

Consultation on the implementation of the Official Controls Regulations

Summary report of stakeholder responses

The consultation on the implementation of the Official Controls Regulations was issued on 29th August 2019 and closed on 11th October 2019.

The consultation covered the directly applicable Official Controls Regulation (EU) 2017/625 (OCR) which took effect on 14 December 2019. 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 focused on the implementation of legislation in England to provide for the execution of powers and enforcement of the OCR, only in relation to the Food Standards Agency (FSA) areas of responsibility for food and feed law and animal health and welfare. Parallel and simultaneous consultations exercises were launched in Scotland, Northern Ireland and Wales

The consultation provided stakeholders with the opportunity to comment and express their opinions on the Impact Assessment developed by the FSA and shared within the consultation documentation.

The FSA is grateful to those stakeholders who responded and sets out in the table below the themes raised by stakeholders, along with a response from the FSA.

The key proposals on which the consultation sought views were:

- The proposed implementation in England of the legislation 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 England, Northern Ireland, and Wales in relation to FSA areas of responsibility only.

The FSA has considered responses from stakeholders when implementing the Official Controls Regulation in England. Our considered responses to stakeholders' comments are given in the last column of the below table. The FSA made changes to the original Impact Assessment following stakeholder comments. These changes are set out in the final Impact Assessment table.

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While stakeholders were in general in favour of, or did not disagree with the proposed approach, some concerns were raised. These, and the FSA's considered response, are noted below. The FSA has engaged with industry and enforcement authorities about the implementation of the Official Controls Regulation and will continue to do so.

Comments about areas that were not directly within the scope of the consultation will be passed to the relevant officials for their information and consideration.

General OCR

We still perceive there to be an issue for the FSA to join up the intelligence that is gathered, e.g. from any central registration system/database and the information gleaned elsewhere or already received e.g. in relation to FHRS and in UKFSS and also now in relation to intelligence per se.

There is an emphasis that these Regulations will "more stringent rules on fraud will provide greater consumer protection and benefit complaint businesses" however what's changed?

Any (new or altered) inspection framework must focus on high risk, poor producers, ensuring that any 'risk engine' brings forward businesses that pose the greatest risk for more frequent controls.

Controls need to be 'future proof' to help maintain public protection; considering the myriad ways that food is sold and supplied. The OCR does now consider internet sales (distance communication).

Article 2 introduces a new definition of 'other official activities', which includes activities performed by CAs (Competent Authorities) or delegated bodies other than official controls. These activities are not scoped in any detail.

Which? states that consumers are a directly affected group and should be included

Noted. The OCR seeks to clarify and enhance current provisions in respect of fraudulent and deceptive practices. As part of the FSA's Regulating Our Future (ROF) programme we will give further consideration to how the food and feed law risk rating systems have regard to fraudulent and deceptive practices, sources of intelligence, to ensure the requirements of the OCR are fully reflected, including the supply of food and feed by distance communication.

We will look to provide further guidance in the next updates to the Food and Feed Law Practice Guidance due out for consultation late February 2020

Noted. Consumer interests are of primary interest to the FSA and the changes

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within the cost/benefit section as one of the main affected groups.

introduced under the OCR were assessed by the FSA in relation to the impacts on consumers at both the negotiation stage of EU proposals and in the recent implementation of legislation in England. No direct impacts on consumers were identified from the OCR and therefore the narrative provided by the FSA - summarising the intended benefits to consumers through the integrated and simplified approach to controls across the EU - was considered appropriate to explain the indirect impacts on consumers. This approach was considered to be proportionate by the FSA.

The International Meat Trade Association welcomes that the FSA will 'work proactively with business to help them understand and to comply with the rules.' (p. 4) This is a good approach; it can foster a positive working relationship between business and enforcement. IMTA would like more information on what format this work will take and more information on what training or guidance will be provided for exporters.

Noted.

Meat Hygiene

The FSA is not sufficiently independent to continue in its current prosecutor role and should pass that role to the Crown Prosecution Service to ensure that cases are only pursued if they pass the public interest test.

Noted.

