Title: Post Implementation Review of The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013	Post Implementation Review
PIR No: Click here to enter text.	**Date: 29/03/2019**
Original IA/RPC No: Click here to enter text.	**Type of regulation: EU**
Lead department or agency: Food Standards Agency	**Type of review: Statutory**
Other departments or agencies: Click here to enter text.	**Date measure came into force: 31/10/2013**
	Recommendation: Keep
Contact for enquiries: **Nasreen Shah**	**RPC Opinion:** Choose an item.

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

The England statutory instrument (SI) was introduced to simplify the system of food safety legislation, consolidating 5 separate food additives SIs, under the Red Tape Challenge Initiative[1]. The consolidated SI also introduced compliance notices for non-food safety related contraventions and updated the food additives legislation to reflect changes to the EU Regulation 1333/2008 (establishing Annexes II and III; and to amend the flavouring legislation in relation to a revised transitional measure).

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 local authority enforcement monitoring, formed the evidence basis for the initial review and analysis. Stakeholder engagement and public consultation was undertaken to challenge and support the FSA assumptions. *(An Impact Assessment was not produced for the consolidated SI, as the measure was deemed trivial and mechanical).*

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

[1] An innovative cross-government programme to tackle the stock of unnecessary and over-complicated regulation, saving taxpayers money, and supporting economic growth by increasing business competitiveness. The programme offered businesses and the general public the opportunity to challenge the government on regulation.

The EU measures and the England SI have been effective in meeting its objective of putting in place a simplified system of food safety legislation through consolidation, introducing compliance notices for minor non-food safety related contraventions and providing guidance to assist local authorities on the use of civil sanctions. Moreover, the purpose of the Regulations continues to be necessary; fully effective and fit for purpose.

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) That the consolidation of 5 separate national SIs into a single SI would benefit industry by simplifying the rules, and that compliance notices for for certain minor breaches of the Regulations (non-food safety related breaches) could be used in place of criminal sanctions.
5. Were there any unintended consequences? (Maximum 5 lines) No. The England SI provides for the execution and enforcement of the EU legislation and the consolidation of existing national legislation of food additives, flavourings, enzymes and extraction solvents into a single SI, thereby simplifying the system of food safety legislation.
6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines) No. The England SI does not impose any national rules over and above the EU harmonised legislation they implemented (i.e. there is no 'gold-plating'); they merely provide 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.

Post Implementation Review

The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 five years after implementation

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.

1.1 The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013[2] ("the 2013 Regulations) make provisions for implementing EU legislation on food additives (this includes flavourings, enzymes and extraction solvents) and for their enforcement. The 2013 Regulations also revoked and re-enacted, in whole or in part, the following legislation within the FSA's remit into a single consolidated Statutory Instrument (SI).

(a) The Extraction Solvents in Food Regulations 1993[3];
(b) The Smoke Flavourings (England) Regulations 2005[4];
(c) The Food (Suspension of the Use of E128 Red 2G Food Colour) (England) Regulations 2007[5];
(d) The Food Enzymes Regulations 2009[6];
(e) The Food Additives (England) Regulations 2009[7];
(f) The Flavourings in Food (England) Regulations 2010[8].

Thus, the changes to the Regulations were consolidated, resulting in a single Statutory Instrument.

1.2 Prior to the 2013 Regulations, criminal sanctions were in place for all breaches of food safety / non-food safety related contraventions. The 2013 Regulations reduced the number of those criminal sanctions for certain minor breaches of the Regulations and introduced the use of compliance notices for non-food safety related breaches; such as labelling of food additives, flavourings and enzymes. For example, *Requirements for the labelling of flavourings intended for sale to the final consumer.*

1.3 However, where a business fails to comply with the compliance notices served on them, a 'backstop criminal offence' would then apply.

[2] SI 2013 No. 2210
[3] SI 1993 No. 1658
[4] SI 2005 No. 464
[5] SI 2007 No. 2266
[6] SI 2009 No. 3235
[7] SI 2009 No. 3238
[8] SI 2010 No. 2817

1.4 This Post Implementation Review (PIR) fulfils the Food Standards Agency's (FSA's) obligation to carry out a review of The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 ("the 2013 Regulations") within five years of the Regulation coming into force. To this end, the FSA has collated evidence of the known views and experiences of key stakeholders, including any costs and benefits arising from its implementation.

1.5 This light-touch PIR sets out the objectives of the consolidation exercise, the extent to which these have been achieved and whether they could have been achieved by means that impose less regulatory burden. The Review also considered evidence provided by interested parties on the effectiveness of the 2013 Regulations and the extent to which they still remain relevant.

1.6 This report on the PIR of the 2013 Regulations assessed the actual effect of the Regulations, 5 years after they were enacted; principally by collating evidence of the known views and experiences of key stakeholders and whether the objectives of the 2013 Regulations have been achieved. It established that there have been no unintended impacts for stakeholders resulting from the implementation of the 2013 Regulations and the introduction of compliance notices was adequate for public health protection and for enforcement authorities carrying out enforcement action.

