Title: The Official Control Regulations (OCR)
IA No: Food 0162

RPC Reference No:

Lead department or agency: The Food Standards Agency

Other departments or agencies:

Impact Assessment (IA)

Date: 11/11/19

Stage: Final

Source of intervention: Domestic

Type of measure: Secondary legislation

Contact for enquiries: Liz Stretton

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option (in 2016 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status Non qualifying provision**
-£0.3m	-0.1m	£0.0m	

What is the problem under consideration? Why is government intervention necessary?

Regulation (EU) 2017/625 or the Official Control Regulations (OCR) addresses official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. The OCR entered into force on 27 April 2017 and will apply in all European Union Member States from 14 December 2019. At this point the OCR will repeal and replace Regulation (EC) 882/2004 and Regulation (EC) 854/2004 on official controls and other legislation, which currently governs the control and enforcement of rules along the agri-food chain.

What are the policy objectives and the intended effects?

To provide the execution of powers and enforcement of the OCR and associated tertiary legislation. Implementation of national legislation will maintain the legal basis for official control activity in relation food and feed law and animal health and welfare. In doing so consumer protection will be maintained along with confidence in the UK agri-food chain.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Implement national legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation. This is the preferred option.

Option 2: Do Nothing – Do not implement national legislation to provide for the execution of powers and enforcement of the OCR. This option does not fulfil UK or FSA statutory objectives and would undermine consumer protection. The option is therefore rejected.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?		No		
Is this measure likely to impact on trade and investment?		No		
Are any of these organisations in scope?	Micro **Yes**	Small **Yes**	Mediu m**Yes**	Large **Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		Traded:	Non-traded:	

8. I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ---------- Date: ----------

Summary: Analysis & Evidence

Policy Option 1

Description: Implement national legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -0.3

COSTS (£m)	Total Transition (Constant Price)	Average Annual (excl. Transition) (Constant price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£0.3	£0.0	£0.3

Description and scale of key monetised costs by 'main affected groups'

We estimate a one-off familiarisation cost to industry of £140,000 (in current prices).
We estimate a one-off cost to Enforcement Authorities of £60,000 for familiarisation, of £180,000 for training and of £10,000 for required updates to templates (in current prices). This translates to a total transitional cost of £0.4m (in 2019 prices) £0.3m in 2016 prices (with a 2017 Base Year).

Other key non-monetised costs by 'main affected groups'

New import requirements could be associated with compliance costs for importers of some products of high-risk food and feed. Selected approved establishments are expected to see some new requirements to verify their compliance with regards to hygiene controls. Enforcement Authorities, including PHAs, OCLs and the FSA, could see minor changes in their responsibility to deliver official controls, e.g. requirements for additional import checks and new data collection tasks.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	n/a	n/a	n/a

Description and scale of key monetised benefits by 'main affected groups'

No benefits have been monetised.

Other key non-monetised benefits by 'main affected groups'

Industry should benefit from a harmonised and coherent regulatory approach to official controls and from a better targeting of risks. Importers of high-risk food and feed should also benefit from the harmonisation of entry documents which will reduce their administrative burden. We assume that Enforcement Authorities will benefit overall from a simplification and consolidation of the legislative framework.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There remains a high level of uncertainty around the implementation of the regulation in certain areas for which
we were unable to monetise the impacts, in particular where tertiary legislation is affected.

The Impact Assessment is based on the assumption that the United Kingdom will be in an Implementation Period in December 2019 and that trade between the UK and the EU remains unchanged compared to the status quo if the OCR was implemented.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: £0.01	**Benefits:** n/a	**Net:** £0.01	£0.1

Summary: Analysis & Evidence

Policy Option 2

Description: Do Nothing – Do not implement national legislation to provide for the execution of powers and enforcement of the OCR

FULL ECONOMIC ASSESSMENT

Price Base Year n/a	**PV Base Year** n/a	**Time Period Years** n/a	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** n/a

COSTS (£m)	**Total Transition** (Constant Price) Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	n/a	n/a	**n/a**

Description and scale of key monetised costs by 'main affected groups'

n/a

Other key non-monetised costs by 'main affected groups'

n/a

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	n/a	n/a	n/a

Description and scale of key monetised benefits by 'main affected groups'

n/a

Other key non-monetised benefits by 'main affected groups'

n/a

Key assumptions/sensitivities/risks Discount rate (%) n

The associated impacts of this option have not been assessed because of the disproportionate negative effects on public health and legal consequences that would be associated with this option.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: **n/a**	Benefits: **n/a**	Net: **n/a**	n/a

Evidence Base (for summary sheets)

Problem under consideration

1. 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.
2. 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.
3. 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.
4. 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 products of animal origin.
5. The OCR is directly applicable in UK law in case of either an Article 50 extension or an Implementation Period. This means, in either of these scenarios, the Regulations that provide the UK basis for feed and food law official controls will no longer apply from 14 December 2019. New secondary legislation in England, Wales and Northern Ireland, is therefore required to repeal and replace current secondary legislation, to provide for the execution of powers and enforcement for the OCR and associated tertiary legislation that is currently being negotiated by Member States and the European Commission.
6. This Impact Assessment assesses the changes that will be brought about from 14 December by the proposed domestic secondary legislation in England, Wales and Northern Ireland that repeals, replaces and amends existing domestic secondary legislation and provides for the execution of powers and enforcement for the OCR and associated tertiary legislation. It also assesses the changes and expected impacts that the tertiary legislation will necessitate in the UK context[1].
7. Impacts are identified and assessed for England, Wales and Northern Ireland. Food Standards Scotland (FSS) are responsible for implementing these changes in Scotland and for assessing the impacts on Scotland.
8. It should be noted that the Impact Assessment covers all impacts and geographical areas for which FSA has full or partial policy responsibility. This ensures that FSA stakeholders receive a comprehensive overview of all impacts they might experience. Due to the broad scope of the OCR and the shared policy responsibilities between FSA and other government departments, especially DEFRA, some of these impacts might also be assessed by other departments.

