systems and this is reflected in the testing requirements. It also has clear criteria for securing negligible risk recognition by compartment, which is a key objective for the UK. The definition of a compartment is flexible, describing a group of holdings which apply controlled housing conditions. This can be on a geographic basis (such as Scotland) or, for example, an integrated production system. It is also possible for all holdings applying controlled housing conditions in a member state may be considered as one compartment. It should also be noted that this regulation dovetails with the direction of travel at Codex Alimentarius (which develops harmonised international food standards for trade and consumer protection) and the World Organisation for Animal Health (OIE), the international trade and veterinary organisations – these bodies are also reviewing the control, testing and negligible risk requirements for *Trichinella*, with a view to greater consistency between the various international standards. This should also have trade benefits, with clarity on standards and the status of derogations from testing requirements.

2.12 The new testing requirements are predicated on the identification of controlled housing holdings, a type of animal husbandry where swine are kept at all times under conditions controlled by the Food Business Operator (FBO) with regards to feeding and housing. It will therefore be necessary for the FSA to identify the pattern of holdings across GB and ensure that these are accurately reflected in the Food Chain Information (FCI) accompanying the animals from the farm to the slaughterhouse. We will also need to establish compartments as far as possible, as this will be a requirement for presenting the necessary data for implementing the derogations from testing.

2.13 The nature of the holding will then determine the testing requirements at the slaughterhouse. These testing requirements are that:

*"a) all carcases of breeding sows and boars or at least 10% of carcases of animals sent in for slaughter each year from each holding being officially recognised as applying controlled housing conditions, shall be examined for *Trichinella*, and*

*(b) all carcases from holdings not being officially recognised as applying controlled housing conditions shall be systematically examined for *Trichinella*".*

2.14 With regard to requirement (a), the core testing programme in GB already sees all breeding sows and boars tested at approved slaughterhouses, with the cost of this being met by the FSA. We therefore consider that this allows Scotland to successfully meet the first requirement of the testing regime.

2.15 The second requirement is that all pigs not from controlled housing conditions must be tested for *Trichinella*. This reflects the greater risk of infection for pigs that spend time outdoors. However, there is a useful degree of flexibility in the definition of controlled housing. Alongside the general requirements relating to issues such as pest control and secure storage of feed, which carry over from the previous regulation, there is scope for pigs to have some access to our door facilities provided that "*the food business operator can show by a risk analysis to the satisfaction of the*

competent authority that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of Trichinella in the holding". It is the intention that as part of the mapping exercise for holdings and compartments, the FSA will use existing evidence, such as wildlife testing data, to inform a preliminary risk assessment and reflect this in the mapping.

- 2.16 In terms of the production and housing systems used in Scotland, discussions with industry suggest the picture is nuanced. Of those pigs that are reared, finished and slaughtered in Scotland (i.e. excluding those reared in Scotland but finished and processed in England), around 80% (circa. 20,000 breeding sows producing 520 – 560k pigs per year) are reared using indoor farrowing systems before being finished in controlled indoor housing, with no outdoor access at all during the entire breeding/rearing cycle. The remaining 20% (circa. 5,000 breeding sows producing 105 – 110k pigs per year) will spend between 4 – 12 weeks outside before being finished indoors, in what is considered controlled housing. Based on discussions with industry we understand there are no commercial organic or free range pigs herds in Scotland that will spend their entire lives outdoors which would be considered as not applying controlled housing conditions. Although there are a number of small free range outdoor pig herds which are slaughtered as private kills.
- 2.17 We assume therefore that the 80% of pigs reared and slaughtered in Scotland that spend their entire lives indoors would be considered as applying controlled housing conditions and would not require Trichinella testing. Of the remaining 20% that spend time both outdoors and indoors, we would anticipate that they are also likely to be considered as being in controlled housing given the flexibility in the Regulation outlined above. However, where the line is drawn will need to be supported by appropriate epidemiological evidence and a risk assessment. For the purposes of this impact assessment we assume a high impact scenario whereby the 8% of pigs that are 'outdoor reared' and spend up to 12 weeks outdoors (circa. 2,000 breeding sows producing 40,000 pigs per year) which are likely to present the highest Trichinella risk could possibly fall outside the definition of controlled housing and require to be tested. (Please note industry has advised that these 'outdoor reared' pigs are unlikely to be part of the Scottish kill until late 2015 at the earliest, but they have been included in the high impact cost analysis for the purpose of impact assessment.)
- 2.18 Based on this high impact scenario a number of slaughterhouses will be subject to increased testing and this will have implications in practical and cost terms, particularly with regard to laboratory capacity and turn-around. This may encourage some larger plants to explore the prospect of setting up an in-house lab, which has costs for government in terms of ensuring that the lab meets the required standards and a capital outlay for the FBO. It is assumed that this will not be a feasible option for the majority of small to medium sized plants in Scotland. This has been confirmed in discussion with industry.

