Explanatory Memorandum to The Official Feed and Food Controls (Wales) (Miscellaneous Amendments) Regulations 2019

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

Minister/Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of [The Official Feed and Food Controls (Wales) (Miscellaneous Amendments) Regulations 2019. I am satisfied that the benefits justify the likely costs.

Vaughan Gething
Minister for Health and Social Services
28 November 2019

PART 1

1. Description

1. Official Feed and Food Controls are the checks conducted by competent authorities, such as the Food Standards Agency, to verify businesses' compliance with food and feed hygiene and safety legislation. On a European level, legislation creates a framework across the European Union to ensure that Member States are performing official controls with a consistent approach and common standards across the EU to secure public and animal health which facilitates the movement of goods

2. These Regulations amend current Regulations on the administration and delivery of Official Feed and Food Controls made necessary by Regulation (EU) 2017/625 and its subordinate legislation all of which are directly applicable to the UK as a Member State of the European Union.

3. Regulation (EU) 2017/625 sets out a framework of requirements for the competent authorities in Member States which have responsibilities for organising and performing official controls and other official activities to verify compliance with agri-food chain legislation

4. Most of the provisions of Regulation (EU) 2017/625 clarify and simplify existing requirements and aim to introduce a more risk-based approach to controls. Therefore, existing enforcement arrangements in the UK are generally already in line with the new requirements.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

5. Section (2) of the European Communities Act 1972 offers a choice between negative and affirmative procedures. The negative procedure will be used in this case as the discretion of the Welsh Ministers is limited over the content of the SI because it is giving effect to EU provisions.

6. The current official controls regulation (Regulation (EC) No. 882/2004) will be revoked when the OCR comes into force on 14 December. The SIs are critical to maintaining official controls and enforcement. If these SIs are not laid, this leaves Wales without a legal framework to enforce official controls and therefore puts public health at risk (as well as animal health and welfare), undermines business and consumer confidence and risks market access to the EU. Without the SIs coming into force on 14 December, the FSA and other enforcement authorities in Wales will not have the legislative powers to enforce food and feed safety laws. For example, food inspectors will be unable to enter and inspect food businesses. Additionally, there will be no official presence at meat processing plants meaning they will need to cease operation, these has implications for food supplies as well as loss of employment as food business operators will not employ inspectors while they are unable to perform their duties.

7. Official controls are integral to protecting consumers' health and other interests and maintaining the integrity of the agri-food chain that provides consumer and business confidence as well as assurance to other Member States and 3rd countries, which is vital to trade. UK enforcement authorities (such as the FSA and local authorities) carry out official controls at all stages of production, distribution, storage, transport, import and export of food and feed. The controls ensure that food and feed businesses are meeting their obligations to produce safe and wholesome food and feed and that unsafe products are removed from the market.

8. Without the SIs coming into force on 14 December we would fail to meet our legal obligations and the FSA and other enforcement authorities would lose the legal powers to effectively enforce food and feed safety laws.

9. Similar legislation is being made in England, Scotland and Northern Ireland to come into force on 14 December.

10. The drafting of the SIs has been delayed because important parts of them depended on the status of the United Kingdom, insofar as whether it was a Member State of the European Union on the coming into force date (14 December 2019) of the OCR. Certainty over this position was not forthcoming from UK Government and the European Union until very shortly before the 31 October.

11. The impact of this on the drafting process in all of the devolved administrations has been significant, and this is the reason why the final SIs were not able to be submitted for scrutiny in time to avoid the recommendation not to adhere to the 21-day convention.

3. Legislative background

12. The Regulations will be made pursuant to powers in section 2(2) of the European Communities Act 1972. Section 2(2) of the European Communities Act 1972 provides that any designated Minister may by order, rules, regulations or scheme make provision for the purpose of implementing any EU obligation of the UK. "Designated Minister" means such Minister of the Crown or government department as may from time to time to be designated by Order in Council in relation to any matter or for any purpose.2(2) of the European Communities Act 1972 enables

13. Section 59 of the Government of Wales Act 2006 provides that the power to designate a Minister of the Crown or government department under section 2(2) of the European Communities Act 1972 may be exercised to designate the Welsh Ministers, and that accordingly the Welsh Ministers may exercise the power conferred by section 2(2) in relation to any matter or purpose in relation to which they have been designated.

14. The Welsh Ministers are designated in relation to measures in respect of food (including drink) including the primary production of food (see European Communities (Designation) (No. 2) Order 2005/1971).

15. The Regulations follow the negative procedure.

Delivery of Official Controls

16. The FSA is the Central Competent Authority (CCA) responsible for the delivery of official food and feed controls in Wales. In Wales, the FSA is responsible for the delivery of dairy hygiene controls and official controls in approved meat premises, including meat hygiene requirements and regulations on the welfare of animals at slaughter. The FSA is also responsible for the classification of shellfish production areas in Wales.

17. There are 22 Local authorities (LAs) in Wales have also been designated to deliver official food and feed controls for matters which are not within the remit of the Veterinary Medicines Directorate (VMD) or the Animal Plant and Health Agency (APHA)

18. In Wales, the FSA is responsible for setting the standards and monitoring performance of the delivery of official controls for food and feed law. The FSA directs and maintains the consistency of delivery of food controls by local authorities through the Food Law Codes of Practice and associated Practice Guidance and for feed controls, the Feed Law Code of Practice and associated Practice Guidance.

19. The FSA also sets out the standards of performance for official control activity in FSA approved establishments through a published Manual for Official Controls (MOC) in Wales and England.

20. Regulation (EU) 2017/625, referred to as the Official Controls Regulation (OCR), is a directly applicable EU regulation and an overarching piece of legislation that sets operational standards for the performance of official controls and other official activities by competent authorities across the European Union.

21. The OCR entered into force on 27 April 2017, with the applicability of the new rules set to apply gradually over a number of years; with the main application taking effect on 14 December 2019. The OCR empowers the European Commission to adopt implementing acts and introduce delegated acts (tertiary legislation) to supplement the regulation.

22. When the OCR main application takes effect on 14 December 2019 it will give effect to applicable tertiary legislation and the new law will apply in all European Union Member States. It will also repeal and replace existing legislation integral to official control activities, including those carried out by the Food Standards Agency (FSA) and local authorities in England, Wales and Northern Ireland. This includes Regulation (EC) No 882/2004 regarding official controls performed to verify compliance with feed and food law, and Regulation (EC) No 854/2004 on official controls on products of animal origin intended for human consumption.

23. The legal framework created by the OCR allows members of the single market to be sure that the competent authorities in other Member States are conducting controls in a suitably rigorous and impartial fashion. The legislation cuts across aspects of the agri-food chain, such as import controls and laboratories, as well as different commodities, such as live animals, plants and food of animal origin.

24. Welsh Government officials in the Office of the Chief Veterinary Officer (OCVO) have been co-ordinating the efforts of all relevant policy teams in Welsh Government towards the introduction of legislation across all areas other than those within the FSA's remit.

Rationale for intervention

25. Failing to provide for the execution of powers and enforcement in Wales for the OCR would present significant gaps to the legislative framework for the delivery of official controls.

26. UK enforcement authorities (such as the FSA and local authorities) carry out official controls at all stages of production, distribution, use, storage, transport, import and export of food and feed. The controls ensure that food and feed businesses are meeting their obligations to produce safe and wholesome food and feed and that unsafe products are removed from the market. Official controls are integral to protecting consumers' health and other interests and maintaining the integrity of the agri-food chain that provides consumer and business confidence as well as assurance to other Member States and 3rd countries, which is vital to trade.

27. When the main provisions of the OCR take effect on 14 December 2019, the OCR will repeal the European regulations that currently provide the legislative framework for UK official controls in relation to EU food and feed law. To maintain our legislative framework for EU food and feed law official controls the UK must provide for the execution of powers and enforcement of the OCR in domestic legislation. Failure to do so will undermine the effectiveness of official controls and therefore undermine consumer protection as well as confidence in the UK agri-food chain.