Rationale for intervention

9. Failing to provide for the execution of powers and enforcement in England, Wales and Northern Ireland, for the OCR, in the event the UK remains subject to directly applicable EU Regulations on 14 December 2019 (i.e. an implementation period or extension to Article 50) would present significant gaps to the legislative framework for the delivery of official controls.

[1] An Impact Assessment was produced to address the initial Commission proposal in 2013. Since then there have been significant changes to the legislation following European negotiations which necessitates a change in scope of the Impact Assessment. The 2013 IA can be accessed via https://www.reading.ac.uk/foodlaw/pdf/uk-13026-enforcement-consultation.pdf.

10. 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.

11. 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.

12. 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[2]. 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.

13. Official controls also help maintain a level playing field for honest and diligent food and feed business operators, which is in the interest of industry as a whole. In particular, adherence to the principles contained within (or requirements of) the OCR will help the UK to demonstrate that food and feed produced and processed within the UK have been produced and handled in accordance with EU requirements. Consequently this will help to ensure continued confidence in the UK agri-food sector which contributed £121.7 billion (6.7%) to national Gross Value Added in 2017 and employs around 4.1 million people (14% of GB employment).[3] In terms of sales, the manufacture of food products remains the largest division within the whole UK manufacturing sector, contributing £71.8 billion (18.4%) of total UK manufacture in 2018[4], providing inputs for a multiple of secondary industries, including importing, exporting, processing, storage, distribution and retail. There is hence also a strong economic rationale for implementing the OCR and maintaining and strengthening confidence in food and feed produced in the UK.

Policy objective

14. 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 national powers are in place to effectively enforce food and feed law and maintain the high level of consumer protection currently in place. The national 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.

15. Through the implementation of national legislation in England, Wales and Northern Ireland 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 national legislation 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

[2] 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.

[3] Defra (2019): Food Statistics in your pocket: Summary (National Statistics, updated 8 April 2019): https://www.gov.uk/government/statistics/food-statistics-pocketbook.

[4] https://www.ons.gov.uk/businessindustryandtrade/manufacturingandproductionindustry/bulletins/ukmanufacturerssalesbyproductprodcom/2018provisionalresults#manufacturing-of-food-products-contributes-to-growth-in-2018.

system including the legal basis for the execution of necessary powers and enforcement of official controls and other official activities.

16. 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.

17. 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); and
    - Businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls.

Consultation Outcome

18. The FSA held a six-week consultation (separate consultations were published in England, Wales and Northern Ireland) and held stakeholder workshops to help fill the evidence and knowledge gaps which were identified in the early impact assessment (a combined Impact Assessment was produced to identify the impacts in England, Wales and Northern Ireland). While several evidence gaps remain, the IA has been revised in line with the consultation responses where possible. The full extent to which previous information issues were or were not addressed during the consultation period shall be discussed thoroughly in the appraisal sections below.

19. During the consultation period, we received 24 responses from individuals, 11 responses from businesses and trade associations and groups, 2 from a consumer group 4 from scientific services organisations and 10 from local authorities. While the responses were mixed the majority of respondents acknowledged the need for government intervention.

20. Amongst those that support the preferred option in general, concerns were raised about the timing of implementation and the amount of consultation. Although generally in support of the regulations, stakeholders also raised concerns over insufficient consultation on the charges element, the potential flexibilities for OVs and that not all of the potential impacts had been identified. The FSA acknowledges these concerns, however, more meaningful consultation was constrained due to a number of factors, including ongoing EU negotiations on the tertiary legislation and uncertainty in relation to implications for EU Exit.

21. The majority of responses (21) related to concerns about the role of Port Health Officers and Environmental Health Practitioners enforcing controls on these food imports as the legislation does not specifically list this role. We have provided greater clarity on these issues through stakeholder engagement and in the revised Impact Assessment.

22. In general, there was support for the proposals to review the criminal sanctions, although it is noted

that there should be further consultation and more consistency. One response made a number of suggestions of how sanctions could be used. It was highlighted that a review or potential removal of criminal sanctions could have a negative impact on consumers.

23. There were also comments that the familiarisation costs had been underestimated and that we had not correctly identified all of the affected stakeholders. We have addressed these concerns in the revised IA and have provided further explanation where we were unable to take any further action of the issues raised in consultation responses. Concerns were raised about the charging elements of the OCR and how they were likely to be implemented. While the FSA will discuss charging with the trade associations shortly, we do not yet have sufficient clarity on the implications to include more details in the Impact Assessment. There were also comments on the flexibilities which the OCR may allow which will be considered further when the all of the tertiary legislation has been published.

24. As well as the digital submissions, a series of stakeholder engagement workshops were held for port health authorities and local authorities across England, and Northern Ireland to get a better understanding of stakeholders' views. Over 25 people attended these workshops and contributed to our evidence base. Information gathered both through the workshops and the digital submissions has been used to develop the analysis of the preferred policy option.

Background

Delivery of Official Controls

25. The FSA is the Central Competent Authority (CCA) responsible for the delivery of official food and feed controls in England, Northern Ireland and Wales. In England and 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. In Northern Ireland the Department of Agriculture, Environment and Rural Affairs (DAERA) carry out hygiene controls on behalf of the FSA in Northern Ireland in these premises. The FSA is also responsible for the classification of shellfish production areas in England, Wales and Northern Ireland.