Testing requirements for horses and wild boar

- 2.19 The new Regulation also requires that "*Carcasses of horses, wild boar and other farmed and wild animal species susceptible to Trichinella infestation shall be systematically sampled in slaughterhouses or game-handling establishments as part of the post-mortem examination.*" This carries over the requirements of the existing Regulation and is already carried out in GB. As this is consistent with the general

intention to test animals at greater risk of exposure to infection, such as wild boar and horses, the FSA intends to continue to test all horses and wild boar in slaughterhouses and game handling establishments (although there are currently no abattoirs approved to slaughter horses in Scotland). In addition, the UK will continue with the programme of surveillance with regard to susceptible wildlife, such as foxes.

Food Chain Information (FCI)

- 2.20 The FCI accompanying the animals from the farm to the slaughterhouse will need to capture whether the pigs need to be tested for *Trichinella* (i.e. if they come from a non-controlled housing holding or are a breeding sow/boar). We propose to capture this very simply with a single box, to tick where the pigs need to be tested. This will be integrated into the revision of the existing FCI forms and as such should not represent an additional cost to farmers.

Auditing and verification of controlled housing conditions

- 2.21 Whilst the FSA will conduct an exercise to map controlled housing holdings, it is a requirement that this be supported by a structured, risk-based audit and verification programme. The Competent Authority is obliged to “ensure that audits are carried out periodically of holdings officially recognised as applying controlled housing conditions” and that “the frequency of audits shall be risk-based, taking account of disease history and prevalence, previous findings, the geographical area, local susceptible wildlife, animal husbandry practices, veterinary supervision and farmers' compliance”.

- 2.22 It is intended that auditing of controlled housing holdings in Scotland will be integrated as far as possible into existing farm inspections. We are exploring what role can be played by earned recognition through third party farm assurance schemes, such as the QMS Specially Selected Pork scheme, which would help to minimise the impact on farmers.

Derogations from testing requirements

- 2.23 Aside from the continuing derogations from testing where the carcases have undergone suitable freezing treatment (as defined in the regulations) or are from unweaned pigs aged less than 5 weeks, there is scope for what was previously described as negligible risk recognition. However, as the Regulation has been brought closely into line with the OIE requirements and terminology, negligible risk status for a country or region is no longer recognised and instead, such recognition is linked to compartments applying specific controlled housing conditions.

- 2.24 The mapping of compartments and holdings to determine the extent of controlled housing conditions has already been outlined. A compartment is essentially a common group and in the context of *Trichinella* could be a geographic area, such as Scotland or another region of the UK, or an integrated production system. The new regulation would allow for all of the controlled housing holdings in GB to be considered as a single compartment but this could present a risk were a positive to be found (the entire compartment would have any derogations from testing suspended subject to further investigation), so the assessment and mapping of compartments will be supported by a risk assessment.

