

Title: The Food Safety and Hygiene (England) Regulations 2013 (As Amended) PIR No: Click here to enter text. Original IA/RPC No: Click here to enter text. Lead department or agency: Food Standards Agency Other departments or agencies: Click here to enter text. Contact for enquiries: Michelle Beer	Post Implementation Review
	Date: 26/11/2020
	Type of regulation: Domestic
	Type of review: Statutory
	Date measure came into force: 31/12/2013
	Recommendation: Keep
	RPC Opinion: Choose an item.

1. What were the policy objectives of the measure? (Maximum 5 lines)

The Food Safety and Hygiene (England) Regulations 2013 came into force on 31st December 2013, they are a fundamental element of food safety law and provide enforcement authorities with the tools to ensure food businesses meet their obligation to provide safe food.

The Regulations were an outcome of the UK Government 'Red Tape Challenge' (RTC), which recommended review and consolidation of existing Statutory Instruments and amendments. This simplified food legislation consolidated 'food hygiene' and 'food safety' provisions for businesses and enforcement authorities and ensured necessity and proportionality. As a result:

- Proportionate provision for food safety was retained
- Penalties and offences were rationalised and harmonised
- The number of Statutory Instruments were reduced.

The SI also gave effect to important EU Regulations concerning the hygienic production of sprouts and seeds intended for sprouting to safeguard public health.

The consolidation delivered an overall reduction in both powers of entry for enforcers and the number of potential offences, without losing important measures to protect public health.

2. What evidence has informed the PIR? (Maximum 5 lines)

Routine FSA engagement with business, local enforcement authorities and some EU Member States, as well as FSA annual monitoring of local authority enforcement, and consumer surveys formed the evidence basis for the initial review and analysis. Stakeholder engagement and public consultation was undertaken to challenge and support the FSA's assumptions. A short economic analysis was carried out based on the original Impact Assessment of the consolidation exercise.

3. To what extent have the policy objectives been achieved? (Maximum 5 lines)

The original objectives were achieved.

The importance of the consolidated food safety and hygiene legislation is underpinned by the revised enforcement and penalties sections. They provide greater clarity and continue to offer a range of proportionate enforcement sanctions for protecting public health and consumer choice, including a significant deterrent for the most serious of food crimes.

Reduction of regulatory burden in line with the RTC was achieved with a reduction in the number of Statutory Instruments, offences, and powers of entry. Further simplification for both business and enforcers was achieved by providing a single point of reference.

The regulations also introduced necessary measures to provide for execution and enforcement of EU regulations on sprouts and seeds for sprouting. These important regulations, introduced following serious multi-country food-borne disease outbreaks caused by sprouts, have brought about a significant reduction in sprout-related outbreaks within the EU.

Consultation respondents confirmed that the Regulations continue to be necessary, fully effective and fit for purpose. Stakeholders (business and enforcers) had as anticipated benefit from having all the rules on food safety and food hygiene contained in a single SI, instead of having to refer to separate and much amended domestic Regulations. This assumption was supported by comments made by respondents to the consultations. Necessary Amendment regulations have somewhat reduced the benefits of the 2013 Regulations, but the FSA does not consider it appropriate to carry out a further consolidation of these regulations at the present time.

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: [Click here to enter text.](#)

Date: [Click here to enter a date.](#)

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions? (Maximum 5 lines)

Consolidation would:

- Ensure provisions were necessary and proportionate
- Simplify and harmonise the system of food safety and hygiene legislation benefiting businesses, enforcers and ultimately consumers
- Contribute to the delivery of RTC recommendations
- Efficiently provide opportunity for the necessary execution and enforcement of new EU Regulations on Sprouts and Seeds for Sprouting.

5. Were there any unintended consequences? (Maximum 5 lines)

No, the bulk of the 2013 Regulations is concerned with providing enforcement provisions for directly applicable EU legislation, which will become retained EU law following end of Transition Period.

The FSA reviewed the Regulations during the development of the Official Feed and Food Controls (England) (Miscellaneous Amendments) Regulations 2019, This was in-line with obligations to UK Ministers to reduce the reliance on criminal sanctions in England. The purpose of this review was to identify whether criminal sanctions could be reduced and whether there were gaps in the enforcement hierarchy. These matters will be considered as part of a wider review of regulatory enforcement and sanctions to address non-compliance with food and feed law.

6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines)

There were no changes in requirements on businesses. The England Statutory Instrument does not, in the main, impose any national rules over and above the EU harmonised legislation which it enforces; it mostly provides for the execution and enforcement of EU Regulations that were directly applicable in England prior to the UK's departure from the EU. No new burdens for business were introduced and there was no indication from respondents that this was the case.

7. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business? (Maximum 5 lines)

The approach to enforcement is similar in the EU Member States we contacted. There is no evidence to suggest that, overall, burdens on UK businesses complying with the 2013 Regulations exceed those on businesses complying with equivalent enforcement Regulations in EU Member States.

The Food Safety and Hygiene (England) Regulations 2013 (As Amended)

Post Implementation Review

22/09/2020

Foods Standards Agency

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1. Executive Summary

The UK exited the EU on 31 January 2020. There is now a transition period until the end of 2020 while the UK and EU negotiate additional arrangements. EU law continues to apply in the UK during the transition period, including rules on food and feed.

The Food Safety and Hygiene (England) Regulations 2013 (SI 2013 No. 2996) came into force on 31 December 2013, they are a fundamental element of food safety law and provide enforcement authorities with the tools to ensure food businesses meet their obligation to provide safe food.. This routine Post Implementation Review (PIR) is required as part of the Statutory Review requirements of the legislation. In order to do this, the FSA has collated evidence from key stakeholders based on their views and experiences, including on any costs and benefits arising from its implementation.