28. The FSA estimates that there are around a million cases of foodborne illness in the UK each year, generating an economic burden of treatment costs and loss of productivity in excess of £1 billion each year in resource and welfare costs for the UK[1]. A failure to introduce the required legislation to enforce official food and feed controls would undermine the effectiveness of official controls, likely leading to an increase in non-compliance and cases of foodborne disease, involving severe consequences for public health and costs to society.

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[1] 2017/18 Annual Reports and Consolidated Accounts, p. 16. It should be noted that the FSA is currently updating the way it estimates the economic burden of foodborne illness. These figures are therefore preliminary and will be updated as soon as new evidence is available.

Policy objective

29. The existing legal framework enables competent authorities to effectively enforce food and feed law. The statutory instruments to provide the execution of power and enforcement for the OCR will ensure sufficient powers are in place in Wales to effectively enforce food and feed law and maintain the high level of consumer protection currently in place. The domestic legislation will also ensure that domestic law is up to date with the European Union acquis including the changes brought about by the provisions of the OCR on 14 December 2019.

30. Through the implementation of legislation in Wales the FSA will repeal and replace current secondary legislation, to provide for the execution of powers and enforcement for the OCR and associated tertiary legislation currently under negotiation by Member States and the European Commission. Implementation of legislation in Wales will maintain a strong legal basis for future official control activity in relation to food and feed law and animal health and welfare. It will also ensure that consumer protection is maintained and that confidence in the UK agri-food chain is maintained through the demonstration of the effectiveness of our regulatory control system including the legal basis for the execution of necessary powers and enforcement of official controls and other official activities.

31. The intention of the European Commission is to simplify and further harmonise control systems across the EU agri-food chain through the implementation of the OCR. The organisation of such controls is harmonised at an EU level to ensure a consistent high-level of consumer protection, provide confidence in the safety and standards of food produced in the EU or imported from third countries and provide for effective functioning of the internal market.

32. The new legislation builds upon and clarifies the existing risk-based approach towards the performance of official controls. The main intended effects identified by the Commission are summarised below:
    - A harmonised and coherent regulatory approach to official controls and enforcement actions along the agri-food chain;
    - Increased transparency and greater accountability required by Member States competent authorities through the publication of information about the organisation and performance of official controls;
    - More stringent rules on fraud will provide greater consumer protection and benefit compliant businesses;
    - A common set of rules for controls at EU borders that overcomes the current fragmentation and makes the control system less burdensome for enforcers and businesses;
    - An integrated computerised system to improve the exchange of information between Member States on official controls;

- Greater flexibility in relation to the accreditation of official laboratories (i.e. formal recognition of competence in their field);
- Businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls.

33. For the most part, the legislative changes required in Wales are technical, such as the changing of references to previous EU legislation to refer to Regulation (EU) 2017/625 and associated tertiary legislation.

General Changes to the Delivery of Official Controls

34. The OCR will introduce changes across a number of policy areas. However, for the most part it is expected that these changes will result in relatively few impacts, as they relate to the overarching principles of conducting official controls to which the UK is already aligned. The key changes identified by the FSA in relation to the main provisions of the OCR that apply from 14 December 2019 are set out below.

35. Further impacts, associated with provisions laid down in the tertiary European legislation, which sets out in further detail how official controls should be carried out, are also identified and assessed.

Other official activities

36. Article 2 of the OCR introduces a new definition of 'other official activities', which includes activities performed by competent authorities (CAs) or delegated bodies other than official controls. For example, enforcement measures and/or remedial actions following non-compliance; management of lists of registered/approved food and feed business operators or the issuance of official certificates. The OCR sets out rules necessary to ensure that such activities are properly and effectively performed. Our assessment is that the FSA Food and Feed Law Codes of Practice, and associated Practice Guidance, likewise, the FSA Manual for Official Controls, already acknowledge and align with the OCR requirements in respect of the way these activities are carried out by CAs in England, Wales and Northern Ireland. We therefore do not expect any incremental impact associated with this change.

Risk-based controls

37. The general risk-based approach of existing legislation and current practice, detailed in Article 9 of the OCR, is maintained. However, a new provision in Article 9 paragraph 2 strengthens the fight against fraud along the agri-food chain by clarifying that CAs are required to carry out regular, risk-based official controls, directed at identifying fraudulent and deceptive practices.

38. Our assessment is that the FSA Food and Feed Law Codes of Practice, and associated Practice Guidance already acknowledge and have regard to

fraud and deceptive practices as part of the food and animal feed law risk rating schemes. Likewise, the FSA Manual for Official Controls also identifies the need to have regard to fraudulent practices during routine audits. We do not expect any change to the frequency or number of official controls as a result of this new provision.

39. Consumers will benefit from greater protection against misleading claims about the properties, quality, composition or country of provenance of the food they buy where there have been intentional violations perpetrated through fraudulent and deceptive practices. Especially, when purchasing food or feed from a food or feed business operators in an EU country other than the UK, who have not yet adopted measures to identify such violations within their risk rating regimes.

40. Furthermore, there is now a requirement on competent authorities that the penalties associated with fraud convictions must represent the economic advantage gained by the perpetrator as a result of that fraudulent action. Such penalties are already available for fraudulent activities prosecuted in the UK through the Proceeds of Crime Act 2002. We therefore do not expect any incremental impact from this change.

Transparency requirements

41. Transparency requirements for competent authorities are clarified in Article 11 of the OCR by identifying the minimum level of information which must be made public and at what frequency. Competent authorities are required to provide FBOs with copies of reports where non-compliance has been detected as well as where compliance has been achieved. New provisions regulate the delegation of specific tasks relating to 'other official activities' and the conditions to be met for delegating certain official tasks.

42. Our assessment is that the current practice in Wales already meets these requirements. We therefore do not expect any incremental impact from this change.

Sampling

43. Articles 35 and 36 of the OCR relating to 'second expert opinion' and 'sampling of animals and goods offered for sale by means of distance communication' provide greater clarity to enforcers that a sample ordered on-line by the CA without identifying themselves can be validly used for the purposes of an official control. While also making provision that they need to inform the operator that such a sample has been taken and, where appropriate, is being analysed in the context of an official control.

44. Our assessment is that this provision of notification already exists in UK law. We therefore do not expect any incremental impact from this change.

Official Controls for products of animal origin

45. Article 18 of the OCR creates specific rules on official controls and for action taken by the competent authorities in relation to the production of products of animal origin intended for human consumption. This Article derives from the now revoked Regulation 854/2004 and provides the legal basis for the work of the FSA in establishments or areas where products of animal origin for human consumption are produced or processed. The implementing and delegated acts made under Article 18(7) and Article 18(8) establish detailed rules in this area. Our analysis of the OCR requirements indicates that OAs can continue provide assistance to OVs in undertaking ante-mortem and post-mortem inspection. The impact of these changes is analysed in further detail below.

Import controls

46. Articles 43 – 77, 90, 126 -128 and Article 134 of the OCR are revised rules regarding import controls and import conditions on animals and goods arriving in the European Union from third countries. These changes are intended to create a common framework for all goods covered by the OCR across the agri-food chain. Central to this project is the re-designation of all existing specialised border facilities, such as Designated Points of Entry (DPEs) and Border Inspection Posts (BIPs) as Border Control Posts (BCPs). Furthermore, existing entry documents, such as the Common Entry Document (CED) for high-risk food not of animal origin and the Common Veterinary Entry Document (CVED) for products of animal origin, will be amalgamated as Common Health Entry Documents (CHEDs). These systemic changes will be underpinned by a new Information Management System for Official Controls (IMSOC). This platform will link existing systems, such as RASFF and TRACES, rather than replacing any elements of the Commission's computational architecture.

47. Although the groundwork for this new common framework for imports is established in the OCR, the legislation itself provides the power to make detailed implementing tertiary legislation. Since 2017 these rules have been negotiated between European Union Member States and the European Commission. The UK has participated fully in this process. As these detailed rules establish, to a much greater extent, the shape of the new regime, their impact is examined below in greater, individual detail.