26. There are 387 Local authorities (LAs) in England, Northern Ireland and Wales delivering official food controls.[5] Of these, 149[6] LAs in England and 22 LAs in Wales have also been designated to deliver official feed controls for matters which are not within the remit of the Veterinary Medicines Directorate (VMD) or the Animal Plant and Health Agency (APHA). In Northern Ireland, the Department of Agriculture, Environment and Rural Affairs (DAERA) is responsible for delivery of all animal feed controls including veterinary medicines and regulating the use of specified materials in animal feed, including the ban on feeding animal proteins to ruminants and processed animal proteins to farmed animals.

27. In England, Wales and Northern Ireland 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. For feed controls, in England and Wales the Feed Law Code of Practice and associated Practice Guidance and in Northern Ireland the Feed Law Enforcement Guidance document, issued to DAERA. 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 England and Wales. In Northern Ireland, DAERA maintain and publish a parallel MOC which broadly reflects the content of the FSA MOC.

Impact of the OCR

28. The OCR is part of a wider initiative to simplify EU legislation to establish a more integrated approach to official controls in all areas across the agri-food chain to ensure consistency across the legislation. The new OCR expands the scope of the official controls legislation to include official controls on animal health (including aquaculture), plant health, Plant Reproductive Material (PRM) and plant protection products in addition to food and feed and animal welfare. This includes the 'Animal Health Law' (Regulation (EU) 2016/429) and the 'Plant Health Law' (Regulation (EU) 2016/2031).

29. The OCR also empowers the creation of tertiary legislation ('implementing acts' and 'delegated acts') which allow the European Commission to create further detailed rules in specific areas. The majority of this tertiary legislation so far, which has been under development since 2017, has addressed import controls and conditions. New rules have also been published regarding hygiene inspection for products of animal origin. This tertiary legislation will also apply from 14 December 2019.

30. Though the OCR entered into force on 27 April 2017, the applicability of the new rules was set to apply gradually over several years; with the main application taking effect 14 December 2019. In the event the UK remains subject to directly applicable EU Regulations on 14 December 2019 (i.e. an implementation period or extension to Article 50) the new rules will fully apply and the current legislative framework for food and feed law official control will be repealed.

31. This impact assessment assumes that the domestic legislation will be implemented fully in December 2019. It focuses solely on the changes in relation to the aspects of the OCR that apply from 14 December 2019, and only in relation to the FSA areas of responsibility for food and feed law

[5] Annual report on local authority food law enforcement 2017/18, http://www.reading.ac.uk/foodlaw/pdf/2018-FSA-LAEMS-2017-18.pdf

[6] This figure refers to the number of local authorities as at 1st April 2019. Source: FSA Animal Feed Enforcement Return 2019/20.

and animal health and welfare. In this space the new OCR introduces reforms in certain areas but does not deviate significantly from the existing legal architecture and general approach to official controls. Separate legislation is being prepared by Defra for their areas of responsibility and the impacts assessed accordingly.

32. In the event the UK leaves without a deal the FSA will update stakeholders further in relation to the proposed implementation of the OCR. We will also consult further on any proposals to align national legislation with the OCR, including an updated assessment of the impacts.

General Changes to the Delivery of Official Controls

33. 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.

34. 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

35. 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

36. 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.

37. 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 identify 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.

38. 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 has 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.

39. 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

40. 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.

41. Our assessment is that the current practice in England, Wales and Northern Ireland already meets these requirements. We therefore do not expect any incremental impact from this change.

Sampling

42. 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.

43. 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

44. 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 (EC) 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

45. 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.

46. 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)

47. 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.

48. It is also the FSA's understanding that all designated UK OCLs will retain their designation status on EU Exit. Minor changes to the responsibilities of OCLs will be applicable from December 2019 and will mean that competent authorities are required to have closer contact with the laboratories and greater oversight of delegated laboratories. The OCR also introduces a requirement for OCLs to make publicly available the names of the methods used for analyses, tests or diagnoses performed in the context of official activities on the request of the Competent Authority. The main issue in this area is a legislative change which means that the CA can only designate 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 is currently being assessed.

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 in due course.

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 national 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:

60. 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.

61. 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.

62. 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.

63. 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 (EU) 2019/627 or else cease harvesting.

64. 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.

65. 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

66. 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 England, Wales and Northern Ireland is shared between ministerial departments (such as Defra) 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.

67. Legislative responsibility for the policies which underpin the import controls regime is also shared between the FSA and Defra. 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.

68. 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.

69. 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

70. 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.

71. 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.

72. 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.

73. 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.

74. 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.

75. 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.

76. 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 in to 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

77. 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.

78. 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.

79. Regulation (EU) 2019/625 reforms 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.

80. Reptile meat is currently imported in the United Kingdom from third countries under national rules. 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.

81. 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 Annex III Part XIII of Regulation (EU) 2019/628. 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.

82. 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.

83. 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 of 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.

84. 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 III Part XV 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.

85. 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.

86. 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.

87. 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.

88. 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: IMSOC

89. 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.

90. 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.

GROUPS AFFECTED

The following groups will be affected by the proposed changes.

Food and Feed Business Operators

91. 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.

92. 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

93. 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.

94. 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.

95. We have identified the following number of affected food and feed business operators (FBOs) across England, Wales and Northern Ireland. To note, total figures may be subject to rounding.

Table 1: Affected food and feed business operators (FBOs)

FBO	England	Wales	NI	Total
Approved Establishments[7]	1,612	133	77	**1,822**
Importers of high-risk food and feed[8]	1,794	19	56	**1,869**
Private OCLs[9]	1	1	1	**3**

96. 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

97. 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.

98. Local Authorities, as CAs, which deliver official regulatory controls across food and feed will have to familiarise themselves with the new requirements. Similarly, LAs and Port Health Authorities (PHAs), 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. LAs and PHAs have a variety of authorised officers to carry out official controls and other functions as required by their service. These include

For PHAs:

- Port Health Officers (PHOs) and Official Fish Inspectors (OFIs) (who are all qualified

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

[8] The number of importers has been extracted from TRACES (https://ec.europa.eu/food/animals/traces_en). Regional splits 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).