2.25 Within those controlled housing compartments, the requirements for derogation is that there must have been “*no autochthonous Trichinella infestations in domestic swine kept in holdings officially recognised as applying controlled housing conditions have been detected in the Member State in the past 3 years*”. During this period, a testing regime compliant with the requirements set out earlier must have been fully implemented. We consider that this requirement for the derogation is a realistic aim for Scotland and the rest of GB.

2.26 Alternatively, the other option is for the Member State to present “*historical data on continuous testing carried out on slaughtered swine population provide at least 95 % confidence that the prevalence of Trichinella does not exceed 1 per million in that population*”. The FSA has made previous assessments of the UK testing data with a view to this standard, but there are not the necessary volumes of testing over a suitable number of years to meet the statistical threshold. The assessment of historical data put the confidence percentage of 1 per million prevalence level at 85-90%. To attain the requisite 95% confidence threshold would have required a least 1.5 - 2 million additional Trichinella tests carried out per year, which would mean, at considerable expense, a very significant increase in testing for a period of several years. The FSA does not consider this a realistic prospect for securing derogation from the specified testing requirements.

Laboratories and permitted testing methods

2.27 The permitted testing methods for Trichinella will remain the same under the new regime and are set out in the legislation. With regard to carrying out testing, it is expected that some plants across GB may decide to set up their own in-house laboratory rather than sending samples to an external laboratory for testing, as this approach would allow carcasses to be turned round more quickly. However, in Scotland we anticipate this only being a realistic possibility for the largest pig slaughterhouse (processing over 100,000 pigs per year) due to the capital costs that would be incurred (estimated to be around £5k, not including staff costs).

2.28 We anticipate that in-house laboratories will not be commercially viable for most small to medium sized pig processors in Scotland given the smaller size of the Scottish pig industry compared with rest of GB. Smaller slaughterhouses may prefer either to send samples to an external laboratory as most do at present, or, as already happens in some parts of the country, use the in-house laboratory of a larger FBO nearby – this innovative approach has proved useful, subject to proper procedures to ensure traceability and remove the possibility for cross-contamination.

Sensitivities

2.29 Trichinella testing is an important aspect of international trade in pig meat, both within the EU and with third countries. The Trichinella testing regime of a Member State is part of trade agreements and can come under close scrutiny, so ensuring compliance with EU regulations is critical both to safeguard existing UK trade agreements and facilitate future trading opportunities, particularly with third countries.

2.30 The current Trichinella requirements, set out in EU regulation 2075/2005, have been consistently under-implemented in the UK and this has been cited in numerous Food and Veterinary Office (FVO) audit reports over the last few years, with specific recommendations to address this matter. Should the new Trichinella requirements

not be fully implemented then not only would this present a risk to international trade but there would also be a significant risk of infraction proceedings against the UK.

3. CONSULTATION

Within Government

- 3.1 The FSA set up a Cross Government Group on Meat Official Controls (CGGMOC) in 2010. This group includes policy officials from all relevant UK departments, including the FSA in Scotland and the Scottish Government Directorate for Agriculture, Food and Rural Communities. The group was instrumental in developing the high level UK negotiating principles on the new pig meat inspection rules and played a key role during EU negotiations.
- 3.2 FSA officials with responsibility for operational delivery in pig slaughterhouses are also represented on the CGGMOC and were engaged throughout negotiations on the pig proposals and the development of supporting scientific research.
- 3.3 The Scottish Government Better Regulation and Industry Engagement (BRIE) team, Directorate for Justice, and Legal Directorate have also been consulted during the preparation of this BRIA.

Public Consultation

- 3.4 A series of nationwide citizen's forums² 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.
- 3.6 In addition, the FSA in Scotland issued a full public consultation on the new pig rules from 25 March to 28 April 2014.³ 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 3 responses to this consultation from a Local Authority, abattoir and farming union which provided detailed comments on the estimated costs and benefits and likely impacts.