The Regulations revoked and re-enacted, in whole or in part (details indicated), the following Regulations and Orders into a single consolidated Statutory Instrument (SI):

Regulation/Order	Revoked by Food Safety and Hygiene (England) Regulations 2013
The General Food Regulations 2004 (S.I. 2004/3279)	Regulations 3, 4, 5, 6, 6A and 7
The Food Hygiene (England) Regulations 2006 (S.I. 2006/14)	The Whole Regulations
The Food Hygiene (England)(Amendment) Regulations 2010 (SI 2010/534)	The Whole Regulations
The Food Hygiene (England)(Amendment) Regulations 2012 (SI 2012/1742)	The Whole Regulations
The Food (Cheese) (Emergency Control) Order 1998 (SI 1998/1277)	The Whole Order
The Food (Cheese) (Emergency Control) (Amendment) Order 1998 (SI 1998/1284)	The Whole Order
- The Food (Cheese) (Emergency Control) (Amendment) Order 1998 (SI 1673)	The Whole Order

This consolidation provided better accessibility and clarity for businesses and enforcers without affecting business requirements. The harmonisation of enforcement including

finer for serious 'food safety' and 'food hygiene' offences which are often inextricably linked acknowledged widely held views that there was no good reason for the continued difference.

The consolidation delivered an overall reduction in both powers of entry and the number of potential offences, improving clarity and simplicity without losing important measures to protect public health.

The Regulations have been amended since coming into force on 31 December 2013. These amendments were (most recent first):

Amending Regulation	Effect on Food Safety & Hygiene (England Regulations 2013)
The Official Feed and Food Controls (England) (Miscellaneous Amendments) Regulations 2019 (SI 2019 No. 1476)	Updating references to relevant EU legislation which has been revoked or replaced by Regulations (EU) 2017/625 of the European Parliament and of the Council on 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 Food Safety and Hygiene (England) (Amendment) Regulations 2016 (SI 2016 No. 868)	Provided for the execution and enforcement of Regulations (EU) 2015/1375 on official controls for <i>Trichinella</i> in meat.
The Food Safety and Hygiene (England) (Amendment) Regulations 2014 (SI 2014 No. 2885)	Update offences and penalties section. Make continuing provision for the labelling of raw milk intended for direct human consumption with prescribed information relating to the absence of heat treatment.
The Official Feed and Food Controls (England) and the Food Safety and Hygiene (England) (Amendment) Regulations 2014 (SI 2014 No. 2748)	Enforces Regulation (EU) 579/2014 by amending Schedule 1 on definitions of EU legislation; schedule 2 on specified EU provisions; and schedule 3 on bulk transport in sea going vessels of liquid oils or fats and the bulk transport by sea of raw sugar.) Implements Regulation (EU) 218/2014 by revoking regulation 35 and schedule 8 in relation to the special health mark. ¹

The requirements introduced by the amending SIs are reviewed as part of this exercise. This PIR reviews the objectives of the consolidation exercise; the extent to which those objectives have been achieved; and, whether they could be achieved by means that

¹ Impact Assessment - https://www.legislation.gov.uk/ukia/2014/302/pdfs/ukia_20140302_en.pdf

impose less regulatory burden. The PIR also considers evidence provided by interested parties on the effectiveness of the regulations and the extent to which they are still relevant.

A light touch review was considered proportionate for this combined PIR due to the low impact identified in the regulatory impact assessments. The FSA view is that the Regulations remain effective and fit for purpose - based on routine engagement and monitoring of UK official controls and enforcement. The level of evidence sourced is commensurate to the scale of the Regulations and associated impacts.

2. Introduction and Background

The Food Safety and Hygiene (England) Regulations 2013, came into force on 31st December 2013, consolidating 'food hygiene' and 'food safety' provisions into a single Statutory Instrument.

The aims of the consolidation exercise were as follows:

- To introduce a simplified system of food legislation, in line with the aims of the UK Government's Red Tape Challenge (RTC) initiative²
- To rationalise and equalise the penalties and offences for food safety and for food hygiene
- To give effect to the European Commissions package of Regulations for the hygienic production of sprouts and seeds intended for sprouting to safeguard public health

The FSA conducted a formal 6-week public consultation from 02 September 2013 to 14 October 2013, seeking comments on the draft 2013 statutory instrument and the changes in sanctions and powers. (Further consultation was carried out in relation to the amending regulations).

² A programme undertaken by the 2010 Coalition Government that offered businesses and the general public the opportunity to challenge the Government on regulation.

The consultation was published on the FSA website and stakeholders were emailed with the link to the site. Stakeholders contacted included major industry organisations, organisations representing local authority enforcers and the not-for-profit sector – 15 responses were received. Impact assessment³ accompanied the consultation, asking stakeholders to comment on the FSA’s preliminary analysis of the costs and/or benefits of:

- The consolidation of the national food safety and food hygiene law; and
- The new hygiene regulations for seeds and seed for sprouting sector.

No significant impacts were identified as a result of the consolidation, including the rationalisation of the offences and penalties.

3. Scope

As part of the Government’s commitment to review provisions in secondary legislation that regulate businesses, the 2013 Regulations, and each of the four subsequent amending Regulations, require the FSA to undertake statutory review and set out the conclusions in a report within five years of the measure coming into force.

A combined, light-touch, review was considered proportionate for these SIs, reflecting the low impact identified in the regulatory impact assessments and the FSA’s view on the continued need and effectiveness of the Regulations.