National Reference Laboratories (NRLs) & Official Control Laboratories (OCLs)

48. National Reference Laboratories (NRLs) & official control laboratories (OCLs) will see minor changes to the responsibilities placed upon them (Articles 34, 38, 40, 42, 92, 94, 100 & 101). The changes for NRLs have in fact applied since April 2018. Changes to the responsibilities of OCLs (applicable from December 2019) will mean that competent authorities are required to have closer contact with the laboratories and greater oversight of delegated laboratories. The main issue in this area is a legislative change which means that a laboratory can only send a sample to a laboratory in

another member state if the second laboratory has been designated an official laboratory in the receiving member state. The impact of this change has been assessed in further detail in the appraisal section.

Cross-border incidents

49. Articles 102 – 108 of the OCR subjects CAs to tighter rules and more formalised processes for interacting with authorities in other Member States when responding to cross-border incidents. For example, CAs must set out within ten days their intentions regarding notifications from other Member States.

50. Our assessment is that the UK already consistently complies with these requirements. We therefore do not expect any incremental impact.

Financing of Official Controls

51. The OCR also expands upon the European Union's existing legal basis for the financing of official controls. This includes, in particular at Article 85, a greater emphasis on transparency.

52. The FSA does not anticipate introducing any changes now or immediately after 14 December 2019. Further stakeholder engagement will take place as appropriate

Tertiary Legislation: UK Integrated Multi-Annual National Control Plan (MANCP) – Annual Report

53. It is a European Commission requirement that all member states have a national control plan. The purpose of this plan is to ensure that effective systems are in place for monitoring and enforcing feed and food law, animal health and animal welfare rules, and plant health law. Progress on implementation is continually monitored and annual reports are prepared and submitted to the European Commission.

54. In order to ensure the uniform presentation of annual reports, the OCR provides for implementing acts to adopt and update as necessary standard model forms to be used for annual submission of the information. The EU have now finalised and published these model forms under Commission Implementing Regulation (EU) 2019/723. This requirement applies from 14 December 2019, however, the first annual report against the new template is not required until August 2021. We do not expect any incremental impact associated with this requirement.

Tertiary Legislation: Hygiene controls on products of animal origin (POAO) for human consumption

55. Article 7 of Regulation (EU) 2019/624 places maximum thresholds limiting the use of official auxiliaries (OA) carrying out post-mortem inspection (PMI)

at what are now referred to as low-capacity slaughterhouses and low-capacity game handling establishments (GHE) based on maximum number of animals slaughtered annually. The Regulation also permits this level to be raised where the total Member State production of the low-capacity facilities which take advantage of the increased threshold do not exceed 5 percent of the total market for the species concerned.

56. Currently PMI can be undertaken in slaughterhouses and GHEs which do not operate continually throughout the working week by OAs, without an official veterinarian (OV) being present, following a risk-assessment by the competent authority.

57. The FSA will look to make use of the provision within Article 7 of Regulation (EU) 2019/624 to maximise the use of OAs at low-capacity slaughterhouses and low-capacity GHEs on a risk-basis.

58. Article 36 of Regulation (EU) 2019/627 includes a new requirement for CAs to verify food business operator compliance with campylobacter process hygiene criterion (PHC) as set out in Regulation (EU) No 2073/2005 on microbiological criteria of foodstuffs, which applies only to slaughterhouses where the approved activity is broiler production.

59. The Regulation provides two options for how the competent authority can undertake its verification, sampling or collection of industry data:

    - The first option is for official sampling using the same method and sampling area as food business operators. At least 49 random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation.
    - The second option is to collect information on the total number of samples and the number with more than 1,000 cfu/g taken by food business operators in accordance with Article 5 of Regulation (EC) 2073/2005 and take samples only where it is considered necessary.

60. The FSA currently considers option 2 to be the preferred policy option but no decision has yet been taken and proposals will be discussed with industry stakeholders before any final decision is taken.

61. From the implementation of the OCR on 14 December 2019, echinoderms will no longer be permitted to be harvested from unclassified areas. This will create an impact on LAs and the FSA as any FBOs that harvest echinoderms from unclassified areas will require the area to be classified in accordance with the Regulation 2019/627 or else cease harvesting.

62. Article 61 of Regulation (EU) 2019/627 specifies that sampling frequency for toxin analysis in live bivalve molluscs shall be weekly. The provision for less frequent monitoring, through a risk assessment, still applies. This is more

stringent than the current sampling frequency carried out in England, Wales and Northern Ireland. A Risk Assessment has been carried out to consider the appropriateness of the current regimes and consideration of the evidence in relation to the new requirements is still under review. The FSA will consult further with stakeholders, including an assessment of the impacts, once our analysis is complete.

63. The OCR also changes some existing requirements in the following areas of official controls on POAO:

- Ante-mortem inspection allowed to take place at the holding of provenance for all species and not limited to poultry and lagomorphs.
- There is the capacity for delayed post-mortem inspection for up to 24 hours in low capacity slaughterhouses and game handling establishments.
- It is possible for authorities to introduce less supervision of on-line checks of poultry and lagomorphs when certain criteria are met by the food business operator in accordance with Article 25.
- The age at which post-mortem inspection of bovine animals can be carried out without incision has been lifted from six weeks to eight months reducing risks of cross-contamination and retaining the value of meat, a higher percentage of which will remain intact
- There are reduced post-mortem requirements for cattle which are from herds that are certified by the competent authority as being ‘free’ of cysticercosis.
- There is provision, based on a risk assessment (only on a temporary and non-recurring basis) to permit continued harvesting of live bivalve molluscs when health standards have not been met in Class A areas, without the closure or reclassification as long as the area and all approved establishments are under a single competent authority and are subject to appropriate restrictive measure.

Tertiary Legislation: Import Controls & Conditions

64. The new OCR and its tertiary legislation are intended to streamline, modernise and harmonise rules regarding the import of animals and goods into the European Union. Responsibility for the delivery of official controls on imported food and feed in Wales is shared between Welsh Government and the FSA. Port Health Authorities and Local Authorities (at designated airport points of entry) deliver veterinary controls on products of animal origin arriving from third countries on behalf of the ministerial departments, although these controls have a public health element and therefore a significant degree of FSA interest. Port Health Authorities and Local Authorities (at designated airport points of entry) also perform controls on high-risk foods not of animal origin (FNAO) on behalf of the FSA.

65. Legislative responsibility for the policies which underpin the import controls regime is also shared between the FSA and Welsh Government. This includes legislation which determines the rules and criteria for the performance of controls, as well as import conditions which must be met before goods can enter the European Union. Tertiary legislation empowered by the OCR updates existing rules in the area of import conditions for products of animal origin intended for human consumption in the European Union.

66. Given the division of responsibility in this area between competent authorities, this impact assessment addresses the two aspects of the legislation for which the FSA can be understood to have primary legislative responsibility: controls on high-risk FNAO and import conditions for products of animal origin for human consumption. It is also necessary to examine the impact that the Commission's new Integrated Management System for Official Controls (IMSOC) will have on the general performance of import controls.

67. Although negotiations have been ongoing since 2017, legislation in some areas is yet to be finalised or published. This is clearly set out below where relevant.

Import controls on high-risk FNAO

68. Certain foods are subject to a higher level of import controls as a result of the elevated risk they are deemed to pose to consumers. Specified commodities from specified countries are subject to physical inspection and laboratory sampling at a rate agreed by Member States on a biannual basis. This system is currently based on Regulation (EC) 882/2004 and Regulation (EU) 669/2009. Rules in this area are replaced by the relevant provisions of the OCR and an as yet unpublished Implementing Regulation. It is foreseen that evidence-based frequency rates will be agreed at a committee of Member States at regular intervals. This would allow for a more transparent and efficient review of risks and for a swifter revision of these measures. As the fundamental mechanics of the system will remain the same, no further impact beyond existing practice is expected in this area in the short-term; current sampling frequencies would remain unchanged unless new evidence suggests that the level of risk has changed e.g. the product may be de-listed or subject to a higher frequency of checking or enhanced controls.