Conclusions and Recommendations

1.7 Based on the findings of the PIR, the FSA concludes that the 2013 Regulations continue to deliver reduced administrative burdens through the simplified presentation of a single SI in England. The England SI provides the execution and enforcement of food safety requirements in relation to food additives, flavourings, enzymes and extraction solvents, which remain necessary, fully effective and fit for purpose.

1.7.1 Stakeholder responses to the original 2013 consultation to consolidate the Regulations and in response to the FSA post implementation review support the FSA view on the impacts of the consolidated Regulations.

1.7.2 The FSA therefore recommends that the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 are retained without the need for further amendment at this time, other than for those proposed outside the scope of this review for the purpose of fixing inoperability, in relation to the UK exiting the EU.

2. Introduction and Background

2.1 The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, which came into force on 31st October 2013, consolidated all England SIs that related to food additives, flavourings, enzymes and extraction solvents, in force at the time into a single SI.

2.2 The aims of the consolidation exercise were as follows:

2.2.1 To introduce a simplified body of legislation for these substances, delivered under the UK Government's Red Tape Challenge (RTC) initiative[9].

2.2.2 To introduce the use of compliance notices for non-safety related offences for enforcement purposes.

2.2.3 To update the food additive legislation to reflect the establishment of Annexes II and III to the Regulation (EC) No. 1333/2008 on food additives and the removal of the existing transitional measures for the earlier legislation: Directive 95/2/EC for additives other than colours and sweeteners, Directive 94/36/EC for food colours and Directive 94/35/EC on sweeteners.

2.2.4 To amend the flavouring legislation to refer to a revised transitional measure.

2.2.5 To revoke The Food (Suspension of the Use of E128 Red 2G as Food Colour) (England) Regulations 2007 No. 2266.

2.3 The FSA conducted a public consultation from 10 April to 5 June 2013, seeking comments on the draft SI and the introduction of compliance notices for non-safety related contraventions.

2.4 The consultation was published on the FSA website and sent directly to key stakeholders (207) including food industry organisations, sector specific businesses (e.g. manufacturers of food additives, flavourings and enzymes), consumer groups, non-government organisations, enforcement bodies and

[9] An innovative cross-government programme to tackle the stock of unnecessary and over-complicated regulation, saving taxpayers money, and supporting economic growth by increasing business competitiveness. The programme offered businesses and the general public the opportunity to challenge the government on regulation.

other parties with an interest in food additive, flavouring, enzyme and extraction solvent legislation.

2.5 Eleven responses were received. Generally, the respondents supported the consolidation as it reduced the volume of legislation needed to be referred to and the majority supported the use of compliance notices (civil sanctions) for non-safety related contraventions.

2.6 Guidance was introduced for local authorities to aid their understanding of the use of civil sanctions shortly after this consolidation was published which addressed these concerns.

2.7 An impact assessment was not prepared for the consolidation of the 2013 Regulations as the changes were considered trivial and mechanical at the time, and no significant impacts were identified. A view supported by the consultation responses to the 2013 Regulations, with no significant impacts identified by respondents.

3. Scope

3.1 As part of the Government's commitment to review provisions in secondary legislation in England that regulate businesses, the 2013 Regulations require the FSA to undertake a PIR of the said Regulations and set out the conclusions in a report within five years of the measure coming into force.

3.2 A light touch PIR was considered proportionate for this SI based on the low impact understood to have arisen from the 2013 Regulations in England, which have the main function of providing enforcement provisions for EU legislation that was directly applicable in England prior to the UK's departure from the EU. The 2013 Regulations implemented the enforcement provisions of of food safety requirements in relation to food additives, flavourings, enzymes and extraction solvents, which are routinely considered and updated by the EU Commission - with input and agreement from Member States including the UK prior to exit. The FSA considers that the requirements remain necessary and relevant and that the England SI remains fully effective and fit for purpose. The FSA view is informed by routine engagement with industry and local enforcement authorities and monitoring of UK official controls and enforcement. Therefore, the level of evidence sourced is commensurate to the scale of impact identified for the consolidated 2013 Regulations.

3.3 Key stakeholders were consulted to collect preliminary evidence to support the FSA views on the implementation of the 2013 Regulations, which have been included in this report. The preliminary evidence gathering consultation included stakeholders who engaged with the FSA in 2013 and key interested parties.

4. Objectives

4.1 The PIR assesses the actual effect of the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations (SI 2013 No. 2210). The 2013 Regulations specify (in regulation 22(1-4)[10] that such a review of the operation and effect of these Regulations should be undertaken and a report with the conclusions published before the end of 5 years. The PIR also considers whether the objectives set out by the FSA for the consolidated legislation regarding food improvement agents (i.e. food additives, flavourings, enzymes and extraction solvents) in response to the Governments Red Tape Challenge (RTC)[11] have been achieved.

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

5. Impacts

5.1 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. No significant impacts have since been identified during this review of the regulations, including comments received through our engagement with key stakeholders.

5.2 It was anticipated that stakeholders should benefit from having all the rules on the use of these substances contained in a single SI, instead of having to refer to five separate national Regulations. This assumption was supported by comments received from respondents to the preliminary evidence gathering consultation and by respondents to the public consultation.