The bulk of the 2013 Regulations is concerned with providing enforcement provisions for directly applicable EU legislation. This legislation has been routinely considered and updated by the EU Commission - with input and agreement from the UK whilst an EU Member State (and the then other Member States) and has been given effect in the UK through ambulatory reference. The requirements which the SI enforces are all considered to remain necessary for the protection of public health and consumers’ interests.

³ https://www.legislation.gov.uk/ukia/2013/194/pdfs/ukia_20130194_en.pdf

The 2013 Regulations also provides Schedules⁴, some of which contain national law providing requirements for businesses for the following areas:

- Bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar (Schedule 3)
- Temperature control requirements (Schedule 4)
- Direct supply by the producer of small quantities of meat from poultry or lagomorphs slaughtered on the farm (Schedule 5)
- Restrictions on the sale of raw milk intended for direct human consumption (Schedule 6)
- Derogations relating to low throughput establishments (Schedule 7)

It should be noted that the Regulations were recently reviewed in order to fix inoperability's arising from the UK leaving the EU once the transition period ends. This is outside the scope of the PIR.

4. Objectives

The PIR considers whether the objectives of the 2013 Regulations (as amended) have been achieved, and whether they could be achieved by means that impose less regulatory burden. The Review also considers evidence provided by interested parties on the effectiveness of the regulations and the extent to which they remain relevant.

The PIR also reviews the offences and penalties in the 2013 Regulations (as amended) and specifically the inclusion of criminal offences, in line with the FSA's commitment to reduce reliance on criminal sanctions.

Stakeholder views were sought in the initial exploration with key stakeholders, and on the draft PIR via public consultation.

⁴ The Schedules also covered 'Definitions of EU legislation', 'Specified EU provisions' and 'Revocations'. The 'Special Health Mark' (Schedule 8) was revoked by SI 2014/2078)

5. Impact

No significant impacts were identified by the FSA when undertaking the consolidation and no significant impacts were highlighted by respondents during the formal consultation in 2013, or during the consultations of the amending Regulations.

It was anticipated that stakeholders should benefit from having all the rules on food safety and food hygiene contained in a single SI, instead of having to refer to separate domestic Regulations. This assumption was supported by comments made by respondents to the consultations. The Amendment regulations have reduced the benefits of the 2013 consolidated safety and hygiene regulation, but the FSA does not consider it necessary to carry out a further consolidation of these regulations at the present time.

Annex 2 contains the evidence base forming the 'Economic Analysis' undertaken. In summary this review determines that no substantial costs to businesses, enforcement bodies or consumers have been sighted. The post-implementation economic analysis identifies an overall saving of the consolidation exercise far in excess of the original forecasted figure identified in the FSA Impact Assessment produced for the 2013 Regulations.

6. Questions Asked and Collated Responses

In the development of this report, an informal consultation was carried out by the FSA which included Industry, Consumer and Central and Local Government stakeholders. The questions asked, and the responses received are detailed in Annex 3.

The draft report was then subject to public consultation on the FSA website, we asked seven questions, these and the summary of responses received relevant to this Post Implementation Review, are provided in Annex 1.

Consultation responses received to this PIR document in some instances go beyond the remit of the PIR – these comments will however be subject to the FSA's normal

consultation summary of responses reporting. Local Authority (LA) respondents also raised issues regarding enforcement provisions within the scope of this PIR namely:

- *Online sellers – concern that current powers do not ensure members of the public are informed when Hygiene Emergency Prohibition Notice (HEPN) are served.* This matter has been raised by LA's through the focus group forums. The FSA is working with other Competent Authorities to determine if similar approaches can be utilised. It is likely that this matter will be reviewed post January 2021 (end of Transition Period), as such matters may be affected by the negotiated outcome and Northern Ireland protocol.
- *Remedial Action Notices – ability to use these for all premises (not just those requiring 'Approval'), particularly for short-term intermittent issues which could be resolved prior to the current 3-day turn around for Hygiene Emergency Prohibition Notice/Order.* Again, this matter has been raised through the Focus Group Forums and FSA is considering the appropriate response. It is likely that this matter will be reviewed post January 2021 (end of Transition Period), as such matters may be affected by the negotiated outcome and Northern Ireland protocol.
- *Range of Enforcement Tools - Increasing these to include Compliance Notices, Fixed Penalty Notices, Enforcement Costs Recovery Notices with criminal sanctions remaining available. This would allow for flexibility in enforcement approach based upon the individual circumstances of the case and the LA's own enforcement policy.* As explained below (see Chapter 8. Enforcement) – on-going review actions are being discussed. Further consideration of proposals is required and is being considered as part of a wider review of regulatory enforcement and sanctions to address non-compliance with food and feed law. This will likely include consideration of the negotiated outcome of the Transition Period and the Northern Ireland Protocol.
- *Regulation 29 (Food which has not been produced, processed, or distributed in accordance with the Hygiene Regulations can be subject to a notice as it fails to meet the food safety requirements detailed in Section 9. of the Food Safety Act 1990 – 'Inspection and Seizure of suspected food'), currently does not allow for issues of traceability to be included on the notice, therefore where non-compliance is found, the options are to use an informal approach or prosecute.* We have identified this as an issue – at the next update of these regulations the possibility of

extending Regulation 29 to include traceability requirements under Regulation (EC) No. 178/2002 will be consulted on with a view to introduction

- *Limitations in using measures such as Hygiene Emergency Prohibition Notice (HEPN)/ Hygiene Emergency Prohibition Order (HEPO), due to the current definition given to the pre-requisite 'health risk condition' there is a perceived inadequacy of current enforcement sanctions. There is no ability to use immediate action to prohibit on-going and future acts or omissions, if they do not involve the 'use for the purposes of the business of any process or treatment', as currently required to meet the 'health risk condition'. We have identified this as an issue – at the next update of these regulations the possibility of extending the definition in regulation 7(2) to provide that any act or omission that causes any of the requirements of the Hygiene Regulations to be breached in such a manner that the sale of food, presents or would present, an imminent risk of injury to health will be consulted on with a view to introduction*

7. Consumer Perspective

Consumers rarely engage directly on the technical/legal requirements, for food safety and hygiene, however it is accepted that consumers expect a comprehensive, clear and robust regulatory framework as this is essential to underpin confidence in the UK food supply. There is little distinction made between national and European legislation when issues are raised by consumers.