69. Existing border control facilities for the control of high-risk FNAO are currently classified as Designated Points of Entry (DPEs). As the OCR unifies all border control facilities under the definition Border Control Posts (BCPs) these facilities will now be required to meet the standards established in Regulation (EU) 2019/1014. These rules go beyond existing standards as set out in Regulation (EU) 669/2009. As a result, the operators of these BCPs will be required to ensure that their facilities are compliant with the new legislation.

70. Detailed rules regarding how competent authorities should deal with transit and transhipment of goods entering the European Union have also been developed. This legislation, to be made under Article 51(1)(a) of the OCR, has, however, not yet been published. The rules, as currently drafted, build on existing processes but have introduced an increased degree of flexibility for Member States in most instances. For example, there are some proposed changes to the minimum time in port requirements and the Commission is proposing no checks at the BCP of first arrival on animal products which are destined to third countries when consignments are staying on the same means of transport for onward travel to the BCP of destination. As a result of the limited nature of these changes, no costs beyond familiarisation costs for operators or competent authorities are foreseen.

71. Regulation (EU) 2019/1013 establishes that the operator responsible for a consignment of high-risk food and feed not of animal origin arriving in the European Union must be notified at least one working day prior to the expected arrival of the consignment. This is consistent with many of the existing requirements which also require notification one day prior to the expected arrival except for POAO which must be notified 'in advance'. In certain scenarios, where there are 'logistical constraints', for example a short journey, this can be reduced to four hours at the discretion of the competent authorities of the BCP. As such minimal additional impacts are anticipated as a result of this new legislation, on operators or competent authorities.

72. A draft regulation is also under development which would allow for the performance of identity and physical checks on high-risk FNAO to be performed at an inland control point, away from the immediate point of entry for the commodity. This inland control point would be required to meet the same criteria as an inspection centre at a BCP. A process for permitting and management of the transfer of goods would also be established, to ensure the traceability of potentially high-risk foods. As this is flexibility available to the operators of BCPs it does not create potential impacts but could be used in the future to allow for the establishment of more inspection facilities at lower costs. These would require suitable legal designation and approval. Current rules which allow for the onward movement of consignments of high-risk FNAO pending the results of laboratory testing have also been retained.

73. The basic act of the OCR establishes that existing formats of certification will be unified as Common Health Entry Documents (CHEDs). The contents of these categories will vary according to the relevant commodity. The current format of the Common Entry Document (CED), used for consignments of high-risk FNAO, will become the CHED-D. This will require some familiarisation costs for operators and competent authorities alike. The FSA is currently undergoing an internal piece of work to better understand the details of the proposed changes to entry documents and the potential impacts on importers beyond familiarisation costs.

74. Legislation is also yet to be finalised regarding certain derogations for border controls. For example, legislation regarding derogations for the designation of BCPs (such as instances where facilities can be situated away from an entry point into the Union). As these rules create the potential for derogations and flexibilities, no immediate significant impact is foreseen.

Import Conditions for POAO for human consumption

75. Regulation (EC) No 853/2004 establishes that all products of animal origin imported into the European Union must come from a listed third country. This requirement has not been applied fully in the EU since its inception and has been subject to recurrent transitional measures. Legislation, empowered by the OCR, has been made in order to effectively enforce this requirement and to further harmonise import conditions for POAO and some other high-risk goods across the European Union. Regulation (EU) 2019/625 creates an overarching framework for the reformed import conditions regime. This is supplemented by Regulation (EU) 2019/626, as regards third country listing, and Regulation (EU) 2019/628, as regards certification.

76. The most significant new element of this package of legislation is the increased scope of goods which will be subject to certain forms of harmonised import conditions for the first time. These changes will affect the movement of reptile meat, insects and products derived from insects, composite products, raw materials for the production of gelatine and collagen, sprouts for human consumption and fats and greaves.

77. Regulation 2019/625reforms to the way composite products are controlled. All composite products (with some exceptions) will need to be channelled through BCPs and there will be a move away from a percentage approach to temperature control requirements. The Regulation will not take effect until April 2021, and as such is not included in the appraisal section.

78. Reptile meat is currently imported in the United Kingdom from third countries under domestic legislation. It is still subject to official controls at Border Inspection Posts. The new rules will require imports of reptile meat to derive from an approved third country, as set out in Regulation (EU) 2019/626. As of December 2019, this list will include only Switzerland, Botswana, Vietnam, South Africa and Zimbabwe. These consignments must also arrive with a model health certificate as established in Annex III Part XII of Regulation (EU) 2019/628, which clearly sets out that the products have been produced in line with the relevant European hygiene legislation. This requirement for a model health certificate is subject to a transitional period until 13 March 2020, allowing time for familiarisation and preparation. Regardless, this introduction of harmonised paperwork may create further work for Port Health Authorities and operators involved with the trade of reptile meat for human consumption. Operators in third countries will require the services of an official veterinarian to sign certificates prior to export.

79. Food consisting of, isolated from or produced from insects or their parts will also now be subject to harmonised import conditions in a similar fashion to reptile meat. This will involve the introduction of a third country list established in Regulation (EU) 2019/626 and a certificate in Regulation 2019/628 Annex III Part XIII. In terms of third country listing, this is dependent upon the prior approval of exporting countries or regions in line with novel foods legislation, Regulation (EU) 2015/2283 and Regulation (EU) 2017/2470. Equally this may create a greater administrative burden on Port Health Authorities and new regulatory requirements on operators.

80. Regulation (EU) 2019/625 also establishes a framework of new risk-based rules on importing composite products from third countries based on shelf stability and composition. These measures, however, will not apply until April 2021. As such their impact will not be assessed at this time.

81. Raw materials for the production of gelatine and collagen are also subject to a slight change in the legislation. The new rules provide that raw materials, intended for the production of gelatine and collagen, referred to in point 4(a), Chapter I of Sections XIV and XV, Annex III to Regulation (EC) No 853/2004, for import into the European Union must be obtained from listed slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products. Existing rules state that raw materials for the production of gelatine and collagen must derive from a listed third country (as set out in Regulation (EU) 2016/759) and originate from a registered or approved establishment. Although at present there exists an approved list of establishments for *treated* raw material for the production of gelatine and collagen, Regulation (EU) 2019/625 sets out that this requirement will be expanded to such raw materials. As these goods are already subject to certification and veterinary controls, this means that the impact on Port Health Authorities will be limited. However, this could potentially have an impact on the movement of goods from third countries and could affect operators adversely as a result of short-term trade disruption.

82. Sprouts and seeds intended for human consumption produced within the European Union are currently subject to heightened rules as a result of the risk they pose to spread foodborne illnesses. In addition, sprouts and seeds imported into the European Union from third countries must be accompanied by a health certificate, as set out in Regulation (EU) 211/2013. As a result of Regulation (EU) 2019/625, sprouts falling under specific CN codes will be required to derive from a listed establishment in a third country which is approved in accordance with the requirements of Article 2 of Regulation (EU) 210/2013 and Regulation (EU) 852/2004. This means that third country establishments producing sprouts are subject to equivalent legislation as those within the European Union. The model health certificate for sprouts is also reformatted and is now published in Annex 3 Part 15 of Regulation (EU) 2019/628. While this could, in theory necessitate some familiarisation costs for Port Health Authorities and operators, it is understood that this is primarily an inland control.

83. Rendered fats and greaves are currently required to derive from an approved establishment in any third country. Regulation (EU) 2019/626, however, requires these products in future to derive from third countries authorised for the import of meat products into the Union in accordance with point (b)(i) of Article 3 of Decision 2007/777/EC.