The East of England Trading Standards Association suggested the use of criminal sanctions in the case of non-compliance should be used less and replaced by civil sanctions. Noted, the FSA is currently reviewing the use of penalties and sanction for food and feed law offences in England, with particular focus on identifying opportunities to reduce reliance on criminal offences and penalties. The FSA and local authority enforcers use a hierarchy of enforcement measures to address non-compliance with hygiene

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	requirements and will only instigate criminal proceedings in the most serious cases or where other measures have failed to bring about compliance.
The Association of Independent Meat Suppliers welcomes the right of appeal on decisions made by the official veterinarian.	Noted.
The avoidance of official sampling to verify that broiler slaughterhouses are complying with the process hygiene criterion is the preferred option by those who commented.	The FSA will discuss with stakeholders how the collection of industry data should be carried out, how the data will be used and in what circumstances official control sampling will be considered.
The new thresholds on reduced official veterinary presence during PMI will have a financial impact on small slaughterhouses	The FSA believes that very few slaughterhouses will be affected by the change but will examine the effects further before implementing any changes to the current requirements.
The flexibility in the Official Control Regulations could be maximised to reduce the use of official veterinarians in slaughterhouses	The FSA believes that the room for further reducing the use of official veterinarians to undertake official controls is limited but will discuss this further with stakeholders.
Ante-mortem inspections (AMIs) away from slaughterhouses is a significant shift for other species and will reduce the burden of lairage based inspections but is already permitted in poultry. Further clarification as to who can be authorised to carry out such AMIs and what will be the timeline prior to slaughter.	Ante-mortem must be conducted by official veterinarians. Private practice veterinarians may be authorised by the FSA to perform these activities. The FSA will consult with stakeholders before it introduces changes to the current requirements on AMI at holdings of provenance.
Clarification is sought on what a representative sample from a flock would be as referenced in Article 11 of Commission Implementing Regulation 2019/627 and on whether this would reduce the number of loads checked by the OVs on arrival at the slaughterhouse if used alongside the Food Chain Information.	The requirements on AMI of poultry have not been changed, but stakeholders will be consulted as any changes are made.

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The reduction in on-line checks for poultry are welcomed, however, we would like to see FSA guidance on what is meant by a representative sample to ensure a consistent approach is taken across the whole of the UK.

Noted. The FSA will produce guidance on how this new requirement will be implemented and consult with stakeholders before any changes are made.

Clarification is sought on the conditions that have to be met in order for the derogation in reduced on-line checks to be applied and our members would support any pilot studies undertaken.

Noted.

Charging

Identification of costs and benefits in the	The Impact Assessment (IA) set out the
Impact Assessment	FSA's position on charging, i.e. no
	immediate changes planned for, or soon
	after, the implementation of OCR on 14
	December 2019. The fact that no immediate
	changes are planned was the reason the IA
	did not provide detailed information on costs
	and benefits. Subsequent to the consultation
	the FSA has met with industry
	representatives and confirmed its
	commitment to stakeholder engagement in
	relation to changes to the charging
	arrangements. As part of this process on 17
	December 2019 the FSA met industry
	representatives from a number of trade
	associations to hear their views on current
	and future charging.

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Options for charging under OCR

Article 82 of (EU) 2017/625 gives Member States the option of charging the actual costs of the controls or a flat rate. The FSA's current system of charging incorporates discounts for slaughterhouses and game handling establishments. The uncertainty around the UK's exit from the EU was a factor in how (EU) 2017/625 was implemented and the resulting compressed timetable for the implementation of the necessary domestic legislation. The FSA has already committed to industry stakeholders that there will be continued engagement on future charging arrangements.

Costs included in the charges

The FSA notes the consultation response that (EU) 2017/625 limits the costs that can be included in the charges for the controls. This is not how the FSA interprets the Regulation. The FSA does not see (EU) 2017/625 making radical changes to the recoverable costs. The new legislation refines the provision in the previous legislation ((EU) 882/2004) but it does not move away from the existing principles. The FSA considers that the costs that comprise its charges are appropriately included. The FSA is fully transparent on this with an annual exercise that explains the calculation of its hourly charge rates and the costs those charges include. The FSA opens this exercise to scrutiny by industry representatives. The FSA has updated its contractual arrangements with its third party supplier of Official Veterinarians and Meat Hygiene Inspectors so that the current supplier is designated as a delegated body within the terms of (EU) 2017/625. This ensures that it remains appropriate to continue including the costs of the

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contractor within the charges for the controls.