The FSA carries out extensive routine consumer engagement with stakeholders (via surveys, research, etc.) to understand consumers' concerns and interests in relation to food, to best represent these in our approach to the development and delivery of regulatory requirements. Questions from consumers are commonly on the safety of certain practices, particularly those that have received media attention, rather than the legislation.

The FSA publishes the results of its public attitudes tracker which has been running on a bi-annual basis since 2010. The findings are based on 2,150 interviews from a representative sample of adults aged 16 and over across England, Wales and Northern

Ireland. Questions cover several topics of interest for the Agency, including concern about food safety issues, awareness of food hygiene standards, awareness of the FSA and its responsibilities, trust in the FSA and the food industry, and confidence in food labelling. At Wave 18 (May 2019), a new set of questions were added to monitor trust in the FSA and the wider food system. Some of the key and relevant findings are given below:

- The top food safety issue of concern was ‘Food Hygiene when Eating Out’
- 62% of respondents said that they thought the food system was regulated fairly
- Reported concerns have continued to decrease slightly over time, indicating a general decline in concern about food safety in UK food outlets

No consumer responses were received in relation to the Consolidated SI, in preparation of this PIR or to the formal consultation of the draft PIR.

8. Enforcement

In England, the 2013 consolidation exercise reduced the number of enforcement authority powers of entry (from 4 to 3); the number of offences was reduced (subsuming specific offences into a more general breach of EU requirements); and fines rationalised to realise reduction of burden on FBOs and provide consistency of approach.

Criminal sanctions for food and feed offences are always an action of last resort by local authority food enforcement officers, or where food business operator behaviour or offences are considered severe enough to warrant criminal prosecution. Authorised officers are required to have regard to a hierarchy of enforcement when dealing with non-compliance and, subject to the severity of the offence, their first course of action is to seek compliance through education and information, moving to issuing an improvement notice where this approach does not lead to a change in business behaviour.

The Regulations provide default provisions so that enforcement action can be correctly directed and provides a statutory defence of due diligence to protect responsible FBOs. There is also a right of appeal to the magistrates’ court and where appropriate the Crown Court.

The harmonisation of enforcement including fines for serious ‘food safety’ and ‘food hygiene’ offences which are often inextricably linked acknowledged widely held views that there was no good reason for the continued difference. Although the maximum financial penalty on summary conviction for food safety offences was reduced from £20,000 to £5,000, the ability for Magistrates Courts to refer to the Crown Court for sentencing was maintained and extended to all applicable offences allowing for penalties of up to 2 years imprisonment and an unlimited fine for the most serious offences. Due diligence defences were maintained balancing the safety of consumers with the rights of businesses not to be convicted where they have taken all reasonable care to ensure compliance.

FSA reviewed the Food Safety and Hygiene (England) Regulations 2013 during the development of the Official Feed and Food Controls (England) (Miscellaneous Amendments) Regulations 2019, This was in-line with obligations to UK Ministers to reduce the reliance on criminal sanctions in England.

The purpose of this review was to identify whether criminal sanctions could be reduced and whether there were gaps in the enforcement hierarchy. Engagement was carried out with LA officers, via the Food Hygiene and Food Standards Focus Groups (FH/FSFG), to consider proposals identified as possible options to meet the FSAs obligations. The focus groups provided valuable feedback identifying opportunities and issues of concern. Based on the evidence provided by LAs it was decided that further consideration of proposals is required and is being considered as part of a wider review of regulatory enforcement and sanctions to address non-compliance with food and feed law.

9. Comparison of Enforcement of the legislation in EU Member States

In England (as well as Scotland, Wales and Northern Ireland) EU harmonised legislation is enforced by means of Statutory Instruments which provide penalties and enforcement powers for infringements. We reviewed current and past FSA commissioned research materials concerning the delivery of ‘Official Food & Feed Controls’ across the EU in order to assess major disparities in enforcement of the EU legislation. In reviewing available materials, we have established that the approach to enforcement is consistent in that:

- Member States (MS) either deliver this EU legislation centrally or as in the UK across a network of Central and Local Government departments
- Approaches to enforcement are reasonably consistent across MS – in utilising risk-based intervention frequencies, using similar staged enforcement systems, i.e. advice, issuing formal notices and prosecution, as necessary. Two MS (Denmark and France), are also currently using on the spot fines or similar for infringements
- Approval/registration of Food Business Operators (FBOs) is similar across MS with most using on-line registration facilities and allowing operation of registered FBO's before the first inspection
- Powers of entry and authorised officer requirements are also reasonably consistent across MS.

We do not believe there is any evidence of unnecessary or disproportionate burdens in the enforcement of the EU regulations in England.

Schedule 3 to the Regulations allows for the bulk transport of raw sugar in receptacles, containers or tankers which are not exclusively used for foodstuffs provided hygiene requirements are observed. This offers a practical and flexible approach for bulk transporters to conduct their undertakings in an efficient manner.

Schedule 4 to the Regulations concern temperature control requirements in relation to the hygiene and safety of foods, concerning:

- Chill holding and general exemptions from requirements, upward variation, and tolerance periods all of which ensure food safety whilst accepting the practicalities of food transport, storage, delivery, and display
- Hot holding including defences for non-compliance.