84. Regulation (EU) 2019/626 will introduce a list for products of animal origin not otherwise covered by the regulations. This will provide greater clarity than is currently the case under Article 6 of Regulation (EC) No. 853/2004. It is not foreseen yet what this will encompass, but we do not anticipate that this will have a significant impact.

85. Regulation (EU) 2019/628 also creates a new format for the model health certificate required for specific goods. Although this format will only be introduced for goods for which the previous certificates had a legal basis pursuant to Regulation (EC) No. 882/2004, it is anticipated that the new format will eventually be extended to all commodities. This new format will incur familiarisation costs for operators and Port Health Authorities alike.

86. Regulation (EU) 2019/628 also creates new rules for the issuance of replacement certificates at Article 6. It is anticipated that these will also result in familiarisation costs.

Tertiary Legislation: Integrated Management System for Official Controls (IMSOC)

87. The IMSOC will act as a unifying platform for existing EU system such as TRACES, RASFF, Administrative Assistance and Cooperation and the Food Fraud Network. The legal basis for the IMSOC and how it will function will be further expanded upon in an Implementing Regulation empowered under Article 134 of the OCR.

88. Operators and competent authorities will be required to familiarise themselves with the new platform and its interface. However, it is anticipated that in the long run the new system will create efficiency savings for businesses and authorities alike.

5. Consultation

89. The FSA in Wales published a six-week consultation on the proposals from 28 October to 9 October 2019

90. Four substantive responses were received. Three were from enforcement bodies and one was from a consumer advocacy organisation.

91. There was broad agreement to all of the proposals in the consultation regarding the legislation. No amendments were considered necessary to the draft Regulations.

92. Some comments requested a reassessment of the costs, particularly of familiarisation costs for enforcement authorities, where responders suggested that we had underestimated the impact. We have therefore updated the costs to reflect this.

93. A question was asked on the provision of sanctions for non-compliance, tore conflicting responses. Enforcement authorities welcomed an examination of criminal sanctions to see if there were any areas that were suitable for replacing with civil sanctions, with a backstop criminal offence for continued non-compliance. The consumer organisation suggested that such changes would send the wrong message.

94. In the event the examination of the sanctions did not identify any areas where criminal sanctions could be replaced and so reference is made to this question for completeness only.

95. A summary of the responses will be available on the FSA website at www.food.gov.uk within two months of the close of the consultation.

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Options

Baseline: Status Quo

96. This is the baseline option against which all other options have been assessed. It reflects the status quo, i.e. a situation in which there were no incremental changes to the current legislation.

97. It should be noted that this is not a realistic option as the OCR has already been published in April 2017 and will be directly applicable in the UK from 14 December 2019 in an Article 50 extension or transition period. The baseline solely serves the purpose to quantify the expected impacts of all policy options against a consistent baseline.

Option 1: Implement domestic legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation.

98. Take appropriate action to fully implement the provisions of the OCR into UK law. This would require making legislation to enable the delivery of the requirements.

99. This is the preferred option.

Option 2: Do Nothing – Do not implement domestic legislation to provide for the execution of powers and enforcement of the OCR.

100. Regulation 2017/625 (OCR) will repeal the current legislation on official controls. If the new legislation is not implemented prior to the current legislation being revoked, the UK would have no legal framework to enforce official controls and therefore the UK would be unable to demonstrate that it can meet one of its primary objectives which is to protect human health.

101. The OCR is directly applicable European legislation, so failure to put in place the measures needed to implement could lead to the European Union bringing infraction proceedings against the UK. This policy option is rejected.

7. Costs and benefits

Option 1: Implement Regulation 2017/625 - OCR

COSTS & BENEFITS

102. The cost benefit analysis that follows assesses a range of different costs and benefits that we expect under option 2. These are:

- **Familiarisation costs :** one-off / transitional costs for all affected stakeholders to acquaint themselves with the new requirements of the legislation. This ensures a smooth transition between the two regimes. Figures are presented in current prices.
- **Training costs:** one-off costs to the central competent authority providing training to local authorities that deliver official controls and for local authorities to complete the training.
- **Non-monetised costs:** potential outcomes from the legislation where it is currently not possible to quantify their impact. Where we are unable to quantify expected impacts, we have explained in detail why the required data is not available and how we seek to substantiate the assessment and our understanding going forward.

103. All quantified costs and benefits in this section are estimated in current prices and measured over a 10-year appraisal period. This appraisal period was deemed appropriate as all monetised costs and benefits are transitional in nature. All total costs and benefits highlighted throughout are rounded to the nearest ‘000 to aid interpretation.

104. To ensure consistency in our calculations we have adopted an established method based on the Standard Cost Model (SCM) Approach published by BEIS. Where we have used wage rate data, we have taken hourly wage

rates from the 2018 Annual Survey of Hours and Earnings (ASHE)[2], using the median rate of pay. Furthermore, when using wage rate data, we have uplifted rates to account for overheads by 30%, in line with The Green Book [3] guidance.

2 https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/ashe1997to2015selectedestimates

3 https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent

Affected Groups

Food and Feed Business Operators

105. As the current landscape and the general performance of official controls under the OCR remains substantially the same for FSA policy areas, for the majority of food and feed industry stakeholders there will be no requirement to familiarise themselves with the requirements of the Regulation.

106. However, where the OCR necessitates changes to the tertiary legislation, selected Food and Feed Business Operators will need to familiarise themselves with the changes and comply with new requirements. Selected FSA Approved Establishments, which are subject to official hygiene controls performed for the verification of compliance, will be affected by new tertiary requirements. These include businesses in the following sub-sectors:

a) Slaughterhouses
b) Cutting Plants
c) Fish Auctions
d) Wholesale fish markets, factory vessel and freezer vessels
e) Game Handling Establishments
f) Operators of vessels catching and handling live bivalve molluscs, shellfish and fishery products
g) Milk and Colostrum Production Holdings

107. In addition, we assume that all UK importers of high-risk food and feed will be affected by new import requirements and changes to border procedures.

108. Official Control Laboratories (OCLs) are designated by CAs for the purpose of analysing samples taken during official controls and for food and feed enforcement. They will see minor changes to the responsibilities placed upon them, requiring them to have closer contact with the laboratories and greater oversight of delegated laboratories. As some OCLs are privately funded those laboratories have been identified as an affected industry stakeholder.

109. We appreciate that additional industry stakeholders might be affected by incoming tertiary legislation which has not yet been agreed. Due to the high level of uncertainty surrounding this legislation we have been unable to assess the associated impacts at this stage.

Enforcement Authorities

110. The OCR primarily addresses the responsibilities of Member States' CCA and their designated enforcement authorities who carry out official controls to check that business operators comply with the relevant law.

111. Local Authorities, as CAs, which deliver official regulatory controls across food and feed will have to familiarise themselves with the new requirements. Similarly, some LAs as CAs, for the delivery of official regulatory controls with regards to imports of POAO and high-risk FNAO will be affected by the new requirements. As there are no PHAs in Wales that are recognised as official BIPs, DPEs or DPIs, we assume that the new import requirements for controls undertaken on high-risk food and feed will not affect any PHAs in Wales

112. Operational staff from FSA (in England and Wales) and DAERA (in Northern Ireland) will be affected by changes to the delivery of official controls in relation to meat hygiene, which are directly undertaken by FSA and DAERA operational staff respectively. In addition, selected FSA staff will be required to familiarise themselves with the proposed changes and acquire sufficient expertise to provide guidance and training to stakeholders.

113. Official Control Laboratories (OCLs) are designated by CAs for the purpose of analysing samples taken during official controls and for food and feed enforcement. They will see minor changes to the responsibilities placed upon them, requiring them to have closer contact with the laboratories and greater oversight of delegated laboratories.

Consumers

114. Consumers are not directly affected by the OCR, although a more integrated and simplified approach to controls across the EU should in theory lead to improved consumer protection and increase consumer confidence in food and feed produced within the EU and imported third countries. Harmonisation of official controls will provide reassurance to consumers on the functioning of control systems and increase their ability to make informed choices.

