CONSULTATION DOCUMENT

CONSULTATION ON THE IMPLEMENTATION OF THE OFFICIAL CONTROLS REGULATION

CONSULTATION SUMMARY PAGE

Date launched:	28 August 2019	Closing date:	9 October 2019

Who will this consultation be of most interest to?

- Local authority and port health authority food and feed enforcement officers as well as any other body responsible for undertaking official controls.
- Food business operators that import food and feed products into the European Union (EU).

What is the subject of this consultation?

The Official Controls Regulation (EU) 2017/625 (OCR) applies from 14 December 2019 and will be directly applicable in Wales if, on 14 December 2019, the UK:

- remains in the EU
- or has agreed an implementation/transitional period with the EU.

The 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.

This consultation focuses on the implementation of legislation in Wales to provide for the execution of powers and enforcement of the OCR only in relation to the FSA areas of responsibility for food and feed law and animal health and welfare.

What is the purpose of this consultation?

To seek stakeholder views and comment in relation to:

- The proposed implementation legislation in Wales to provide for the execution of powers and enforcement of the OCR in relation to the FSA areas of responsibility for food and feed law and animal health and welfare.
- Our assessment of the impacts associated with the implementation of the legislation in Wales in relation to FSA areas of responsibility only.

Responses to this consultation should be sent to:

Elizabeth Hirst
Regulatory Policy Team

FOOD STANDARDS AGENCY
Tel: 02920 678940

11th Floor, Southgate House
Wood Street
Cardiff CF10 1EW

Email: Food.Policy.Wales@food.gov.uk

Impact Assessment included?	Yes x	No ☐

CONSULTATION ON THE IMPLEMENTATION OF THE OFFICIAL CONTROLS REGULATION

DETAIL OF CONSULTATION

Introduction

1. Regulation (EU) 2017/625, known as the Official Controls Regulation (OCR) was adopted by the European Parliament and the Council on 15 March 2017 and entered into force on 27 April 2017. The applicability of the new OCR rules, however, were set to apply gradually over a number of years with the main application taking effect on 14 December 2019. A table listing the different application dates is available on the European Commission website.[1]

2. The 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. It repeals and replaces Regulation (EC) 882/2004 on official controls, and other legislation which currently governs the control and enforcement of rules along the agri-food chain. This legislation is detailed in Annex D

3. The Food Standards Agency (FSA) consulted stakeholders previously, during EU negotiations, on the impacts of the proposed OCR - including the extended scope of the Regulation to integrate controls in relation to plant health and plant protection products with those of food, feed, animal health and welfare.[2]

4. This consultation focuses on the implementation of legislation in Wales to provide for the execution of powers and enforcement only in relation to those 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. On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the EU. The UK will remain a Member State up until the exit date and as such, the UK Government will continue to negotiate, implement and apply EU legislation.

6. The OCR is due to apply across the EU from 14 December 2019.[3] The FSA is preparing the legislative groundwork to implement the OCR in the event that the UK and EU ratify a Withdrawal Agreement before the end of October that would entail the UK entering into an implementation period. During any implementation period it will be necessary to maintain alignment with EU Regulations for food and feed safety and hygiene.

7. In the event that the UK leaves the EU without a deal the FSA will update stakeholders further in relation to the proposed implementation of the OCR.

1 https://ec.europa.eu/food/sites/food/files/safety/docs/oc_application_timeline_20170407.pdf
2 https://webarchive.nationalarchives.gov.uk/20141204222847/http://www.food.gov.uk/news-updates/consultations/2013/officialcontrols-consult
3 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0625

Proposals

8. The OCR is 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. The provisions of the OCR that apply from 14 December 2019 will repeal and replace existing legislation integral to official control activities carried out by the FSA and local authorities in Wales. This includes:

    - Regulation (EC) 882/2004 regarding official controls performed to verify compliance with feed and food law, and
    - Regulation (EC) 854/2004 on official controls on products of animal origin intended for human consumption.

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

Key aspects of OCR application that apply from 14 December 2019 :

- **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 (those organisations with responsibility to organise or perform official controls) through the publication of information about the organisation and performance of official controls;**
- **More stringent rules on fraud will provide greater consumer protection and benefit compliant businesses;**
- **A common set of rules for controls at EU borders that overcomes the current fragmentation and makes the control system less burdensome for enforcers and businesses;**
- **An integrated computerised system to improve the exchange of information between Member States on official controls;**
- **Greater flexibility in relation to the accreditation of official laboratories (i.e. formal recognition of competence in their field);**
- **Businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls.**

10. A more detailed breakdown of the changes which the OCR and the tertiary legislation will implement are provided in **Annex D**.