Imports

Concerns were raised that under article 49(2b) reference was made only to the Official Veterinarian (OV) and staff trained in accordance with the article to deliver official controls in relation to the importation of aquatic animals, products of animal origin other than the ones referred to in point (a) of this paragraph, germinal products or animal by-products. It has been suggested that the reference to trained staff is too generic and should be more specific to include Authorised Officers or Environmental Health Practitioners (EHPs). Respondents highlighted that it is important that it is important that EHPs are recognised as staff trained to carry out existing official controls on certain food products imported into the UK.

The FSA values the work of all those involved in delivering imported food checks, whether this is Port Health Officers or OVs. This is applicable across all Member States which will use a wide variety of titles to describe trained staff. It would be difficult to list a specific title to identify other groups who could undertake import functions in the regulations that would be common to all Member States. Trained staff provides that flexibility for all Member States to involve other groups delivering Official Controls for the products detailed in the Article 49 (2b, other than the OV. The inclusion of trained staff provides the opportunity to use staff other than the Official Veterinarian to deliver official controls relating to the importation of those products listed in the article, which provides greater flexibility resourcing this control Article 49 allows others that are not OVs to deliver Official Controls for imported aquatic animals, products of animal origin, (other than the ones referred to in point (a) of Article 49) germinal products and animal by-products. The Food Law Code of Practice and Practice Guidance continues to recognise qualifications that would be suitable for those involved in delivering Official Controls for imported foods. The FSA does not anticipate that there will be any change for those EHPs that are employed to undertake official controls on certain imported food products.

There was concern that the reference to trained staff in Article 49(2b) may exclude those Environmental Health Practitioners

Concern noted, however, while Article 49(2b) does not specifically refer to Authorised Officer, Official Auxiliary or EHP,

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that currently undertake this work. It is it still allows others that are not OVs to important that EHPs are recognised as staff deliver Official Controls for imported aquatic trained to carry out existing official controls animals, products of animal origin, (other on certain food products imported into the than the ones referred to in point (a) of Article 49) germinal products and animal by-UK products. The Food Law Code of Practice and Practice Guidance reinforces this position. The FSA does not anticipate that there will be any change for those EHPs that are employed to undertake official controls on certain imported food products. While OA's can 'continue to provide Noted. assistance to OV's in undertaking' ante and post-mortem inspections, a respondent noted that qualified Environmental Health Practitioners with the Veterinary Auxiliary (VA) qualification could an effective alternative for the certification of imports currently assigned to OVs. The International Meat Trade Association Noted. (IMTA) would welcome any decrease in checks based on good compliance which would also best target resources and reward compliance. The consultation document says 'import Noted. 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.' (p. 34) IMTA would welcome testing this and working closely with FSA on this. On IMSOC IMTA welcomes moves towards the Single

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Window, for modern trade and moving towards e-certification. We very much welcome the FSA's Noted. acknowledgement of the key role played by imports: '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.' (p. 37) Importing members have an important role in ensuring there is sufficient quantity and choice available to the consumer. The UK is not self-sufficient in meat and imports are vital to ensure that the UK is food secure and consumers have choice. Anything that can make it easier for importers to fulfil this role is to be welcomed. The consultation document also notes the importance of exports: 'The UK exports £22bn worth of food, feed and drink annually, 40% of which are exported to third countries. Maintaining and strengthening confidence in UK produce is therefore likely to benefit the UK industry.' (p. 37) Export of meat helps to balance the carcase and increase returns to the producer. IMTA welcomes any change under the OCR that contributes to facilitating

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two-way trade.

Sanctions and Enforcement

There was Local Authority interest in a review of the sanctions and penalties which apply to breaches of food and feed law. The Hertfordshire and Bedfordshire Food Liaison Group was broadly in favour of the outlined approach as well as the use of fixed penalty notices (FPN) in some circumstances. However, without further details of when an FPN might be appropriate, such as the type(s) of business in which they could be used, or the offences for which they might be suitable, it was difficult to comment further. Accordingly, clarification would be welcomed in due course, and, should alternative sanctions come into use, some official guidance on their applicability.

Comments noted. The FSA is considering consultation responses made in relation to sanctions and penalties as part of our wider review of sanctions and penalties. We will be consulting further in future in relation to any specific proposals.