This schedule provides benefit to small and micro food businesses who can rely on the prescriptive requirements rather than undertaking their own scientific food safety assessments in relation to temperature control. There is also flexibility to allow deviation where the FBO has well-founded scientific assessment of the safety of the food at temperatures used.

Schedule 5 to the Regulations provides FBOs with flexibility in relation to the direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm.

Schedule 6 to the Regulations provide restrictions on the sale of raw milk intended for direct human consumption, this schedule allows for this practice whilst ensuring that scientifically evidence-based controls are in place to improve food hygiene and safety. Following a review by the FSA Board, we produced guidance (in early 2020) to help food business operators who are producing Raw Drinking Milk (RDM) to control these risks and comply with the relevant legislation, in particular to have an effective Food Safety Management System in place, verified by carrying out regular tests for pathogens which can be found in RDM. The FSA continues to monitor and review the effectiveness of controls and will take steps to strengthen these controls if required.

Schedule 7 to the Regulations concerns historical derogations granted to certain low throughput slaughterhouses. These derogations make provisions for smaller slaughterhouses licensed before 31 December 2005 with lesser facilities to be compliant through meeting equivalent safety standards. The derogations concern the provision of detained-meat facilities, and cleaning, washing and disinfection facilities for livestock vehicles. Post Implementation Reviews⁵ of these two derogations were undertaken in 2017, responses received at this point led to the conclusion that the small percentage of the Industry sector using these derogations depended upon them to operate economically, the controls around the derogations are sufficient and therefore at this point should not be changed. Annex 5. summarises the questions asked, and responses received.

The principles and requirements of EU general food safety law are set out in Regulation (EC) 178/2002 and the requirements of microbiological food safety in the EU food hygiene regulations⁶. Regulation (EC) 178/2002 establishes and requires that: -

⁵<https://www.food.gov.uk/news-alerts/consultations/views-wanted-on-review-of-two-exemptions-currently-under-the-food-safety-and-hygiene-england-regulations-2013>

⁶ The basic EU food hygiene regulations are Regulation (EC) 852/2004 which lays down general food hygiene rules for all food businesses; Regulation (EC) 853/2004 which lays down specific hygiene rules for products of animal origin; Regulation (EC) 2073/2005 which lays down microbiological criteria for foodstuffs and Regulation (EC) 2075/2005 laying down specific rules on official controls for *Trichinella* in meat. There are a number of other Regulations which amend, implement or provide derogations from these Regulations and some standalone Regulations.

- ‘unsafe’⁷ food must not be placed on the market
- suitable and accurate information must be provided to consumers
- there must be traceability of food; in that food businesses must be able to identify any supplier or food businesses they have supplied; and
- food businesses must both inform the competent authorities and immediately withdraw food from the market if they have a reason to believe that their food is not safe.

The EU food hygiene regulations place requirements on food businesses to produce and handle food safely. They also place requirements on competent authorities⁸. The regulations include the following requirements:

- registration or approval with the competent authority depending on the food business establishment’s activities
- food safety procedures based on HACCP principles⁹
- food safety rules on foodstuffs, premises, equipment, transport and food handler hygiene and training throughout the food chain, starting with primary production (e.g. fishing and farming)
- application of basic common hygiene requirements, with specific rules for the manufacture of products of animal origin; and
- details of competent authority responsibilities in certain areas.

At the 2013 consolidation, consideration was given to replacing The General Food Regulation 2004 (as amended) and The Food Hygiene (England) Regulations 2006 (as amended) with guidance. This option was rejected because, both European treaty obligations and the EU Regulations themselves require the UK to ensure that directly applicable EU regulations covering food safety and food hygiene can be enforced in all parts of the UK. Guidance would not have had any legal authority to enable enforcement action to be taken against non-compliant businesses. This would have resulted in the following concerns:

⁷ The definition of ‘unsafe’ is set out at Article 14 and means both ‘injurious to health’ and ‘unfit for human consumption’.

⁸ The ‘competent authority’ in the UK will be the local authority in all cases except establishments where the FSA has a veterinary presence, or where the FSA has a central role to play such as general oversight of enforcement, dissemination of information or liaison with the European Commission.

⁹ HACCP-based principles are not required for farming activities but procedures giving consideration to food safety hazards in farming are still required.

- The potential for sale or supply of unsafe food and/or the provision of misleading information about food being supplied, impacting disproportionately against vulnerable groups such as the elderly or persons with long-term health problems.
- Adverse impact on food businesses that are compliant and therefore put at a disadvantage. Potential damage to the market by reducing consumer confidence in the food sector.
- Concern regarding UK food businesses being prevented from selling products to food businesses located in EU Member States.

10. Conclusion

These Regulations are a fundamental element of food safety law and provide enforcement authorities with the tools to ensure food businesses meet their obligation to provide safe food. Our analysis is that the consolidated SI continues to deliver reduced administrative burdens through the simplified presentation of consolidating Food Safety and Food Hygiene provisions. Accepting there are now four amending SIs; at present the FSA does not perceive a significant benefit in pursuing a further consolidation. The SI has the main function of implementing the enforcement of directly applicable EU regulations and our view is that this remains necessary, fully effective and fit for purpose. A further review of the regulations and the over-arching retained EU law should be carried out, at an appropriate time following the conclusion of the Transition Period. These Regulations will be considered as part of a wider review of regulatory enforcement and sanctions to address non-compliance with food and feed law.