[9] https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories, split between private and public OCLs has been informed by FSA policy leads.

Environmental Health Officers (EHOs) / Environmental Health Practitioners (EHPs))

- Trading Standards Officers
- Official Veterinarians (OVs);

For LAs:

- Environmental Health Officers (EHOs);
- Trading Standard Officers (TSOs)

99. In addition to the above authorised officers, some Enforcement Authorities employ administrative and technical staff.

100. 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.

101. 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. Only publicly funded OCLs have been identified as Public Enforcement Authorities, privately funded OCLs have been identified as an industry stakeholder.

102. We have identified the following number of affected enforcement authorities and staff across England, Wales and Northern Ireland.

Table 2: Number of affected enforcement authorities by country

Competent / enforcement authority	England	Wales	NI	Total
Local Authorities (LAs)[10]	354	22	11	**387**
Port Health Authorities (PHAs)[11]	17	0	1	**18**
Official Control Laboratories[12]	12	3	3	**18**

Table 3: Number of affected enforcement staff by country, in FTE

Competent / enforcement authority	England	Wales	NI	Total
Local Authorities[13]				
EHOs	1376	155	62	**1592**
TSOs	308	56	33	**396**
Port Health Officers[14]				

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

[11] This analysis only concerns PHAs that are classed as either DPE/DPI/BIP (https://www.food.gov.uk/business-guidance/port-designations *and* https://www.gov.uk/government/publications/uk-border-inspection-posts-contact-details/live-animals-and-animal-products-border-inspection-posts-bip-in-the-uk). The number of PHAs has changed compared to the consultation IA because we had previously identified each BIP/DPE as an affected stakeholder whereas we are now identifying each PHA as an affected stakeholder to avoid double-counting of staff numbers.

[12] https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories, split between private and public OCLs has been informed by FSA policy leads.

[13] LAEMS 2018/2019 data

[14] PHO numbers are as reported by FSA areas managers in November 2019. Figures for NI have been estimated.

PHOs (incl. EHOs and OFIs)	97	0	4	**101**
TSOs	53	0	0	**53**
OVs	12	0	0	**12**
Lead Analysts in Official Control Laboratories (public)[15]	12	3	3	**18**
FSA Field Operations managers[16]	28		N/a	**28**
DAERA Operations managers[17]	N/a		5	**5**

Consumers

103. 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.

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

[15] 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.

[16] Figures based on internal intelligence.

[17] Five regional managers in DAERA (four meat and one dairy) require IMSOC, based on internal intelligence.

POLICY OPTIONS

Two policy options have been identified:

Baseline: Status Quo

105. 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.

106. 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 national legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation.

107. 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.

108. This is the preferred option.

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

109. Regulation (EU) 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.

110. 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.

111. The associated impacts of this option have not been further assessed because of the disproportionate negative effects on public health and legal consequences that would be associated with this option.

OPTION APPRAISAL

112. The following option appraisal has been revised to reflect stakeholder consultation responses. A number of responses argued that the scale of familiarisation and training costs identified for Enforcement Authorities had been underestimated.

113. During the consultation period, targeted stakeholder engagement was carried out to improve our understanding of the likely impacts and the evidence-base on which we have assessed these impacts. This engagement covered workshops as well as ongoing conversations with Port Health Authorities, port visits, discussions with OGDs and LAs as well as other key stakeholders via e-mail and in working groups.

114. The following table summarises the main concerns that were raised during the consultation period with regards to the assessed impacts and captures all changes we have made to the appraisal following the consultation responses:

Table 4: Summary of consultation responses and changes			
Feedback	**Number of responses addressing this issue**	**Initial assumption**	**Updated assumption**
Familiarisation costs for Local Authorities have been underestimated	4	We assumed that it would take one manager 1 hour to read the new legislation and 2 hours to disseminate to other members of staff.	We assume that it would take one manager 1 hour to read the new legislation and 2 hours to disseminate to other members of staff and that all other staff members would have to spend 30mins to receive relevant information from managers.[18]
Familiarisation costs for Port Health Authorities have been underestimated	2	We assumed that it would take 1 EHO per PHA 1 hour to read the new legislation and 2 hours to disseminate to other members of staff.	We assume that it would take 1 manager per PHA 1 hour to read the new legislation and 2 hours to disseminate to other members of staff and that all other staff members would have to spend 30mins to receive relevant information from managers.
Import training costs for PHOs and inland LA officers have been underestimated	2	We assumed that 4 officers from each PHA would receive general OCR and IMSOC training.	We assume that 6 officers from each PHA would receive IMSOC training. We do no longer assume that PHOs would receive formal training on the general provisions of the OCR as they are expected to familiarise themselves with the changes through reading the relevant regulation and SIs.
Inland Local Authorities need to familiarise themselves with the Integrated Management System	1	We assumed that only PHOs and FSA staff would need training for IMSOC.	We assume that PHOs, FSA and 1 EHO per LA and inland LAs receive IMSOC training and/or guidance.

[18] It should be noted that the familiarisation costs assessed in this IA only take into account 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 required to understand the practicalities of implementing the changes will be assessed in the next FLCoP and MANCP updates and via other appropriate communication channels once the details of the changes have been bottomed out.

for Official Controls (IMSOC) system as local authorities are asked for preliminary advice in this area by importers and exporters registered in their districts.			
The administrative burden on PHAs has been underestimated	1	We have assumed that 1 EHO per PHA will have to deal with an additional number of queries over a period of 1 month. We did not take into account any additional workload for PHAs.	We assume that 1 EHO per PHA will have to deal with an additional number of queries over a period of 1 month. We assume that it would take 1 manager per PHA 1-2 days to work out required changes and 1 technical member of staff per PHA approx. 1 day of work to update templates, websites, guidance, etc. We also take into account the costs this would impose on the FSA.
Concern that OFIs might no longer be authorised to conduct controls on fish products when they are not a qualified OV.	1	We have assumed that all OFIs will fully meet the requirements without any further training needs.	While we understand that most OFIs will meet the requirements, we have taken into account the possibility that between 10% and 100% of all OFIs might need to be upskilled to perform controls on fishery products. We have also taken into account the additional costs for the FSA to produce and deliver this training.