11. The FSA proposes to prepare up to three Statutory Instruments (SIs) to provide the execution of powers and enforcement to the OCR and its tertiary legislation in Wales. The SIs are not available for publication at the time of consultation. It is intended that the new SIs will follow the framework of the existing SIs which provide enforcement powers for the current official controls regulation (Regulation EU (No) 882/2004 and Regulation EU 854/2004).

Enforcement and sanctions

12. Criminal sanctions have broadly proven to be an effective means of securing compliance with feed and food law in Wales where other enforcement action has not succeeded in doing so. However, in relation to some failures of compliance that have very limited public health impacts, criminal sanctions can sometimes be disproportionate and impose unnecessary burdens on enforcement authorities and undermines the effectiveness of their enforcement action. As part of the policy development work on the implementing regulations, the FSA will consider whether it is more appropriate to provide for non-criminal sanctions for breaches that meet these criteria.

Impacts

13. An Impact Assessment is provided that seeks to assess the changes brought about by the incoming domestic Regulations It provides an overview of the changes and expected impacts that the directly applicable European legislation will necessitate in the UK context.

14. The FSA assessment identifies very few direct impacts on business from the implementation of the OCR in Wales, and those impacts that are identified are not considered to be significant. This is largely due to the changes to the overarching principles of conducting official controls, to which the UK is already aligned.

15. The FSA in England and Northern Ireland are consulting separately on their respective national legislation, and on the impacts identified in this combined impact assessment.

Engagement and Consultation Process

16. Stakeholders views are being sought on this consultation and the associated FSA Impact Assessment. The FSA would particularly welcome any evidence that stakeholders may be able to provide towards this and as such we have provided a list of questions below:

Questions asked in this consultation

Please explain your answers as a far as possible, and where available please also include evidence to support your views.

Q1: Have we appropriately identified the key aspects of the OCR application that apply from 14 December 2019.

Q2: Have we appropriately identified the impacts of the changes that apply from 14 December 2019 in our Impact Assessment?

Q3: Do you agree with the assumptions made in our Impact Assessment?

Q4: Are you aware of any other significant impacts of the changes that apply from 14 December 2019 that we have not identified?

Q5: Do you consider that the Regulations will have an effect on opportunities for use of the Welsh language

Q6: We would like to know your views on the effects our proposed regulations would have on the Welsh language, specifically, on:

i) opportunities for people to use Welsh and
ii) on treating the Welsh language no less favourably than English.

Q7: What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Questions asked in the Impact Assessment (Annex B)

Groups Affected:

Q.I: Is the total list of identified affected sectors/groups representative? If you partly agree, or do not agree please identify other sectors/affected groups that should also be considered and why.

Costs:

Q.II: We would welcome evidence from affected businesses on the expected costs on their establishment if the FSA were to verify compliance by either a) collecting industry data or b) by sampling.

Q.III We would welcome supporting evidence on the total throughput levels of low capacity slaughterhouses and Game Handling establishments, and the distribution of such establishments in relation to the new maximum annual threshold. We would also welcome views on our assumption that the new requirement may result in additional costs on such businesses and the degree to which this change is likely to impact them.

Q.IV: We would welcome any evidence stakeholders are able to provide in relation to the number of food business operators that currently harvest echinoderms from unclassified areas

Q.V: We would welcome views, and where possible supporting evidence, from

UK-based business importing one or more of the products, subject to the above changes. What impact do you believe the harmonising of controls will have on your business?

Q.VI: We would welcome evidence from stakeholders and in particular Port Health Authorities what controls are currently carried out on reptile meat and insects and where these controls are being performed?

Q.VII We would welcome enforcement authority views on our stated assumptions on the required training requirements to support delivery of the changes introduced by the OCR? Please provided details of any specific training needs you think will be necessary.

Q.VIII In a call for evidence, we would welcome information on what necessary changes and/or upgrades certain existing Designated Points of Entry/Introduction and Border Inspection Posts would be required to have in order to obtain certification as Border Control Posts.

Q.IX: We would welcome views from Official Control Laboratories representatives, or LAs that currently send/receive sub-contracts samples to/from other non-designated laboratories in other MSs. Specifically, we invite evidence on the impact(s) that may arise from this change.

Benefits

Q.X: Do you agree that a harmonised and coherent regulatory approach to official controls will deliver any benefits and/or cost savings to industry? If you partly agree or disagree with this statement, can you please provide evidence on what benefits (if any) you expect to be delivered.

Q.XI: We would welcome stakeholder views on any benefits you foresee from the implementation of the OCR. Where possible, please explain your views and provide quantifiable evidence.