In general, stakeholder responses received have supported the FSA's view and provided supporting evidence that The Food Safety and Hygiene (England) Regulations 2013 are helpful in combining Food Safety and Food Hygiene controls and the system has become more simplified. As explained in Chapter 6, Local Authority consultation respondents have raised some issues with enforcement provisions, the FSA have identified from these two specific issues which will be reviewed and debated for inclusion in the next review of these Regulations – including traceability under Regulation (EC) 178/2002 as an option for the regulation 29 notice, and extending the definition under regulation 7(2) to provide that to fulfil the 'health risk condition', **any act or omission** that causes any of the requirements

of the Hygiene Regulations to be breached in such a manner that the sale of food, presents or would present, an imminent risk of injury to health. Other issues raised in relation to enforcement provisions as discussed in Chapter 6, will be reviewed as part of the on-going and larger project to consider proposals as part of a wider review of regulatory enforcement and sanctions to address non-compliance with food and feed law.

Annex I - Consultation on Draft PIR – Summary of Questions & Responses

Question 1 Do you agree with the view, that the consolidated SI created a simplified system? Please explain your response with evidence where possible

We received three responses to this question, all agree that consolidation generally simplifies the system however there should be recognition of the administrative burden on Local Authorities such as updating officer authorisations and references to the new legislation.

Question 2 How significantly do you feel the subsequent amendments to the consolidated SI reduced the benefits of the original consolidation?

We received two responses to this question, there was no indication that the initial benefit of consolidation was reduced by the subsequent amending Regulations.

Question 3 Do you agree with the view, that there were no significant impacts resulting from the consolidated SI? Please explain your response with evidence where possible.

We received two responses to this question, no significant impacts were highlighted.

Question 4 Do you agree with the FSA conclusion that the consolidated SI remains effective and relevant in meeting the intended objectives? Please explain your response with evidence where possible

We received two responses to this question both agreed with our conclusion

Question 5 Do you agree with the FSA conclusion that there is no evidence of unnecessary or disproportionate burdens in the enforcement of the EU regulations in England?

We received two responses to this question both agreed with our conclusion

Question 6 We would welcome any additional comments or views in relation to the consolidated SI or the proportionality of this PIR? Please explain your response with evidence where possible.

We received no responses to this question

Question 7 Do you have any views on the use of sanctions generally, or the inclusion of criminal sanctions, in The Food Hygiene and Safety (England) Regulations 2013. Please explain your response with evidence where possible.

We received four responses to this question areas of relevance specifically to this PIR:

- Online sellers – current hygiene powers do not ensure members of the public are informed when HEPN served.
- RANS – ability to use for all premises particularly for short term intermittent issues which could be resolved prior to current 3-day turn-around for HEPN/HEPO.
- Reg 29. Does not allow for issue of traceability to be included on notice, therefore where non-compliance found, the options are to use an informal approach or prosecute.
- Perceived need to carry out a further review in 2021 to take into account the proposed regulatory changes coming in from 1 January 2021 with the implementation of the Border Operating Model for GB and the Northern Ireland Protocol.
- Increasing the range of enforcement tools to include Compliance Notices, Fixed Penalty Notices, Enforcement Costs Recovery Notices with criminal sanctions remaining available. The legislation should allow for flexibility in enforcement approach based upon the individual circumstances of the case and the LA's own enforcement policy.
- Limitations in using measures such as HEPN/O, due to the current definition given to the pre-requisite 'health risk condition' inadequacy of current enforcement sanctions to enable immediate action to prohibit on-going and future acts or omissions, if they do not involve the 'use for the purposes of the business of any process or treatment', as currently required to meet the 'health risk condition'. Rather, since the risks arise due to acts or omissions in handling, practice, or procedures, seemingly the imminent risk of injury to health is ignored. Our proposed solution to the above would be to reframe the definition of 'health risk condition' accordingly, so the use HEPN/O and RAN where appropriate are not so unduly restricted. We understand that the regulation 7(2), reflects the Food Safety Act 1990 section 11 (2), and consider that similar reframing of the definition in Food Safety Act 1990 is also warranted. It has

been suggested that simply including 'any act or omission that cause any of the requirements of the Hygiene Regulations to be breached in such a manner that the 'sale' of food, presents or would present, an imminent risk of injury health', might be a good catch-all approach.

Annex 2. Economic Analysis

Evidence Base

Implementation of Option 2 - Consolidation of *The General Food Hygiene Regulations 2004 (as amended)* and *The Food Hygiene (England) Regulations 2006 (as amended)*.

The economic analysis of the post implementation review analyses actual recorded data over an 8-year period from 1st April 2011 to 31st March 2019 in determining an economic cost/benefit analysis. Whereas, the impact assessment for implementation of option 2 i.e. consolidation of regulations uses estimated data covering the period from 2011 i.e. 1 year before consolidation to the year 2021, which is over a ten-year period.

Costs to Industry- *Familiarisation Costs*

The consolidation of The General Food Hygiene Regulations 2004 (as amended) and The Food Hygiene (England) Regulations 2006 (as amended) into the FSH regulations 2013 did not change any of the requirements on food businesses and therefore the associated familiarisation costs to industry are assumed to have been negligible as originally forecasted.

Costs to Enforcement - *Familiarisation Costs*

Similarly, the consolidation into the FSH regulations 2013 did not change any of the requirements on food businesses and therefore it is assumed that the associated familiarisation costs to enforcement teams are also assumed to have been negligible as originally forecasted.

Costs to Consumers

The costs to consumers are not easily quantified. However, it is our assumption that these have been negligible as originally forecasted.

Benefits to Industry - *Reduced familiarisation time for new entrants into the sector*

Simplification benefits to industry as a result of the consolidation of national food legislation are not easily quantified. However, post implementation concerns from new entrants arising from consolidation have not been registered. It is therefore assumed that familiarisation with one single principal statutory instrument instead of the two original regulations and several amending instruments has benefited the industry.