Baseline: Status Quo

COSTS & BENEFITS

115. This is the baseline against which all other options have been assessed. There are no incremental costs and benefits associated with this option.

Option 1: Implement Regulation (EU) 2017/625 - OCR

COSTS & BENEFITS

116. 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 and to disseminate relevant information to staff and other stakeholders.[19] This ensures a smooth transition between the two regimes. Figures are presented in current prices;

Training costs: one-off / transitional costs for all affected stakeholders to attend or complete training associated with the new requirements of the OCR;

Increased admin burden for Port Health Authorities: one-off / transitional cost for Port Health Officers to update relevant templates, websites, guidance;

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 why the required data is not available and how we seek to substantiate the assessment and our understanding going forward.

117. 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.

118. 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)[20], 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[21] guidance.

COSTS

Food and Feed Business Operators

119. As outlined above, the substance of OCR largely repeals and replaces much of the existing legislation governing official controls of food and feed. Most businesses will not experience any material changes in the way official controls take place and/or are currently delivered. We understand that the main affected sectors will be:

120. Importers (including freight handlers) of high-risk food not of animal origin (FNAO) and products of animal origin (POAO) for human consumption;

121. Analysts in privately funded OCLs; and

122. Selected FSA Approved Establishments which are subject to official hygiene controls performed for the verification of compliance. We understand that only the following approved establishments will be affected:

    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, shell fish and fishery products
    g. Milk and Colostrum Production Holdings

[19] It should be noted that this IA only accounts for familiarisation costs with those pieces of legislation which have already been published as at November 2019. For most stakeholders, this only requires familiarisation with the SIs and the general provisions of the OCR. Where the practicalities of the delivery of Official Controls and other official activities might change but this is not yet known, the FSA will assess these impacts, including additional familiarisation costs, in separate assessments.

[20] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/ashe1997to2015selectedestimates

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

Familiarisation

123. 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). 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 regulation, and another hour disseminating to staff and key stakeholders during routine staff updates. 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 85,000 which is equivalent to £45.29 per importer[22].

124. 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 1822 applicable Approved Establishments operating across England, Wales and Northern Ireland 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 £56,000 or £30.62, on average, per establishment.[23]

125. 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 by official control scientists in OCLs, some of which are privately funded. Anticipating that one professional scientist at each private laboratory will spend one hour reading the SIs and OCR and one hour disseminating the relevant information to staff during routine staff meetings we estimate a cost of need to each OCL of £50.18, or £150 in total.[24]

126. At the aggregate level, we estimate the total familiarisation cost to industry to be £141,000. This is equivalent to £38.06 per affected business.

127. As outlined above, this estimate is based on the assumption 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.

128. It should be noted that Defra takes a different approach to familiarisation costs, in line with Defra's broader policy remit. Where there is an overlap between affected Defra stakeholders and affected FSA stakeholders, familiarisation costs for such businesses (of up to £141,000) might therefore be double counted.

Changes to the delivery of Official Controls

General performance of Official Controls

129. 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. If these changes have an impact on industry, this will be captured by a separate impact assessment at a later date.

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

[23] 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.

[24] Based on the median wage rate for *Biological scientists and biochemists* (Code 2112), ASHE (2018), table 14.6a.

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

130. 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. 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.

131. 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 national production provision outlined in Regulation (EU) 2019/624, as explained in paragraph 56. 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.[25]

132. Assessing the total throughput levels of low capacity slaughterhouses and GHEs, as well as allocating individual establishments above or below 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. We are therefore currently unable to quantify this impact

133. 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.

134. 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 next year.

New import requirements

135. 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 Member States.

136. 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.

137. In addition, the FSA understands that some of the affected products are already subject to border

[25] 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

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.

138. 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[26].

139. Under Regulation (EU) 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.

140. 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.

Funding of analyses carried out by private OCLs

141. As explained in paragraph 48, the OCR introduced a legislative change which means that the CA can only designate a laboratory in another member state if the second laboratory has been designated an official laboratory in the receiving member state. FSA is therefore currently assessing whether sub-contracting of samples would still be permissible under the changes to the OCR. If these changes imply that sub-contracting of activities were no longer permissible, this could have an associated cost for privately funded OCLs. As we are still assessing the implications of the new requirement, 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.

Total costs to Food Business Operators

142. As the FSA many of the practicalities associated with implementing the OCR will be determined by ongoing policy development, 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 £141,000 over a ten-year appraisal period, as reflected in paragraph 126.

143. As internal workstreams progress on the specific additional requirements placed on industry, across all identified policy areas, we will seek to update this analysis to deliver a more thorough representation. We welcome any intelligence from industry stakeholders that can assist in gaining a better understanding of the general impacts and associated costs and benefits.

[26] 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.

Enforcement Authorities

144. 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.

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

General Familiarisation with the secondary legislation

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

147. 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 take into account 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. Where 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 outline the practicalities of implementing the changes, the associated familiarisation costs to Local Authorities, FSA and DAERA staff performing official controls and other official activities, will be captured by a separate impact assessment at a later date.

148. We anticipate that for each of the 387 LAs, one manager will spend one hour reading the new SIs and two hours disseminating this information to affected staff. In addition, we expect that it will take each EHO and TSO 30 mins to read the disseminated information. We estimate a total one-off familiarisation cost to LAs of £47,000[27].