Business

- 3.7 The FSA has worked in collaboration with industry groups throughout the development of the revised pig meat inspection rules through the Current and Future Meat Controls (CFMC) Stakeholder Group. The CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers from across the UK, including key stakeholder bodies in Scotland. The

² <http://food.gov.uk/multimedia/pdfs/publication/cfsummreportmeathygiene.pdf>

³ <http://www.food.gov.uk/news-updates/consultations/consultations-scotland/2014/pigmeat-inspect-consult-scot>

Group meets three times a year and contributes to discussions on strategy and planning, both in respect of research and future negotiations.

- 3.8 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.
- 3.9 The FSA in Scotland has also held discussions with the largest pig producer co-operative in Scotland, representing around 75% of commercial pig producers, and Quality Meat Scotland (QMS) to assess the likely impacts of the new rules. 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.

- 4.2 This will involve maintaining the current core testing programme, without specifically targeting any pigs not in controlled housing conditions for more testing. The plants that conduct testing to meet export requirements would continue to test all pigs for the foreseeable future, until such time as these requirements are amended; such a review could not begin to take place until the relevant Codex chapter (which frames international trade standards in this area) has been agreed.
- 4.3 This option would mean no additional costs and the framework for this is already in place, so the administrative burden would be minimal. However, this approach would mean that the UK would continue to be non-compliant with EU testing requirements and given that this would be perceived by the Commission as persistent refusal to comply, previous experience in other policy areas suggests that it would carry a significant risk of infringement proceedings. These proceedings would represent a large cost to government in financial and administrative terms and jeopardise EU and third country trade.

Option 2: Full Compliance

- 4.4 This will involve maintaining the current core testing programme to fulfil the first requirement. Meeting the requirement to test all pigs not from controlled housing will necessitate a significant mapping exercise by the FSA to ascertain holdings where all pigs need to be tested across GB, supported by epidemiological analysis and a suitable risk analysis, together with a programme of audit and verification to support the identification of holdings. Based on the high impact scenario outlined in paragraph 2.17 above, this will also require increased testing at slaughterhouses which process pigs that are not from controlled housing holdings and may have an effect on laboratory capacity, with the need for more in-house laboratories.
- 4.5 Whilst the core testing programme will continue, this option involves an increase in the testing of pigs not from controlled housing and will have costs for government and

industry. However, if fully implemented, this will support current and future expansion of trade and provide the necessary evidence for application of derogations from testing in due course.

Sectors and groups affected

Slaughterhouses

- 4.6 Under Option 2, 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.
- 4.7 There are currently a total of 17 slaughterhouses in Scotland that slaughter pigs. Of these, 2 are pigs only plants and 15 are multi-species slaughterhouses, which slaughter pigs as well as other species.
- 4.8 In 2013, a total of 300,732 pigs were slaughtered in these 17 plants. There is a significant amount of consolidation in the pig industry with the 2 pig-only plants accounting for 75% (225,934) of all pigs slaughtered in Scotland. A single multi-species plant accounts for a further 29,558 pigs, which means that combined together the 3 largest pig plants account for 85% (255,492) of all pigs slaughtered in Scotland. The remaining 45,240 pigs were slaughtered in 14 small and micro plants.

Table 1: Number and size of affected slaughterhouses in Scotland

	Pig only	Multi-Species	Total
Micro	0	11	11
Small	0	4	4
Medium	1	0	1
Large	1	0	1
Total	2	15	17

Source: FSA plant data from (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.

- 4.9 All 17 plants could be affected, as they could potentially slaughter pigs from non-controlled housing conditions based on the high impact scenario outlined in paragraph 2.17, and could therefore incur increased costs of additional testing. The calculations below reflect this possibility. However, given that almost 85% of pigs are processed in 3 plants, it is not unreasonable to expect that a significant proportion of pigs not in controlled housing will be processed at these 3 plants.