115. These indirect impacts on consumers have not been further assessed in the cost-benefit section which follows.

116. Tables on the following page show the numbers affected in the groups identified.

Total number of affected stakeholders

The table below summarises the number of affected Food Business Operators (FBOs), Enforcement Authorities and Enforcement Officers in Wales that we have identified. Where figures for Wales were not available, numbers have been estimated.

FBOs	
Approved Establishments[4]	133
Importers of high-risk food and feed[5]	19
Private OCLs	1
Competent / enforcement authority	
Local Authorities (LAs)[6]	22
Public Official Control Laboratories[7]	3
Competent / enforcement authority	
Local Authorities[8]	
EHOs	155
TSOs	56
Lead Analysts in Official Control Laboratories (public)[9]	3
FSA Field Operations managers[10]	2[11]

[4] A list of all approved establishments is available at: https://data.food.gov.uk/catalog/datasets/1e61736a-2a1a-4c6a-b8b1-e45912ebc8e3

[5] The total number of UK-based importers has been extracted from TRACES (https://ec.europa.eu/food/animals/traces_en). Welsh numbers were calculated using the proportion of importers recorded in the LAEMS annual report (https://signin.riams.org/connect/revision/msy26/Environmental-Health/LAEMS-Annual-report-2017-2018).

[6] Annual report on local authority food law enforcement 2017/18, https://signin.riams.org/connect/revision/msy26/Environmental-Health/LAEMS-Annual-report-2017-2018

[7] https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories

[8] LAEMS 2018/2019 data

[9] These numbers are based on the assumption that only one lead Analyst will need to familiarise themselves with the changes. They do not represent the number of Analysts employed in OCLs.

[10] Figures based on internal intelligence.

[11] The number of field ops managers in Wales has been estimated, assuming there is one area manager, one veterinary lead, one head of operational delivery and one Operations Manager who is in charge of (West of England and) Wales.

Costs

Industry

Familiarisation

117. Importers of high-risk FNAO and POAO (including Freight Handlers) will have to familiarise themselves with the new legislation as it affects the streamlining of new systems and formatting requirements. According to TRACES, there were 1869 unique UK-based importers of high-risk FNAO or POAO who submitted either a CED or CVED in 2018 (see Table 1). Based on the percentage of importers reported on LAEMS, we estimate that 19 of these are based in Wales. This can be regarded as the minimum number of UK businesses that need to familiarise themselves with the proposed legislation as they will be directly affected by changes to official entry documents. We assume that one manager from each importing business will spend one hour reading the legislation, and another hour disseminating to staff and key stakeholders. Following the SCM approach, we multiply the wage rate with the number of importing businesses to calculate the total familiarisation costs. This generates a total cost of familiarisation to importers of £800 (or £45.29 per importer)[12].

118. Selected FSA Approved Establishments will also have to familiarise themselves with the legislation. These FBOs are subject to official controls for verification purposes and may be impacted by the new requirements for OV attendance and campylobacter sampling. They may also be affected by the additional flexibilities that the OCR introduces. As of May 2019, there were 133applicable Approved Establishments operating in Wales which are expected to be affected by the new legislation (see Table 1). We assume that one manager from each establishment will dedicate one hour reading the guidance and another disseminating it to staff and key stakeholders. This implies a total one-off cost to affected Approved Establishments of £5,000 (or £30.51, on average, per establishment)[13].

119. At the aggregate level, we estimate the total familiarisation cost to the Welsh industry to be £6,000. This is equivalent to £36.12 per business.

120. As outlined above, this estimate assumes that the majority of food and feed industry stakeholders will not need to familiarise themselves with the requirements of the regulation for those areas where the FSA has policy responsibility.

Changes to the delivery of Official Controls

[12] Based on the median wage rate for *Managers and directors in transport and distribution* (Code 1161), ASHE (2018), table 14.6a.

[13] Based on the median wage rate for *Managers and proprietors in agriculture and horticulture* (Code 1211) and *Managers and proprietors in forestry, fishing and related services* (Code 1213), ASHE (2018), table 14.6a.

General performance of Official Controls

121. In terms of the secondary legislation, the current landscape and the general performance of official controls under the OCR remains substantially the same. Editorial changes will be made to the FSA Food and Feed Law Codes of Practice, and associated Practice Guidance, the Feed Law Enforcement Guidance document (Northern Ireland) and Manual for Official Controls, which will require familiarisation by local authorities, FSA and DAERA staff performing official controls and other official activities. This will be captured by a separate impact assessment at a later date.

Hygiene controls on products of animal origin (POAO) for human consumption

122. The legislation requires competent authorities to verify the correct implementation by operators of broiler slaughterhouses, of the *Campylobacter* process hygiene criterion (PHC). As of May 2019, there were 63 FSA approved slaughterhouses where the approved activity was broiler production, in England, Wales and Northern Ireland. Collection of sampling data would require FBOs to supply data in a form that permits it to be centrally collated by the FSA. As affected slaughterhouses have existing requirements to test for campylobacter, this additional burden on industry is anticipated to be marginal; the majority of costs will fall on the FSA, as the CCA. Work to look at the feasibility of collecting data as part of OV verification checks has been undertaken which indicate this can be incorporated into their existing duties using current data collection systems. Further work is required to implement this system and will be communicated to industry before it goes ahead. As the details of the system develop, a supporting piece of analysis will be completed which will estimate both the cost to industry and the FSA of the preferred verification option.

123. The introduction of maximum annual throughput thresholds at low capacity slaughterhouses and GMEs will potentially have an impact on the required presence of OVs conducting PMIs at these establishments. It is expected that some affected slaughterhouses and GHEs will exceed threshold levels that have been set, requiring establishments to replace OAs with OVs. However, the FSA would look to maximise the threshold applicable to these establishments, in line with the total Member State production provision outlined in Regulation 2019/624, as explained in paragraph 44. Where this is not possible then extra OV presence required at affected establishments would generate an additional cost to these businesses due to OVs rate of pay being higher than that of OAs. An OV's charge rate is approximately 30% higher than that of an OA/inspector, before any applicable discount.[14]

124. Assessing the total throughput levels of low capacity slaughterhouses and GHEs, as well as allocating individual establishments above or below

[14] Based on 2019/20 Charge Rates to Food Business Operators (https://www.food.gov.uk/sites/default/files/media/document/official-controls-charging-guidance-201920.pdf), Annex A

the maximum annual threshold constitutes a substantial piece of work. Internal engagement and discussions with the OCR Delivery Working Group are taking place to better understand if centrally held data can provide additional understanding in this area.

125. From the implementation of the OCR on 14 December 2019, echinoderms will no longer be permitted to be harvested from unclassified areas. As the number of potential FBOs harvesting echinoderms from unclassified areas is unknown and no new evidence could be collected during the consultation period, we are currently unable to assess the impact of the change being introduced. In addition, it is understood that the inclusion of 'Holothuroidea' was a drafting error and it is not yet known when this error will be corrected. It is understood that there may be minor changes and additional costs incurred in relation to toxin testing of shellfish as a result of the OCR regulations. The impact of these changes will be assessed in a separate impact assessment and consultation which is scheduled for 2020.

New import requirements

126. On balance, we anticipate a marginal overall increase in official controls for imported POAO or high-risk FNAO products. The legislation outlines harmonised controls, for the first time, for imports of reptile meat, insects and products derived from insects, raw materials for the production of gelatine and collagen, sprouts for human consumption and fats and greaves. Previously, enforcement of these commodities was at the discretion of MSs.

127. Increased import controls are associated with a corresponding rise in compliance costs for the importer. Potential costs include charges and time spent for approval processing, relevant certificates and Sanitary and Phytosanitary checks at the border as well as potential disruption to the supply chain if new import routes have to be established. Robust evidence on the scale of these costs is scarce and highly product specific.

128. In addition, the FSA understands that some of the affected products are already subject to border checks under the current operating regime which will mitigate the tangible impact of a formal harmonisation of controls. We are currently engaging with port officials to understand the practical changes to border procedures and the likelihood of trade disruption in more detail.