Q.XII: Please identify, and provide evidence where possible, any benefit you perceive from the changes outlined in this assessment.

17. The FSA will publish a summary of response report within 3 months of the closing date of this consultation.

Other relevant documents

18. A link has been provided to the OCR for ease of reference. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0625-20170407&from=EN

Responses

19. **Responses are required by close 9 October 2019**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Elizabeth Hirst
Regulatory Policy Team
Food Standards Agency Wales

Enclosed

Annex A: Standard Consultation Information

Annex B: Impact Assessment

Annex C: List of interested parties

Annex D: List of changes between existing legislation and the OCR

Disclosure of the information you provide

Information provided in response to this consultation may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA) and the Environmental Information Regulations 2004).

If you want information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Any automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

The Food Standards Agency will be what is known as the 'Controller' of the personal data provided to us.

Why we are collecting your personal data

Your personal data is being collected as an essential part of the consultation process, so that we can contact you regarding your response and for statistical purposes. We may also use it to contact you about related matters.

The Data Protection Act 2018 states that, as a government department, the Food Standards Agency may process personal data as necessary for the effective performance of a task carried out in the public interest. i.e. a consultation.

What we do with it

All the personal data we process is located on servers within the European Union. Our cloud based services have been procured through the government framework agreements and these services have been assessed against the national cyber security centre cloud security principles.
No third parties have access to your personal data unless the law allows them to do so. The Food Standards Agency will sometimes share data with other government departments, public bodies, and organisations which perform public functions to assist them in the performance of their statutory duties or when it is in the public interest.

What are your rights?

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter.

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/, or telephone 0303 123 1113.

Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address: informationmanagement@foodstandards.gsi.gov.uk

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles[4].

[4] www.gov.uk/government/publications/consultation-principles-guidance

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:** 23/08/19 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Elizabeth Hirst

Summary: Intervention and Options

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**
-£0.3m	-£0.2m	£0.0m	Non qualifying provision

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	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

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) Years	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'

One-off familiarisation costs are estimated to accumulate £0.1m for enforcement authorities and £0.2m for businesses.

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: £0.02	**Benefits:** n/a	**Net:** £0.02	n/a

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 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'

n/a

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

n/a

Key assumptions/sensitivities/risks **Discount rate** n/a

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

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[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.

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

Background

Delivery of Official Controls

18. 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.

19. 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.

20. 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

[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.

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

21. 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 2016/429) and the Plant Health Law (Regulation 2016/2031).

22. 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.

23. Though the OCR entered into force on the 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.

24. 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 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.

25. 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

26. 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.

27. 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

28. 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

29. The general risk-based approach of existing legislation and current practice, detailed in Article 9 of the OCR, is maintained. However, a new provision 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.

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

31. 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

28. 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.

29. 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

30. 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.

31. 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

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

Import controls

33. 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.

34. 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)

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

Cross-border incidents

36. 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.

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

Financing of Official Controls

38. 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.

39. 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

40. 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.

41. 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

42. 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.

43. 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.

44. 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.

45. 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.

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

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

47. 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.

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

49. 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.

50. 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

51. 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.

52. 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.

53. 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.

54. 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

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

60. 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.

61. 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

62. 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.

63. 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.

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

65. 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.

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

67. 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.

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

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

70. 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.

71. 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.

72. 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.

73. 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

74. 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.

75. 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

76. The following groups will be affected by the proposed changes.

Food and Feed Business Operators

77. 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.

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

79. 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.

80. 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]	1,676	150	89	**1,915**
Importers of high-risk food and feed[8]	2,812	32	99	**2,944**

Enforcement Authorities

81. 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.

82. Local Authorities, as CAs, which deliver official regulatory controls across food and feed will have to familiarise themselves with the new requirements. Similarly, 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.

83. 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.

84. Official Control Laboratories (OCLs) are designated by CAs for the purpose of analysing samples

[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).

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.

85. We have identified the following number of affected enforcement authorities 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)[9]	354	22	11	**387**
Port Health Authorities (PHAs)[10]	25	0	2	**27**
Official Control Laboratories[11]	14	5	4	**23**
FSA Field Operations (no. of managers)[12]	28		N/a	**28**
DAERA Operations (no. of managers)[13]	N/a		5	**5**

Consumers

86. 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.

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

Q.I: Is the total list of identified affected sectors / groups representative? If you partly agree or do not agree please identify other sectors / affected groups that should also be considered and provide reasons for your suggestion.

POLICY OPTIONS

Two policy options have been identified:

Baseline: Status Quo

88. 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.

89. 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.

90. Take appropriate action to fully implement the provisions of the OCR into UK law. This would require

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

[10] 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)

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

[12] Figures based on internal intelligence.