Farmers

- 4.10 It is anticipated that the effect on farmers will be low. 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 FCI form, which farmers will need to tick if pigs have been reared under non-controlled housing conditions.

- 4.11 The following information on the number of pig holdings in Scotland comes from the Economic Report on Scottish Agriculture 2013.⁴ It should be noted that these figures relate to all farms with pigs, not just pig-only farms and most of these holdings have a small number of pigs as part of a mixed enterprise.

Table 2: Number of Affected Pig Holdings in Scotland

	North West	North East	South East	South West	Total
Female breeding herd	168	118	120	153	559
All other non-breeding pigs (fattening pigs)	358	281	258	315	1,212
Total	399	295	279	355	1,328

Source: *Economic Report on Scottish Agriculture 2013*

Food Standards Agency

- 4.12 Under Option 2, 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 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

- 4.13 There will be a cost to Official Veterinarians 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

- 4.14 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 in the high impact scenario is estimated to be around 8% of the Scottish pig kill, and they may well not require testing following risk assessment, the impact of this measure on consumers in terms of price changes is expected to be negligible.

Benefits

Option 1: Do nothing

- 4.15 The do nothing option would mean no additional Trichinella testing and familiarisation costs for industry and no additional costs for enforcement authorities and the FSA. As the framework for this option is already in place the administrative burden would be minimal.

⁴ <http://www.scotland.gov.uk/Publications/2013/06/5219>

Option 2: Full Compliance

Benefits to Consumers

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

- 4.16 Although UK evidence from testing indicates that the risk from Trichinella is low in Scotland, 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)

- 4.17 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.

Costs

Option 1: Do nothing

- 4.18 Under this option the UK would continue to be non-compliant with EU testing requirements and given that this would be perceived by the Commission as persistent refusal to comply, previous experience in other policy areas suggests that it would carry a significant risk of infraction proceedings. These proceedings would represent a large cost to government in financial and administrative terms and jeopardise EU and third country trade. The maximum fine that could be imposed on the UK is some €703,000 per day or £256 million per year.⁵

Option 2: Full Compliance

Costs to Slaughterhouses

Familiarisation Costs (One-Off Costs)

- 4.19 There will be costs to slaughterhouses from the need to familiarise themselves with the new Regulation. 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 £25.80⁶) 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 17 slaughterhouses potentially affected

⁵ <http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions>

⁶ 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.

generates a maximum total familiarisation cost to Scottish slaughterhouses of £438.00.

Costs from Additional Testing (Ongoing Cost)

- 4.20 Under Option 2, there will be costs to slaughterhouses that slaughter commercial pigs from non-controlled housing conditions. FSA pig plant data suggest that there are around 300,732 pigs that go for slaughter in Scotland each year. Based on the high impact scenario outlined in paragraph 2.17, approximately 8% (24,058) of the Scottish commercial kill could be from what is considered as holdings not operating controlled housing conditions and therefore would have to be tested under the proposal. This would amount to an additional 24,058 samples per annum. As noted earlier, given the fact that almost 85% of pigs are processed in the 3 largest plants it is not unreasonable to expect that a significant proportion of these pigs will be slaughtered in those 3 plants.
- 4.21 Based on existing structures within the Scottish industry which sees all *Trichinella* testing conducted through the private accredited laboratory route we anticipate that all commercial pigs not from controlled housing will be tested by private laboratories, at least initially, which means an estimated cost of £4.09 per pig tested. Based on these assumptions, the total cost to the slaughterhouse sector under this proposal would be £98,397 per annum. If, in the future, testing was to be carried out using in-house laboratories this would significantly reduce the testing cost as the cost of in-house testing is borne entirely by the FSA at £0.60p per test. If industry in Scotland were to go down this route this would result in additional testing costs of £14,434, which would be borne by the FSA.
- 4.22 However, this is a worst case scenario and likely to be an overestimate (as noted in paragraph 2.17 above, although these ‘outdoor reared’ pigs are bred and reared in Scotland they are unlikely to be part of the Scottish kill until early 2015 at the earliest). If, following appropriate epidemiological evidence and risk assessment, all commercial pigs in Scotland are considered to be reared under controlled housing conditions there will be no additional testing costs to industry.
- 4.23 In addition, most micro, small and medium sized plants also slaughter a small number of non-commercial pigs as private kills. These pigs are normally from small organic or free range herds and the meat is either for personal consumption by the owner or for supply to local butchers and retailers. While they will require *Trichinella* testing the overall numbers are small, with feedback from industry suggesting an average range of between 10 – 20 pigs per week, although the numbers can vary quite significantly. Numbers for micro plants, especially those on the Scottish islands, will be much lower. If we assume a mid-point of 15 private kills per week for all 16 micro, small and medium sized plants and an estimated cost of £4.09 per pig tested, this would result in additional testing costs for these plants of £51,000 per annum, although this is again likely to be an overestimate. Any additional testing costs for private kills are likely to either be absorbed by the FBO, passed on to the farmer, or in some cases, FBOs may decide to discontinue a private kills service.
- 4.24 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)