The original impact assessment analysis of historical data on new entrants into the sector showed that, over the period from 2011-2012, the average number of new business entering the sector was 6,700 per annum. Data on new entrants post implementation is not readily available. However, data of total number of food establishments is available.

	2011/2012	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019	Total
Total no. of establishments in England	367,406	375,663	508,630	512,704	517,171	517,686	515,471	568,324	
Difference compared to 2012/2013			132,967	137,041	141,508	142,023	139,808	192,661	886,008

Table 1: Summary of total number of food establishments in England)

An analysis of Table 1 shows a significant increase in the number of food establishments in the period covering 1st April 2013 to 31st March 2014. Assuming this increase is due to new entrants to the food sector we can assume that since implementation to 31st March 2019, there have been 886,008 new entrants as a result of consolidation.

Taking forward the original methodology used to calculate the benefit to industry i.e. to assume that it takes one manager per business one hour to read and familiarise

themselves with the legislation and that before consolidation this was two hours per business.

Using the methodology used in the impact assessment for monetising this benefit as a time saving, i.e. by multiplying the time saved per officer by the wage rate of the business manager (£26.1011) and then again by the number of new entrants into the sector per annum (6,700). This generated a total time saving per annum to industry of £174,870 in the impact assessment. However, using the same wage rate (£26.1011) multiplied by the total assumed new entrants since 2012 a total saving of £23,125,786 to industry can be determined. This is an average saving per year to the industry of £3,854,298.¹⁰

Benefits to Enforcement - *Reduced familiarisation time for new entrants into the sector*

It was originally assumed that there may be simplification benefits to enforcement officers as a result of the consolidation of national food legislation. As with benefits to industry any local authority officer taking up employment in the sector would have to familiarise themselves with just a single principal statutory instrument instead of two and a number of amending instruments.

The original impact assessment indicated that the total number of officers had decreased over previous years but had not advised the total number. It was assumed at the time that this would be representative of the sector in the future. An analysis of current enforcement officers has shown that on average over the past three years there have been 1258.43 officers in post in England. As previous data is not available this benefit has not been monetised and we are therefore not able to compare the level of benefit with the original impact assessment.

	2011/2012	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019	Average
Total no. of FTE local authority officers in England	1998					1275.02	1245.23	1255.04	1258.43

Table 2: Summary of Full Time Equivalent local authority officers in England. (Source LAEMS – [UK food hygiene data](#))

Benefits to Consumers

It was envisaged that the consolidation would not result in any substantial benefits to consumers. We are not able review whether consolidation of the regulations has had an impact on consumers.

Summary of total costs and benefits of consolidation

No substantial costs to businesses, enforcement or consumers had been envisaged in the original impact assessment. It was also envisaged the consolidation of the national food legislation into one statutory instrument would generate benefits to businesses and enforcement teams in terms of time saving to new entrants into the sector. The original impact assessment calculated an indicative estimate of an annual time saving to industry

¹⁰ Source – Annual Survey of Hours and Earnings (Source Wage rate(<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/2012-03-21>))

of £174,870 with an estimated value of £1.5m over a ten-year period. It was therefore the assumption that the consolidation would have a net beneficial impact.

	Year 0 2011/2012	Year 1 2012/2013	Year 2 2013/2014	Year 3 2014/2015	Year 4 2015/2016	Year 5 2016/2017	Year 6 2017/2018	Year 7 2018/2019	Year 8 2019/2020	Year 9 2020/2021	Total
Time Saving	£174,870	£174,870	£174,870	£174,870	£174,870	£174,870	£174,870	£174,870	£174,870	£174,870	£1,748,700

Table 3: Summary of estimated total benefits (Impact Assessment)

	Year 0 2011/2012	Year 1 2012/2013	Year 2 2013/2014	Year 3 2014/2015	Year 4 2015/2016	Year 5 2016/2017	Year 6 2017/2018	Year 7 2018/2019	Year 8 2019/2020	Year 9 2020/2021	Total
Time Saving			£3,470,584	£3,576,921	£3,696,514	£3,706,957	£3,649,143	£5,028,664			£23,125,786

Table 4: Summary of actual calculated total benefits (Post consolidation)

The post implementation review can confirm that no substantial costs to businesses, enforcement or consumers have been sighted.

Although the monetisation of the benefits attained from consolidation of national food legislation into one statutory instrument may be subject to interpretation. We can confirm that new entrants and enforcement teams have benefitted. This is shown in the increase in the number of food establishments recorded since 2013.

The post implementation economic analysis suggests that up to March 2019 a total saving of £23,125,786 can be assumed, which is substantially greater than the original forecast of £1,748,700. An 87% increase on the estimated figure.

The increase in the number of food establishments can be attributed to the increase in the number of small sized food businesses.