149. 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.

150. Across England and Northern Ireland[28] there are 18[29] PHAs, covering only existing Designated Points of Entry (DPEs) and Designated Points of Import (DPIs) for high-risk FNAO and Border Inspection Posts (BIPs) for POAO products.[30] The number of enforcement agents at each PHA will vary in accordance with the volume of trade received, however each PHA will have a team containing a mix of EHOs, TSOs and OVs amongst other professions.[31]

151. We assume that one manager per PHA will spend one hour familiarising themselves with the new regulation and SIs and spend two hours disseminating this information to all PHOs, TSOs and OVs and notifying main stakeholders via appropriate channels. Taking into account consultation responses, we further assume that all Authorised Officers will spend 30 mins reading the necessary guidance. This one-off cost is estimated to be £3,000 in total[32]

152. 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

[27] Based on the median wage rate for EHOs (code 2463) and TSOs (code 3565) extracted from the ASHE 2018.

[28] There are no DPEs/DPIs/BIPs in Wales.

[29] The number of PHAs has been revised compared to the consultation IA to avoid double counting of the ports of London gateway, Thamesport, Tilbury and Sheerness which are all covered by London Port Health Authority.

[30] Under OCR DPEs, DPIs and BIPs will be reclassified as Border Control Posts (BCPs). Refer to par. 75 for potential associated costs for this reclassification with regards to requirements in infrastructure upgrades.

[31] Including auxiliary support staff, technical officers and business support officers, for example.

[32] [32] Based on the median wage rate for EHOs (code 2463) and TSOs (code 3565) extracted from the ASHE 2018.

Laboratories (NRLs) are already familiar with the new changes only OCLs will be required to familiarise themselves. Across England, Wales and Northern Ireland there are 18 public OCLs (see Table 2). 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 to each OCL of £75.27, or £1,000 in total.[33]

153. 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. 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 £126.32 per manager, or £4,000 in total.[34]

154. In NI, 5 field operations managers will be required to familiarise themselves with the new requirements. Assuming that each field manager is a Grade 7 employee and that each manager will also be required to spend one hour reading the guidance and two hours disseminating it to relevant colleagues, including Meat Health Inspectors and other key stakeholders, the cost of this is estimated at £205.92 per manager, or £1,000 in total.[35]

155. Total one-off familiarisation costs to enforcement bodies with regards to the new SIs and provisions included within Regulation (EU) 2017/625 are estimated as £56,000.

Changes to the delivery of Official Controls

General performance of Official Controls

156. 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

157. 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 national 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

Training

158. 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 training will primarily be targeted at PHAs, consultation respondents have raised the concern that Local Authorities will also require training in IMSOC as they will be asked to provide guidance to importers. Respondents

[33] Based on the median wage rate for *Biological scientists and biochemists* (Code 2112), ASHE (2018), table 14.6a.

[34] Based on FSA average salary for FY 2018/19.

[35] Based on DAERA chargeout rates.

have also suggested that the costs incurred by port health officers would be higher than initially expected. We have revised the following assessment accordingly.

159. We assume that various Enforcement Officers will require training and guidance in order to use IMSOC effectively.

160. 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 £1,000.

161. Various authorised officers at each PHA will require additional training use TRACES NT effectively. The new system TRACES NT will be part of the IMSOC platform and will replace TRACES on the 14 December 2019. TRACES NT is a modern user-friendly system that TRACES users should be able to familiarise themselves with quickly. Defra and the FSA are contacting the Commission for further information on training, registration and potentially gaining prototype access to TRACES NT in advance of its implementation. Defra, APHA and the FSA will also develop a plan to cascade training to relevant stakeholders. While the details and financial implications of the training therefore remain uncertain at this stage, we assume that 2 officers from each PHA, and 6 FSA employees will receive TRACES NT training and that the training will take 2 working days (incl. time for attendees to familiarise themselves with the new system).

162. 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).[36] We assume that one EHO and one TSO for each of these 20 LAs 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 place.

163. Those authorised officers trained in IMSOC will be required to cascade training to other officers, including auxiliary support assistants at each port. They will also be required to support industry during implementation by providing in/formal training and guidance to freight handling agents, importers and associated third-country partners. Over a period of one month, from IMSOCs initial inception, it is assumed that one authorised officer at each PHA will spend a full day per week on training stakeholders, responding to general queries and providing guidance. We assume that EHOs at inland Local Authorities will be able to absorb the additional queries from stakeholders as part of their daily job. On average, this will cost each PHA £785.00, or £18,000 in total.

164. Given these assumptions, we estimate that PHAs, LAs and FSA staff will incur a one-off cost to get trained in TRACES NT and to upskill others in using the new system of £72,000 in total.

165. During the consultation, concerns were also raised that some EHPs currently undertaking import controls on fish, fish products and shellfish might no longer be authorised to undertake these controls. It is the FSA's interpretation that suitably trained staff i.e. OFIs will be authorised to deliver official controls on imported fish, fish products and shellfish under the OCR. OFIs currently undertaking these controls should fully meet the requirements, though authorities and OFIs undertaking physical checks on POAO in particular, are encouraged to check the requirements in Article 3 of Regulation (EU) 2019/1081 to assure themselves of this and take appropriate local action where necessary if this is not the case. To assist with OFI training in the future, the FSA is planning

[36] 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.

to create a new online training course. Assuming that between 10% and 100% of all OFIs would take the opportunity to complete this training in the year following implementation of the OCR and that the completion of the training will take 6 hours on average, we estimate one-off training costs to OFIs of £5,000. We do not expect any recurring costs for existing staff and assume that the new training would be integrated into the usual induction phase for all new staff.

166. There is an additional cost for the FSA to develop and deliver the above training for OFIs. We estimate that it would cost the FSA approximately £70,000 to develop the training. We assume that the ongoing costs for FSA to maintain and host the training would be negligible.