As part of the OCR Implementation in England, and in line with the FSA commitment to UK Ministers to reduce reliance on criminal offences in England, the FSA removed the custodial sentence tariffs from two criminal offences under the Official Feed and Food Controls (England) Regulations 2009:

Regulation 41(1) Any person who —

(a) contravenes or fails to comply with any of the specified import provisions(b)contravenes or fails to comply with

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Which? is very concerned by the stated FSA commitment to reduce reliance on criminal offences and sanctions for feed and food law in England through greater use of civil powers and sanctions. This would remove an important deterrent and fail to reflect the severity of the consequences of food and feed law breaches for consumers. It is important that enforcement officers have an appropriate toolbox in order to ensure effective enforcement and compliance. This needs to include both civil and criminal penalties depending on the nature and severity of the breach and the type of consumer harm that can result. In some cases, swift and flexible action will be needed so greater use of fixed penalty notices, for example, would be beneficial. However, it is essential that there remain strong criminal sanctions to deter noncompliance both for safety breaches and for food fraud or other crimes that can lead to consumer detriment, including financial and emotional detriment. Any move away from criminal sanctions would send the wrong message about how seriously breaches to food and feed law are taken.

paragraph (3) of regulation 26 [relating to disclosure of information]

The two offences remain under criminal law, but the tariffs are now fine only. The removal of the custodial sentences for these offences also reflects that these fines are now unlimited.

The Government Chemist is in favour of a guidance for the application of civil powers as opposed to criminal sanctions where explicit account is taken not only of potential adverse effects on public health and product safety but also of any potential adverse impacts arising from food fraud or crime. The Government Chemist also suggest that a light-touch reminder in any developed guidance on the use of civil sanctions, of the availability of a referral to the Government Chemist on disputed issues in measurement science or data interpretation.

Noted

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We recommend the provisions for enforcement provided in The Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018 and would encourage FSA to consider Enforcement Costs Recovery Notice provided in these regulations.	Noted.
Welcome the FSA proposal to provide additional enforcement tools to Local Authorities.	Noted.
Any change to the enforcement regime should be accompanied by FSA low cost or free training. We would also encourage the FSA to consider running national programmes of work similar to that now used by OPSS in product safety	Noted.
National Agriculture Panel and National Animal Feed at Ports Panel members have no objections to proposed changes to sanctions for feed hygiene in principle, but it is difficult to consider the impact of the changes without knowing exactly where they will be applied and have a more involved discussion about the implications of each proposed change.	Noted. The FSA is considering consultation responses made in relation to sanctions and penalties as part of our wider review of sanctions and penalties. We will be consulting further in future in relation to any specific proposals.
National Agriculture Panel and National Animal Feed at Ports Panel are concerned that the FSA do not seem to be taking a holistic approach to the review of sanctions for feed hygiene. It is important that the FSA take the time to ensure that changes to penalties are based on consistent principles, time is taken to ensure that enforcers still have the right tools available and all consideration is given to future proofing the updated system.	Noted. The FSA is considering consultation responses made in relation to sanctions and penalties as part of our wider review of sanctions and penalties. We will be consulting further in future in relation to any specific proposals.
National Agriculture Panel (NAP) and National Animal Feed at Ports Panel (NAFPP) support a range of penalty levels	Noted.

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that could be used flexibly to address issues with differing business types, sizes and situations. It is recognised that guidance would be important in providing consistency on how the scale was used for both businesses and the public, though the ultimate decision would need to rest with the local authority. While the FSA has proposed to use the implementation of the Official Control Regulations to fundamentally update enforcement powers, such as the introduction of Fixed Penalty Notices and removal of custodial sentences, National Agriculture Panel and National Animal Feed and Ports Panel members are keen that the opportunity is taken to tidy up existing powers and ensure they are fit for purpose. Noted. To ensure the success of any new enforcement tools it would be vital to gain further understanding as to why Improvement Notices in the Food

Noted.

Labs

level

Sub-contracting samples for testing to non-designated laboratories in another EU Member States

Information Regulations (FIRINS's) have not been used more regularly at Local Authority

PASS is designated as an Official Control Laboratory in the UK by the FSA and provides Public and Agricultural Analyst service to the UK. PASS is part of the international Eurofins group and as long as PASS/Eurofins group is considered as a single entity, samples tested within the group are not considered to be subcontracted and the change in requirement

Noted. Article 37 of Regulation (EU) 2017/625 permits the Competent Authority to designate an official laboratory in its home Member State, or another Member State (or EEA state). One of these conditions is that, if the competent authority designates an official laboratory in another Member State, that laboratory must have been designated as an official laboratory in its home Member State. Provided the conditions in Article 37 are met, we see no reason why a designated laboratory operating in one Member State might not

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would have no impact. However, if the laboratories within the Eurofins group are not considered to be an integral part of the designated OCL then this would cause major impact on the capability and capacity provided by PASS and would incur an increase in cost for testing if laboratories external to Eurofins have to be sought. The financial impact would be felt by UK importers and Local Authorities.