129. While we are unable to monetise the costs associated with the new import requirements at this stage, it should be noted that the number of affected consignments is likely to be very small. In particular, we understand that there are currently no imports of reptile meat for human consumption from third countries. Furthermore, the estimated import volume of sprouts for human consumption and rendered animal fats and greaves in 2018

accumulated at most 20,000 tonnes, which is equivalent to less than one percent of all UK food and drink imports from third countries in that year[15].

130. Under OCR 2017/625 IMSOC, as well as other criteria, will determine the level of sampling which has to take place for each high-risk commodity. The system seeks to create a unified platform for existing EU systems, including TRACES, rather than replacing the computational architecture. It is understood that initially, changes in frequencies will still be determined by an EU committee that will meet at regular intervals; we anticipate that IMSOC will influence decisions once enforced. The assumption, under our current understanding, is that IMSOC may automatically change frequencies as IMSOC is implemented further into EU processes. These rates will be based on levels of compliance meaning we could see a decrease or an increase in the number of samples required to be taken. As such, it is intrinsically difficult to quantify what the cost will be for business or understand the potential shift in magnitude at the macro level.

131. However, it is assumed that from the outset current rates and frequency of sampling will remain constant. The FSA supports these changes in principle. However, we realise that we will have to work with industry to ensure compliant trade is not disrupted.

Total costs to Food Business Operators

132. As preparations to implement the OCR are currently in their infancy, the FSA is unable to monetise any of the expected impacts on FBOs beyond one-off familiarisation costs. As such, the total monetised cost to industry is estimated to be £6,000 over a ten-year appraisal period.

Enforcement Authorities

133. The 'basic act' of the OCR, Regulation (EU) 2017/625, will make changes across a number of policy areas. However, for the most part these changes will create relatively few impacts for enforcement authorities. Where there are impacts, they will predominantly affect CAs and delegated delivery bodies that perform official controls across a range of areas.

134. In order to perform and deliver statutory obligations, we have identified the number of applicable enforcement authorities across England, Wales and Northern Ireland.

Familiarisation

135. Three of the stakeholders who have responded to our consultation have suggested that familiarisation costs for Local Authorities and Port Health

[15] Import volumes of affected products are based on HMRC UK Trade Info data. It should be noted that we are unable to quantify the import volume of insects and products derived from insects due to a lack of suitable trade statistics.

Authorities will be considerably larger than initially assumed. We have revised the assumptions for each of the affected EAs and updated our assumption where appropriate.

136. Local Authorities, as CAs, which deliver official regulatory controls across food and feed will have to familiarise themselves with the new requirements. This should enable a smooth transition between the two regimes. It should be noted that the familiarisation costs assessed in this IA only consider the time it takes LAs, OCLs and FSA staff to familiarise themselves with the general provisions laid out in the OCR and the Statutory Instruments. The time it will take LAs to understand the practicalities with implementing the changes will be covered in the Impact Assessment for the next Food and Feed Law Codes of Practice, and associated Practice Guidance review which the FSA will consult on in 2020.

137. We anticipate that for each of the 22 LAs, one manager will spend one hour reading the new SIs and two hours disseminating this information to affected staff (EHO, TSO etc.). In addition, we expect that it will take each member of staff 30 mins to read the disseminated information. We estimate a total one-off familiarisation cost to LAs of £4,000.

138. Port Health Authorities (PHAs), as CAs, deliver official regulatory controls with regards to imports of POAO and high-risk FNAO will have to familiarise themselves with the new requirements laid out in the OCR as they will have a direct impact on their operations.

139. There are no Port Health Authorities in Wales that are classed as Designated Points of Entry (DPEs) and Designated Points of Import (DPIs) for high-risk FNAO and Border Inspection Posts (BIPs) for POAO products.

140. Official Control Laboratories (OCLs) are designated by CAs for the purpose of analysing samples taken during official controls and for food and feed enforcement purposes. The analysis of official control samples is carried out in OCLs by official control scientists. As National Reference Laboratories (NRLs) are already familiar with the new changes only OCLs will be required to familiarise themselves.

141. Anticipating that one professional scientist at each laboratory will spend one hour reading the legislation and two hours disseminating it to staff during routine staff meetings we estimate a cost of need to each OCL of £75.27, or £200 in total.

142. All field operation managers involved in the delivery of official controls in relation to meat hygiene will have to familiarise themselves with the new requirements. As the substance of many of the new provisions do not change the performance of official controls; instead providing nuanced revisions in how they are delivered, it is understood that only field operational managers will have to read the guidance and disseminate it as they see fit. Headcount data identifies 28 field operational managers operating across England and Wales (Wales containing 2). Assuming, as a

central estimate, that each field manager is a Grade 7 employee and that each manager will spend one hour reading the guidance and two hours disseminating to staff, this generates a cost estimate of £126.320 per manager, or £500 in total for Wales.

143. We estimate a total one-off familiarisation cost to Welsh Enforcement Authorities of £5,000.

Training

144. We assume that some Enforcement Officers will require training to effectively enforce the new legislation and to provide guidance to stakeholders. While we understand that PHAs will require most training, consultation respondents have raised the concern that the training costs have been underestimated in the consultation IA. In particular, they have raised the concern that Local Authorities will also require training in IMSOC as they will be asked to provide guidance to importers. They have also suggested that the costs incurred by port health officers would be higher than initially expected. We have revised the following assessment accordingly.

145. 1 officer from each LA, and 6 FSA employees will receive IMSOC training of some sort. Assuming that the training (incl. time to familiarise themselves with the system) will take two working days, IMSOC training would incur a one-off cost, in productive time lost, to Enforcement Authorities in Wales of £1,000[16].

146. Following consultation responses, we also understand that some Local Authorities will need to be trained in TRACES NT as they will need to provide guidance to importing businesses with regards to import certificates, onwards transportation, etc. We assume that this would only be required for Local Authorities with an external temporary storage facility (ETSF) that is currently used for storage of high-risk food and feed not of animal origin. We estimate that there are currently at most 20 different Local Authorities with an ETSF that is used as part of an onward transportation facility (under Article 9 of Regulation (EC) 669/2009) in the UK.[17] We assume that at most 1 of these LAs (or 6% of affected LAs) is situated in Wales. Assuming that one EHO and one TSO at this LA will also need to attend the TRACES NT training and that one EHO and one TSO from all other inland LAs will spend one hour reading new guidelines to develop an understanding of the system in case they need to inform local businesses of the changes that will take

[16] These estimates only include 10% of costs incurred on the FSA, as 10% of EHOs across England, Wales and Northern Ireland are located in Welsh LAs, as per LAEMS 2018/19 returns.

[17] A full list of ETSF facilities as at July 2018 can be found on the FSA's website: https://www.food.gov.uk/sites/default/files/media/document/external-temporary-storage-facility-list-july-2018.xlsx_2.pdf. While we are not aware of the exact number of EFTS in use, we assume that the number does not exceed 20. Assuming that in a worst case, each of these EFTS falls in a different Local Authorities, we estimate that there are at most 20 affected LAs in which EHOs need specific TRACES NT training.

place, we estimate a one-off cost to Welsh inland LAs of £2,000 to receive TRACES-NT training.

147. As the CCA, the FSA will be required to hold expert in-house knowledge of the IMSOC system, both in terms of its content and interface but also in its practical applications. It is believed that one FTE employee will familiarise themselves with the IMSOC system until such point they can be deemed an 'expert'. This is in order to provide support in its wider implementation and also in an advisory capacity to affected policy teams. Assuming a SEO grade employee will become the in-house expert and adopting a central estimate of 24 hours (3 full working days) to become fully versed with the IMSOC system, this one-off cost in productive time lost is estimated to be £800o the FSA. As only a small proportion of this training will be delivered to Welsh Enforcement Officers, we have apportioned the costs accordingly. As 10% of all EHOs in England, Wales and Northern Ireland are based in Welsh LAs, we apportion 10% of the total FSA costs to FSA Wales. This is equivalent to a one-off cost of £80 for Wales.