- 4.25 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. Based on current information about testing practices, we would expect that most plants in Scotland will seek to use a private accredited laboratory if additional testing is required, or possibly to make an arrangement to use the laboratory of a nearby FBO or send samples.
- 4.26 While some larger plants may wish to explore setting up their own in-house testing to facilitate faster turnaround of carcasses, we anticipate this only being a realistic possibility for the largest pig slaughterhouse (processing over 100,000 pigs per year) due to the capital costs that would be incurred. We anticipate that in-house laboratories will not be commercially viable for most small to medium sized pig processors in Scotland given the smaller size of the Scottish pig industry compared with rest of GB. This has been confirmed by feedback from industry.
- 4.27 Therefore, if we assume that only the largest pig slaughterhouse in Scotland may consider setting up an in-house laboratory, the total one-off cost to industry would be £5,000.

Costs to Farmers

Familiarisation (One-Off Cost)

- 4.28 The main direct impact on farmers from the new Regulation is that the food chain information that need 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 (see paragraph 20 above). 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 £17.2⁷) 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 2) generates a total one-off cost of familiarisation to farmers of £11,420.

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

- 4.29 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.

⁷ 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 ‘Managers and proprietors in agriculture and horticulture’ was used, £13.26, plus 30% overheads, totalling £17.2.

Costs to Enforcement

Familiarisation (One-Off Cost)

4.30 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 OVs 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 (£36.8, FSA internal data) by the number of hours required and the number of slaughterhouses (see Table 1) generates a total cost to enforcement of £625.

Training (One-Off Cost)

4.31 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 (see paragraph 4.33).

Audit and Verification On-Farm (Ongoing)

4.32 With regard to the costs of auditing and verification this will be integrated as far as possible within existing on-farm inspections and visits, in line with the recommendations of the Interim Report on Doing Better Initiative to Reduce Red Tape in Agriculture. The most appropriate body to carry out audit and verification functions in Scotland has still to be agreed, although AHVLA may be best placed 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, such as the QMS Specially Selected Pork scheme, 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 Cost)

4.33 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 (see paragraph 4.4 above), 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)

4.34 The new Regulation requires that all pigs from non-controlled housing conditions are tested for Trichinella. While the cost of in-house testing is borne entirely by the FSA at £0.60p per test, and this will continue under the new proposal, no in-house testing

is currently carried out in Scotland at present. Therefore there are no additional costs to the FSA from this Regulation. As outlined in paragraph 4.21, if industry in Scotland were to go down the in-house laboratory route in the future we estimate that this would result in additional testing costs to the FSA of £14,434.