Cefas have informed us that sub-contracting does not impact on samples collected for the purpose of algal toxin analysis in shellfish in England as no samples are sent abroad for these analyses and no samples are received from any other laboratories.

send a proportion of its sampling and analysis work to a sister laboratory operating under a common trading name but located in another Member State. FSA has noted that this does not affect samples collected for the purpose of algal toxin analysis.

Submission of sample for second expert opinion

The Government Chemist notes that Article 35 expands on the right for the food and feed business operator to a second expert opinion. It is not explicit that this should be provided by the Government Chemist or any competent accredited laboratory. Many businesses in the UK favour a direct approach to the Government Chemist for a second expert opinion. This enables pressing issues related to scientific measurement, interpretation of results to be resolved by the Government Chemist advisory rather than their statutory remit. Therefore the Government Chemist has recommended that it would assist enforcement officers and traders if links to their guidance on the submission of referee samples

(https://www.gov.uk/guidance/submitareferee-sample-to-the-governmentchemist) and on requests for 'second expert opinion' The FSA has noted the recommendation provided by the Government Chemist on making available Government Chemist guidance on submission of samples.

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(https://www.gov.uk/guidance/submit-a-supplementary-expert-opinion-sample) are inserted into FSA food and feed law guidance.

In relation to shellfish testing, CEFAS commented that the requirements for weekly toxin analysis is correct. This is not currently in place in England and will therefore require implementation by FSA. Additionally, Echinoderms are not currently classified in the UK and the new change will therefore require to be implemented unless a further change to EU legislation is possible. Cefas is unaware of any echinoderm harvesting activity in unclassified areas. Some preliminary discussions have taken place in England re. future harvesting opportunities from areas currently classified for other species.

Noted.

The UK needs to have sufficient lab capacity to undertake sampling in an efficient way to avoid long delays in getting product released, which adds cost in storage, missed delivery slots, loss times increase, as they are already an issue. If lab capacity does become an issue generally, perhaps the UK could consider testing being undertaken by port health rather than at a lab, this could be something worth exploring

Under the official control regulations, imported samples taken at ports by port health officers must be sent to designated official control laboratories for testing and analysis. A list of UK official laboratories can be found on the FSA website. The Certificate of Analysis can only be signed by a qualified official control analyst (Public/Agricultural Analyst or Food Examiner) of the laboratory

Impact Analysis

The feedback we have received from consultation respondents primarily concerned the assumptions underpinning the costing for familiarisation, administration and training costs of enforcement authorities. Stakeholders raised concerns that these costs were irreflective of the true costs, underestimating on average the true impacts. Therefore, several of the assumptions were changed in line with information provided by stakeholders, leading to a substantial increase in the estimated costs to Enforcement Authorities. A more detailed explanation of the adjustments we have made in response to the consultation responses is summarised in the table below.

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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. ^[1]
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 no longer assume that PHOs would receive formal training on the general provisions of the OCR. 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	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.

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Management System 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 Official Fish Inspectors (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.	Whilst we understand that many existing OFIs will meet the new requirements, it is currently unclear exactly how many may require additional training. For the purpose of this impact assessment, we assumed that around half of all OFIs might need training. Since the impact assessment was completed, we now understand that this training is more likely to be focussed on the training of new OFIs rather than upskilling existing ones. However, this is unlikely to

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			significantly alter the costs of the training course accounted for in the impact assessment.
Second Expert Opinion - This is welcome clarification but it would be useful to have further guidance on the taking of formal samples online covering division process, recording of purchase, part sent to trader or preferably just 'made available on request' etc.	2	NA	

^[1] 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.

Additional Impact Changes

Better enforcement tools will bring clear advantage for authorities.	Noted.
The impact assessment for enforcement officers at local authority level should include familiarisation with new Integrated Management System for Official Controls (IMSOC) system as local authorities are asked for preliminary advice in this area by importers and exporters registered in their districts.	Funding has been made available to Local Authorities to ease the impact for Local Authorities in relation to the implementation of the new Official Controls Regulation (OCR) (EU) 2017/625. For further information, Local Authorities can view the communication on the FSA Smarter Communications Platform (https://smartercommunications.food.gov.uk/communications/files/4636)

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