148. Official Control Laboratories (OCLs) might need additional training for sampling and any analytical methods that might be required to carry out enforcement under the OCL, provided these methods change. OCLs will incur costs for the time it takes to complete the training as well as costs to develop and validate methods in house and participation in proficiency testing, i.e. verification of the training received. As it is uncertain whether the required methods will change and whether additional training would be required, we have not quantified this cost.

149. Overall, we estimate a total one-off training cost of £3,000 for Welsh Enforcement Authorities (including a proportion of costs incurred on the FSA).

150. It should be noted that the above estimates are based on assumptions around potential training requirements and delivery. These assumptions reflect our current understanding and could be subject to change.

Changes to the delivery of Official Controls

General performance of Official Controls

151. The secondary legislation necessary to provide for the execution of powers and enforcement for the OCR makes no significant changes which would impact on the frequency or number of inland official food and feed controls undertaken by enforcement authorities. Rather it seeks to clarify and enhance current provisions for example by introducing more stringent rules on fraud and provide greater transparency and accountability required by CAs through the publication of information about the organisation and performance of official controls. Such requirements are already being met in the UK.

Campylobacter sampling in broiler slaughterhouses

152. The legislation requires CAs to verify that broiler slaughterhouses have correctly implemented the *Campylobacter* PHC. As explained above, no policy decision has yet been taken as to how the FSA will undertake the verification. If the FSA decides to collect and analyse industry data, this will likely have cost implications to the FSA, as the CCA. Additional administrative resource would be required to create and maintain a framework that centrally gathers and analyses data. This would enable the FSA to monitor compliance at the individual FBO level and on a UK-wide scale. Once the FSA clarifies its preferred policy position, a supporting piece of analysis will be completed which will estimate both the cost to industry and the FSA of the preferred verification option.

New imports requirements

153. New products covered by the legislation, such as insects and reptile meat, will in future be required to be derived from approved third countries. Raw materials for the production of gelatine and collagen, sprouts for human consumption and fats and grieves will have to be derived from approved establishments in third countries. Under harmonising legislation across these commodities, new controls could result in additional administrative requirements; increasing the burden of work on PHAs. For example, consignments of reptile meat products will be required to arrive with model health certificates, for PHAs to assess and sanction. As trade in these commodities is expected to remain low, any increase in administrative burden for enforcement authorities is expected to be relatively muted; and might further be offset by general simplifications of administrative procedures.

154. *During the consultation period, concerns have been raised that under the preferred option,* Environmental Health Practitioners (EHPs) and Authorised Officers (AO's) might no longer be authorised to undertake UK checks on imported fish, fish products and shellfish.

155. While Articles 49 and 55 of the OCR do not specifically refer to EHPs or AO's they continue to allow suitably trained staff such as EHP and AO the opportunity to continue delivering Official controls for imported fish, fish products and shellfish and the capacity to make the final decision concerning the safe importation of these products.

156. The FSA acknowledges that the current system of OVs and other professionals involved in the delivery of official controls for imported products of animal origin and food not of animal origin works very well for the UK, there is no expectation that future arrangements will change.

Official Veterinarian resource requirements

157. Additional OV resource may be required at low capacity slaughterhouses and GMEs for PMI. Additional costs of OV presence will fall on the affected individual establishment, although there may be some associated

administrative costs to the CCA. Any such additional cost is expected to be marginal as resource activity costs (in this case switching OAs for OVs) would be included in the direct cost element of the hourly rates charged to industry.

Funding of analyses carried out by OCLs

158. It is known that there are UK OCLs that currently sub-contract samples for analysis to partner laboratories in other member states (where the partner laboratory is not officially designated as an OCL in that MS) and these may also receive, and subsequently sub-contract samples from other UK OCLs. Such sub-contracting of samples to other MS would not be permissible under the changes to the OCR which could have a financial impact on OCLs.

159. We are currently unable to quantify this impact as it would have to be calculated on a case-by-case basis where it is known exactly what tests and how many samples are being sub-contracted. The impact of such increased costs of sub-contracting the analysis of samples will be dependent on finding suitable alternative sources for analysis, either by an alternative UK laboratory or another MS OCL. Depending on options, this could have an associated cost for LAs, as the primary funders of OCLs.

160. Importantly, alternative arrangements are being explored for the affected laboratories such that any new situation may not have any incremental impact. As these arrangements are still uncertain, we are unable to assess this impact in further detail. The FSA is conducting work on the future laboratory model and UK OCLs will be consulted in the process and likely impacts.

Total costs to Enforcement Authorities

161. We are only able to monetise the one-off familiarisation costs (including familiarisation and associated training requirements) to enforcement bodies with regards to the new SIs and provisions included within OCR 2017/625. The total identified transitional costs are £7,000.

162. It should be noted that, where there is an overlap between affected Enforcement Authorities between Welsh Government and FSA, transitional costs (of up to £7,000) might be double counted.

Total costs

163. The total costs associated with Policy Option 1 over a 10-year appraisal period are £13,000 with a Net Present Value (NPV) of £13,000. Industry will assume 44% of total costs imposed as a result of this policy, with enforcement agencies assuming the remaining 56%. Benefits were not monetised, therefore the total net cost over the 10-year appraisal period is £13,000

BENEFITS
Food and Feed Business Operators

Simplified legislative framework

164. Overall, industry should benefit from a harmonised and coherent regulatory approach to official controls and enforcement actions along the agri-food chain, and from a better targeting of risks.

165. In particular import controls would be streamlined and adjusted to actual risk levels in the long-term. It is expected that the harmonisation of entry documents and the establishment of a comprehensive management system, IMSOC, will reduce the administrative burden for importers of high-risk food and feed. As CAs and business operators have not yet had the opportunity to test early versions of IMSOC, it is difficult at this time to estimate the extent of these changes. IMSOC aims to provide numerous benefits. The harmonisation of documents will create a familiar and consistent format, making it easier and more accessible for importers and stakeholders to use. IMSOC will allow competent authorities access to various relevant data/intelligence by interlinking a variety of current systems used for imported products. The intended long-term risk-based adjustments to levels of controls aims to make more efficient use of resource, with the aim of shifting resource as levels of risk change. These adjustments aim to allow changes of frequencies to occur quicker as data and information is analysed on an ongoing basis.

166. Closer cooperation among CAs would improve the overall effectiveness of delivery of official controls, reducing duplication, increasing consistency and ensuring non-compliance is dealt with in a timely manner.

Additional changes (POAO official controls)

167. The impact of changing some existing requirements on official controls of POAO should enable certain FBOs to generate cost savings across their operations. As the changes will depend on the take up by FBOs, as well as a high level of uncertainty surrounding the future delivery process, it is not possible to estimate the potential cost savings at present. The ability for an FBO to apply these changes depends on a confirmatory risk assessment by the CA which could limit application at some establishments.

Compliance with EU Regulations

168. By making the Regulations, which allow for the implementation and enforcement of directly applicable EU Regulations, the Welsh Government removes the risk of infraction proceedings from the EU. These proceedings can result in significant fines to a Member State

Enforcement Authorities

Reduced administrative burden

169. We do not expect any substantial benefits for enforcement authorities. While they could benefit, overall, from a simplification and consolidation of the legislative framework, we are unable to substantiate this due to a high level of uncertainty surrounding the future delivery process.

TOTAL NET COST

170. As no monetised benefits are identified the total net cost over the 10-year appraisal period is £13,000

9. Competition Assessment

171. As these Regulations apply to all food businesses operating in the UK (and wider EU), it is not considered that a competition assessment is required.

10. Post implementation review

172. The FSA will be undertaking a further consultation on changes to the Food and Feed Law Codes of Practice and Practice Guidance in 2020. This will give a further opportunity to test the assumptions made in the Impact Assessment and amend them if necessary.