Cost of training OVs (Ongoing)

4.35 We anticipate that the Regulation will result in training costs to OVs. 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 1) generates a total cost to enforcement of £625.

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 3 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 move towards visual only inspection and strengthened salmonella controls. With regard to the new Trichinella rules, most businesses felt they would not be significantly impacted as almost all fattening pigs are sourced from farms that use controlled housing production systems and will not require testing. Cull sows and boars will continue to be tested as part of the core testing regime. However, it did emerge during these meetings that most small and medium sized plants slaughter a small number of pigs as private kills from small non-commercial outdoor herds. This is either for personal consumption by the owner or for supply to local butchers and retailers. While these private kills will require Trichinella testing the overall numbers are small, with an average range of around 10 – 20 pigs per week, and any additional costs are likely to either be absorbed by the FBO, passed on to the farmer, or in some cases, FBOs may decide to discontinue a private kills service.

Competition Assessment

- 5.3 The incoming Regulation is not expected to have any impact either directly or indirectly on competition.
- 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 amendment to the FCI form will be one additional box, to indicate whether the pigs from the farm need to be tested for Trichinella (based on whether the farm has controlled housing). It is anticipated that the cost of this change will be very low. As the changes to the existing form are so minimal we do not anticipate a need to test run the form with business again.

6. LEGAL AID IMPACT TEST

- 6.1 This new EU Regulation 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 of the new Trichinella rules in approved slaughterhouses and game handling establishments will be the responsibility of the FSA. The relevant enforcement powers are provided within the Food Hygiene (Scotland) Regulations 2006, as amended by The Food Hygiene (Scotland) Amendment Regulations 2014

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 this EU Regulation 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 Implementation of the new Trichinella rules will involve identifying and mapping holdings in liaison with industry and AHVLA, using wildlife testing and other data to support the risk profile as outlined in paragraph 4.4 above. To support this mapping exercise an audit and verification programme will need to be designed within the existing audit framework, supported by third party accreditation where possible. The demand for in-house laboratories will also need to be assessed, as will the new FCI requirements to ensure it captures the necessary information on farm and that this is communicated successfully to the slaughterhouse.
- 8.2 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.

Post-Implementation review

- 8.3 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in June 2019 (i.e. 5 years from the direct application of Regulation (EU) No. 216/2014 in the UK).
- 8.4 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

9. SUMMARY AND RECOMMENDATION

- 9.1 The preferred option for implementation in Scotland is Option 2, full implementation of the requirements set out in the Regulation. This will ensure consumers are protected through proportionate and risk-based *Trichinella* controls and mitigate the likelihood of action from the European Commission, while supporting the longer term trade objectives of the UK and Scottish Governments.
- 9.2 A summary table outlining the overall costs and benefits is provided below.

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social policy & administrative
1 Do Nothing	No additional <i>Trichinella</i> testing costs for industry. No familiarisation and costs for industry and enforcement authorities.	Significant risk of infraction proceedings against the UK.
2 Full Compliance	Risk based public health protection for consumers. Potential to secure derogations from <i>Trichinella</i> testing after 3 years.	Familiarisation costs to slaughterhouses: £438.00 one-off cost Costs to slaughterhouses from additional testing of commercial pigs: <ul style="list-style-type: none"> • High impact scenario (using private laboratories): £98,397 per annum • Medium impact scenario (using in-house testing): £14,434 per annum [Note this cost would be borne by the FSA] • Low impact scenario (most likely): £0 per annum Cost to micro, small and medium slaughterhouses from additional testing of 'private kill' pigs: £51,000 per annum (worst case)

		scenario)
		Potential cost to slaughterhouses of moving to in-house testing: £5,000 one-off cost
		Familiarisation costs to farmers: £11,420 one-off cost
		Familiarisation costs to enforcement authorities: £625 one-off cost
		Cost to FSA of UK mapping exercise: £10,000 one-off cost
		Cost to FSA of training: £625 one-off cost

10. 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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