167. In addition, the FSA will need to update some of the existing imported foods training material which has been developed over the last two years as there are elements that will no longer be accurate under the OCR. We estimate that this would be associated with an additional one-off cost of £30,000.

168. Following consultation responses, we understand that Port Health Authorities will need to update their letter, notice templates and websites to ensure the information for stakeholders is in line with the latest legislative changes. The FSA is planning to support officers with guidance and letters which highlight changes to the relevant legislation in order for them to undertake these updates. Assuming that one HEO and one SEO Grade will each spend approximately one to two days to design and write the guidance, this will be associated with a one-off cost for the FSA of approximately £1,000.

169. 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 have been informed by stakeholder engagement but could be subject to change.

170. Given these assumptions, we estimate that the delivery and attendance of training for new import requirements will incur a one-off cost to Enforcement Authorities of £178,000, of which £34,000 fall on the FSA, £41,000 fall on LAs and £102,000 fall on PHAs.

Administrative updates

171. As explained above, we assume that Port Health Authorities will need to update their letter, notice templates and websites to ensure the information for stakeholders is in line with the latest legislative changes. The FSA is planning to support officers with guidance and letters which highlight changes to the relevant legislation in order for them to undertake these updates. Assuming that it will take one manager per PHA between one and two days to read the guidance and to plan and communicate the required updates and one technical member of staff one day to update the templates and websites, we estimate that the one-off costs for these additional administrative tasks accumulate £9,000 for PHAs.

Unquantified impacts

172. The Official Control Regulation 2017/625 rebadges DPEs, DPIs, FPIs and BIPs as Border Controls Posts, or BCPs. BCPs will need to meet specific minimum requirements as laid down in the legislation. Many of the existing DPE and DPI minimum requirements remain in place, but other, new requirements have now been introduced. Any new facilities that wish to become a BCP, once the Regulation has taken effect, will need to fully meet the new requirements and go through the necessary approval process. The changes may therefore affect Port Operators, Port Health and Local Authorities with responsibilities for DPEs, DPIs, FPIs and BIPs and/or existing BIP/DPE/DPI/FPI operators. There may be some work required to ensure that existing facilities meet the new requirements. The financial implications are currently unknown. However, the FSA is engaging closely with current DPEs, DPIs and FPIs to better understand the potential operational and financial implications of the new requirements. In particular, in September and October 2019, the FSA Imports Team held three workshops, with representatives from all of the UKs DPE's, DPI and FPIs attending one workshop each. The workshops were created to engage with the relevant authorities on changes under the OCR in relation to imports of food not of animal origin. In advance

of the workshops, authorities were asked to complete self-assessment checklists of their facilities against the new requirements for BCPs (Border Control Posts). At the workshop, various topics were discussed in detail, for example the legislative changes, BCPs and the new Common Health Entry Documents and authorities were given the opportunity to ask questions or raise any concerns. Following these workshops, visits are now taking place to all DPEs, DPIs and FPIs to review the compliance of their facilities with the new BCP requirements and the aim is for these to be completed by mid-November.

173. 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.

174. 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 and that EHPs might require additional training to continue carrying out these controls.

175. Article 49 refers to the Official Veterinarian (OV) as having responsibility for the inspection of imported animals, meat and edible offal. However, the regulations do allow in the case of imported aquatic animal products, which may include fish, fish products and shellfish that suitably trained staff may undertake the inspection of these products, as well as the OV. In addition, Article 55 refers to the OV having the capacity to make decisions as to whether animals, meat and edible by products can be safely imported into the UK, the same responsibilities are made available to suitably trained staff in relation to imported fish, fish products and shellfish.

176. While Articles 49 and 55 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. The proposed regulations will see no change in the current role of EHP's or AO's in their ability to undertake the inspection of imported fish and fish products.

Official Veterinarian resource requirements

177. As outlined in paragraph 55ff, 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.

Additional workload for OCLs

178. As explained in para 47 the OCR also introduces a requirement for OCLs to make publicly available the names of the methods used for analyses, tests or diagnoses performed in the context of official activities on the request of the Competent Authority. We assume that the CA will only require this information for the minority of all analyses that is performed by OCLs and that the additional workload associated for OCLs would be negligible.

Funding of analyses carried out by OCLs

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. As explained in paragraph 48, the OCR introduced a legislative change which means that the CA can only designate a laboratory in another member state if the second laboratory has been designated an official laboratory in the receiving member state. FSA is therefore currently assessing whether such sub-contracting of samples would still be permissible under the changes to the OCR. If these activities were no longer permissible, this could have an associated cost for LAs, as the primary funders of OCLs. As we are still assessing the implications of the new requirement 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

Total costs to Enforcement Authorities

179. Total one-off costs for Enforcement Authorities to familiarise themselves with the SIs and the general provisions of the OCR are estimated as £56,000. Training costs associated with new imports requirements are estimated as £178,000. One-off cost for PHAs to update their websites and certificate templates are estimated as £9,000. The total identified transitional costs for Enforcement Authorities are £243,000.

180. We are currently unable to monetise any recurring costs to Enforcement Authorities due to a lack of available data and a lack of clarity on the details of tertiary legislation that the OCR empowers.

181. It should be noted that, where there is an overlap between affected Enforcement Authorities between Defra and the FSA, transitional costs (of at most £243,000) might be double counted by the assessments of these government departments.

Total costs

182. The total costs associated with Policy Option 1 over a 10-year appraisal period are £384,000 with a Net Present Value (NPV) of £384,000. Industry will assume £141,000 (or 37%) of total costs imposed as a result of this policy, with enforcement agencies assuming the remaining 63%. As such the Equivalent Annual Net Direct Cost to Business (EANDCB) is £16,000.

BENEFITS

Food and Feed Business Operators

Simplified legislative framework

183. 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.