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

making legislation to enable the delivery of the requirements.

91. 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.

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

93. 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.

94. 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.

153. 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.[33]

154. 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.[34] Maintaining and strengthening confidence in UK produce is therefore likely to benefit the UK industry.

155. 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.

156. 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.

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

[34] 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

			R2017/625 - Article 148(4) apply only to factory and freezer vessels.
Regulation (EC) 854/2004 Annex III, Chapter II	Official Control of Fishery Products – official controls are to include at least the following elements organoleptic examinations, freshness indicators, histamine, residues and contaminants, microbiological checks, parasites and poisonous fishery products checks	70	Minor changes – where there was a previous generic requirement to comply with Community legislation, the specific EU Regulations have been stated in Annex VI, Chapter of 2019/627 A - Council Regulation (EC) No 2406/96 B – In accordance with Annex VI, Chapter 2 C - Regulation (EC) No 2073/2005. D Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on: — maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470; — prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC; — contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and — pesticide residues, in accordance with Regulation (EC) No 396/2005. E - Regulation (EC) No 2073/2005. F – Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex

			laboratories which don't meet required criteria to perform the tests.
		2017/625 Article 38(1) - Obligations of official laboratories	New requirements for laboratories to immediately notify the competent authorities in case of identification of a risk, unless there a specific arrangement in place for this not to be done immediately.
		2017/625 Article 38(2)	Official laboratories to take part in inter-laboratory comparative tests and proficiency tests when requested by EU-RL or NRLs.
		2017/625 Article 38(3)	At the request of CAs, OLs shall make publicly available the names of the methods used for analyses, tests or diagnoses performed in the context of official activities.
		2017/625 Article 38(4)	At the request of CAs, OLs shall indicate, together with the results, the method used for each analysis performed in the context of official activities.
882/2004 - Article 12(4)	CA may cancel an OL designation when the required conditions are no longer fulfilled.	2017/625 Article 39- Audits of official laboratories	CAs will be expected to take a more proactive role in audits of OLs and organise audits of the OLs on a regular basis and as necessary. Audits can be carried out by other bodies, such as in agreement with UKAS.
		2017/625 Article 40 (1)	Introduces new derogations from the mandatory accreditation for certain official laboratories whose sole activity is the detection of Trichinella in meat; or laboratories which carry out analyses in the context of other

			official activities, with specific listed provisions.
		2017/625 Article 40(2)	Clarifies that results performed by laboratories subject to a derogation from mandatory accreditation must be confirmed by a lab that has full mandatory accreditation.
		2017/625 Article 40(3)	Clarifies that no designation in other MS is possible for laboratories subject to a derogation from mandatory accreditation.
		2017/625 Article 41	Delegated act concerning when derogations from mandatory accreditation will be permitted providing labs have met specified conditions.
		2017/625 Article 42	CA has flexibility to temporarily designate existing OLs located in same MS for use of a method they are not accredited for, subject to certain conditions in instances where a new method is required or in an emergency situation. The designation may only last one year and only be renewed once.
Regulation (EC) No 882/2004	Art 30(1)(c) - Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted, in accordance with the procedure referred to in Article 62(3), concerning: (c) qualifications of the certifying staff;	Art 88(2)	Schedule 4 of OFFC 2009 Regulations to be updated.
Regulation (EC) No 882/2004	Art 30(2)(a),(b)	Art 89(1)	Need to check position re: dual language

Official Feed and Food Controls (Wales) Regulations 2009	Regulation 22 provides explanation of 'product' making reference to Article 15 of Regulation 882/2004.	Article 44	This reference should be amended to read 'Article 44 of Regulation (EU) No. 2017/625'
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 25 makes reference to Art 24 of Regulation and Art 10 of Regulation 669/2009 in terms of the functions of the Commissioners.	Art 75(1), Art 57, Art 46 and Art 76	In terms of Art 75(1) and 46 it is proposed that Schedule 4 of the OFFC Regulations 2009 are amended and that guidance on local authority controls and the feed code of practice are updated.
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 29(1) (2) and (3) outlines the checks on feed and food of non – animal origin that need to be undertaken under Art 16 of Regulation 882/2004.	Art 45(1), 44(2), 45(2) and Art 34(5)	No action is required.
-	No equivalent in Regulation 882/2004	Art 38 – obligations of official laboratories	Need to be designated as competent authority. Updated Schedule 4 and Regulation 3 of OFFC 2009 Regulations. Need to liaise with SERD and Imports.
-	No equivalent in Regulation 882/2004	Art 75	Amend Schedule 4 of OFFC 2009 Regulations.