Annex 3. Pre-Consultation Questions, Responses and Comments

No.	Question	Response	FSA Comment
1	To what extent do you feel that these Regulations are achieving their intended objective in relation to the requirements for food businesses to supply safe food, for the traceability of food and for appropriate information on food for consumers?	I think they are achieving their intended objective	Noted
1.a	To what extent do you feel that these Regulations are achieving their intended objective in relation to the requirements for food businesses to supply safe food, to consumers?	I feel the two tier system in the UK with FSA inspection of meat plants and LA inspections of all other food business – causes a big divide in compliance between meat plants, the FSA auditors audit a lot closer the regulations and appear to have a better understanding than EHO's who are very under resourced and do not have such a good understanding of the regulations.	Noted – all LA officers are required to achieve competence and demonstrate this continually through appropriate CPPD.
2	Do the regulations enable you to take the necessary enforcement actions to protect consumers? If there are deficiencies, please provide evidence.	To a certain extent they enable necessary enforcement actions to be taken but I would suggest that the use of RAN's for non-approved premises be extended as these provide an alternative mechanism for dealing with deficiencies.	Unable to review policy as part of this process however official controls are currently being reviewed under other streams of work being undertaken within the FSA and EU level.
3.	Can you give examples of where the Regulations are providing benefits or set any overly burdensome obligations on businesses, including SMEs? If yes please elaborate.		
4	Are the powers of entry provided by the Regulation sufficient? Do you have evidence of any specific challenges/problems with entry powers?	Yes	Noted
5	Are the offences sufficient to ensure protection of consumers? Please provide evidence where you feel this is not the case.	Yes	Noted

6	Has the rationalisation / equalisation of fines for 178/2002 offences with 852/2004 and 853/2004 offences (of general food safety and food hygiene offences) had any impact on prosecutions or how you prepare them? Have there been any consequences of this new system of fines?	No consequence	Noted
		Nothing measurable but will make it easier to explain penalties and consequences to food penalties and easier for courts to apply rarely used legislation.	Noted
7	Have there been any unintended consequences of the legislation such as costs/burdens or benefits which were not highlighted in the Impact Assessment? If yes, please elaborate.	Not that I am aware of	Noted
8	In the Impact Assessment we assumed that as the consolidation exercise did not introduce any new requirements, there would not be any significant impact on costs associated with familiarisation. Was this assumption correct	Yes	Noted
8.b.	In the Impact Assessment we assumed that one official per business would have invested 60 minutes reading and familiarising themselves with the Regulation. Does this assessment of the familiarisation time reflect your experience? Please provide evidence where available to support your response		
9	Are there any other one-off or ongoing costs/benefits to local authorities as a direct result of the Regulations that should have been considered? Please provide evidence where available to support your response	Not sure	Noted
9.b	Are you aware of any other one-off or ongoing industry costs/benefits as a direct result of the Regulations that were not identified in our Impact Assessment? Please provide evidence where available to support your response		

10	Has the consolidation of food safety and food hygiene regulations resulted in any positive or negative impacts (e.g. are they easier to use or have they become less clear as a result of the consolidation etc.)? If possible please provide examples or other evidence to support your view.	Neutral	Noted
		I am not sure the general public even know about these regulations even before or after the joining of the reg's. It also strongly possible that even Small and Medium size food business know of the regs .	Noted
		Not aware of any difficulties, it is obviously easier for food businesses and enforcement authorities to have reference to just one piece of principal (with the caveat that very technical legislation needs to exist for specific goods e.g. jam composition and shellfish) legislation. We are not aware of any measurable benefits.	Noted
		Not significantly	Noted
10.b	How does the implementation of the EU Regulations in the UK compare with other Member States? Does the UK's implementation lead to increased costs or benefits for UK businesses? Please provide evidence where available to support your response		
11	Are you aware of any issues arising from England having had a consolidated SI and so pursuing different legal arrangements to Scotland, Wales and Northern Ireland? If so can you please give examples of this.	Not aware of any issues	Noted
		I am not sure the general public even know about these regulations even before or after the joining of the reg's. It also strongly possible that even Small and Medium size food business know of the regs.	Noted

		It makes it more challenging for a national co-ordination group such as FHFG to issue tailored guidance or create case studies because of all the different permutations of legislation have to be cited and accounted for.	Noted
12	Do you have any further comments, evidence or information of relevance to this review?	No. I wasn't aware that this PIR had been circulated – maybe it needs circulating again.	Noted
		No	Noted
		BMPA members in general do not have any serious issues with the consolidation	Noted

Annex 4. Pre-Publication Consultees

Enforcement Authorities

Local Authority Knowledge Hub – Food Hygiene Forum Group
Local Authority Knowledge Hub – Food Standards & Labelling Group
West Norfolk

Industry

Food & Drink Federation
British Retail Consortium
British Meat Producers Association

Consumer

Which Magazine
Independent Food Consultant/Auditor (name withheld)

Annex 5. Schedule 7 PIR Consultation – Summary of Questions & Responses

Question Topics

To what extent is the existing exemption working?

Is the exemption still needed?

Is the current exemption from the detained meat facilities/requirement for facilities for cleansing & disinfection of livestock vehicles - still the most appropriate approach?

If the exemption in the regulation is still needed, could it be improved?

Responses received

Generic responses received from Industry bodies provided the following feedback:

- Detention facilities – not aware of provision to have separate facilities is being used. Advised that no problems with detention have come to light. Businesses taking advantage of the exemption would not be viable were they removed, forcing closure and loss of small ‘local’ slaughtering facilities, affecting ability for local farmers to utilise and impact on transport/welfare matters.
- General comment – better to not consider changing the exemption while the EU Exit situation is still to be finalised and future legislative landscape unclear.
- General comment - wish to see the exemption for low throughput establishments maintained. Farmers will be supplying these businesses with prime livestock so we would not wish to see additional costs placed on these low throughput abattoirs that would threaten their commercial viability

Background

It is estimated that a maximum of 19 ‘low throughput’ establishments utilise the derogation in relation to detained meat facilities. Lack of space was identified as the main obstacle to providing such facilities – therefore without the exemption the FBO would need to rent/build new premises, potentially in a different geographical location.

It is estimated that less than 4 ‘low throughput’ establishments utilise the derogation in relation to facilities for the cleansing and disinfection of livestock vehicles. Again, available space was identified as the main obstacle for providing such facilities – therefore without the exemption the FBO would need to rent/build new premises, potentially in a different geographical location.