184. 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.

185. 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)

186. 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.

Enforcement Authorities

Reduced Administrative Burden

187. 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

188. The total costs associated with Policy Option 1 over a 10-year appraisal period are £384,000 with a Net Present Value (NPV) of £384,000. Industry will assume £141,000 (or 37%) of total costs imposed as a result of this policy, with enforcement agencies assuming the remaining 63%. As such the Equivalent Annual Net Direct Cost to Business (EANDCB) is £16,000.

189. Benefits were not monetised, therefore the total net cost over the 10-year appraisal period is £384,000.

Wider considerations

Risks and assumptions

190. A summary of key risks and assumptions underpinning the assessment is provided below:

- All impacts have been assessed to the best of our knowledge and ability to date. However, and as outlined in the sections above, there remains a high level of uncertainty around the implementation of the regulation in certain areas, in particular where tertiary legislation is affected. We have been unable to monetise any recurring costs to industry or enforcement bodies, which over time could deliver a larger impact. As such, the exact impacts are therefore likely to differ from the monetised impacts described in this assessment.
- We have only assessed the impacts of the necessary domestic secondary legislation and those pieces of tertiary legislation which have already been negotiated. All impacts of legislation that is still being negotiated by the Commission and that will be implemented after December 2019, has been excluded. This Impact Assessment can therefore not draw a full picture of the impacts that the OCR will ultimately have for FSA stakeholders as a whole.
- The Impact Assessment is based on the assumption that the United Kingdom will be in an Implementation Period in December 2019 and that trade between the UK and the EU remains unchanged compared to the status quo if the OCR was implemented. The consequences of a non-negotiated Exit have not been considered in the assessment.

Small and Micro Business Assessment (SaMBA)

191. EU legislation generally applies to food and feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. It is estimated that there were approximately 170,000 micro businesses and 40,000 small businesses registered in the agri-food sector in 2018, which together represents more than 95% of all food and feed businesses in the UK[37]. It is therefore not feasible to exempt those businesses from the OCR in general as this would fail to achieve the intended effect of reducing risks to consumer health. The negative consequences of an increased risk for public health would be disproportionate to the additional compliance costs to small and micro businesses.

192. The FSA estimates that there are currently a million cases of foodborne disease per year.[38] With an estimated cost per case (in terms of financial losses as well as pain and suffering) of nearly £1,000, even a small hypothetical increase of cases of foodborne disease of 1% could be associated with a societal cost of nearly £10m.[39] The associated costs of severe food incidents exceed these costs by a multiple, with the costs of BSE and Foot and Mouth Disease to the UK economy estimated to exceed several billion pounds.[40] In comparison, the estimated costs to industry in this assessment accumulate to £141,000.

193. That said, the FSA makes every effort to minimise the burden on small and micro businesses and pays attention to impacts on them. The FSA appreciates that micro and small businesses might find it more difficult to familiarise themselves with new import processes. To mitigate for such disproportionate effects, the FSA is planning to provide additional support, detailed guidance and training to Port Health Officers to ensure they can assist micro and small importers in their familiarisation process.

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[37] Based on ONS' Inter Departmental Business Register (IDBR), all businesses registered in SIC Codes 10,11,46,47 and 56.

[38] Costed extension to the Second Study of Infectious Intestinal Disease in the Community: Identifying the proportion of foodborne disease in the UK and attributing foodborne disease by food commodity (2014). Based on model 1 of IID2 extension (see page 58). The numbers are for the 13 pathogens included in the report only, so the total figures will be higher.

[39] The cost per case estimates of £1000/case are based on the latest published Cost-of-Illness figures (see Food Standards Agency Consolidated Annual Report and Accounts 2017/18 (page 16)). It should be noted that The Food Standards Agency (FSA) is updating the way it estimates the economic burden of foodborne illness.

[40] DTZ Pieda Consulting (1998): *The Impact of BSE on the UK Economy*; and DEFRA/DCMS (2002). *Economic cost of foot and mouth disease in the UK: a joint working paper.*

194. The proposed amendments should therefore not have any disproportionate negative impact on small and micro businesses. If anything, a more streamlined and harmonised controls regime across the EU might benefit micro and small businesses because they will be regulated in a proportionate and consistent way according to their business activities across the agri-food chain.

Trade Implications

195. Implementing the OCR could have implications for trade of high-risk food and feed products with third countries as a result of new requirements and changes to existing border procedures.

196. The OCR aims to integrate and harmonise rules across sectors. Assuming the new legislation is successful in reducing the administrative burden on importers, this could facilitate trade with third countries and contribute to lower food prices, as 20% of food consumed in the UK currently originates in third countries.[41]

197. Adherence with the OCR will also enable the UK to demonstrate that food and feed produced and processed within the UK have been produced and handled in accordance with EU requirements. This will help to validate that food and feed is safe and fit for purpose and can stimulate demand for imports from the UK. The UK exports £22bn worth of food, feed and drink annually, 40% of which are exported to third countries.[42] Maintaining and strengthening confidence in UK produce is therefore likely to benefit the UK industry.

198. While the OCR also proposes to introduce some new regulatory requirements for imports of selected products into the Union, including reptile meat, insects for human consumption and rendered animal fats and greaves, trade volumes of the affected products are very small relative to the UK's total import volumes.

199. We are engaging with industry stakeholders and other government departments to understand these implications in further detail. However, as trade flows are dependent on a variety of different factors and complex to model, we will not be able to assess the net impact on trade.

[41] Defra (2019): Food Statistics in your pocket: Summary (National Statistics, updated 8 April 2019): https://www.gov.uk/government/statistics/food-statistics-pocketbook.

[42] Defra (2017): Agriculture in the United Kingdom 2017, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/741062/AUK-2017-18sep18.pdf, chapter 13