6. Stakeholder Responses

[10] http://www.legislation.gov.uk/uksi/2013/2210/pdfs/uksi_20132210_en.pdf
[11] http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/

In the initial development of this report, the FSA directly consulted 46 key stakeholders (a list of questions asked to stakeholders is attached at Annex I). Three responses were received, none of which identified any negative or unintended consequences on stakeholders resulting from the introduction of the Regulations.

6.1.1 All three respondents agreed that the consolidation had created a simplified system. In terms of impact, two respondents stated there were no significant impacts and the other was not aware of any. In relation to the introduction of compliance notices, two respondents indicated that compliance notices provided adequate consumer protection. One respondent noted that compliance notices provide FBOs with an opportunity to take corrective actions. No comments were received in relation to any other impacts from the Regulations.

6.1.2 For openness, and to challenge the FSA assumption further, the FSA launched a public consultation in November 2018. Two responses were received. Both respondents agreed that the consolidated SI created a simplified system and no significant impacts were noted as a result of this. They also agreed that the 2013 Regulations remain effective and relevant in meeting their objective.

6.1.3 The respondents generally agreed with the stakeholder comments received to the FSA's initial consultation with key stakeholder. However, there were contrasting views around the use of compliance notices. One enforcement authority felt that the use of compliance notices, in some situations served no substantive purpose, were often laborious and did not consider them to be an effective deterrent. The authority indicated a desire to see an option for criminal or other punitive sanctions where repeat breaches occur , even if subsequent compliance notices have been complied with.

6.1.4 Conversely another enforcement authority was fully supportive of the use of civil sanctions for non-safety related issues and acknowledged that adequate backstop criminal offences for serious breaches of the legislation were available, should they be required. However, the issues raised by the respondents are addressed in the FSA's guidance document for local authorities, which provides details on the use of compliance notices.

6.1.5 One authority commented that, given the complexity of the subject area of the Regulations, they felt that those familiar with the content would not find the consolidation too unhelpful.

6.1.6 One comment noted that local authorities should be given more freedom to tackle non-compliant businesses with less guidance from the FSA, who do not necessarily understand the local situation. The FSA has noted the comment for further consideration in how the FSA develops enforcement guidance for local authorities.

6.1.7 Criminal sanctions for food and feed offences are always an action of last resort by local authority food enforcement officers. 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 etc., their first course of action is to seek compliance through education and information, moving to issuing a compliance notice where this approach does not lead to a change in business behaviour. A prosecution is therefore the last stage approach to achieve compliance or where an immediate public health risk is presented.

6.1.8 *The FSA is currently considering how to reduce reliance on criminal sanctions across the breadth of food law in England and will be consulting on moving further towards civil sanctions in existing Regulations in due course. Compliance notices for non-food safety contraventions introduced in the 2013 Regulations, is an example of the civil sanctions we are looking to make more consistent use of in the future.*

7. Consumer Perspective

7.1 Consumers rarely engage directly on the technical requirements, such as those on food additives and enzymes in food, as they do not have the specialist knowledge required to make informed decisions about the appropriateness of regulatory requirements. Consumers generally want confirmation that there is comprehensive legislation in place to protect consumer health when such substances are used in foods. There is however, little distinction made between the national and the European legislation when issues are raised by consumers.

7.2 The FSA carries out extensive routine consumer engagement with stakeholders (via surveys, research, etc.), to understand consumers' concerns and interests in relation to food, in order to best represent these in

our approach to the development and delivery of regulatory requirements. The FSA also has a dedicated additives electronic mailbox for queries from consumers and industry from which it is able to draw out consumers' views on additives and other substances. Questions from consumers are commonly on the safety of certain substances such as sweeteners, particularly those that have received media attention.

7.3 Research carried out by the FSA on consumer perspectives on food additives and enzymes in food, indicated that consumers feel there is a need for clear, reliable, accurate and independent information, to be made available about food additives and enzymes; their use, and risks associated with them from sources which consumers trust. The research suggested that consumers trust independent scientists, healthcare professionals, teachers, celebrity chefs and the Government (when it is not perceived to have a close relationship with industry) on this issue. There is therefore, an important role for the independent FSA to play, to ensure these consumer needs are met. Consumer awareness of the food improvement agents regulatory framework is limited, but consumers expect Government to ensure they are adequately protected. The FSA publishes information about food improvement agents on its website to help consumers make informed decisions about the food they purchase.

7.4 We did not receive any direct responses from consumers to our public consultation on the Post Implementation Review for the 2013 Regulations.

8. Enforcement of the legislation in other EU Member States

8.1 In England (as well as Scotland, Wales and Northern Ireland) pre-EU Exit EU harmonised legislation is enforced by means of Statutory Instruments, which provide penalties and enforcement powers for infringements. We contacted a range of EU Member States (MSs), including Germany and Belgium, with whom we have close working relations in this area, as part of this review to ascertain how additives legislation is executed and enforced in those countries.

8.2 The approach to enforcement is similar in the MSs we contacted where additives, flavourings and enzymes are regulated under specific laws, which supplement EU harmonised requirements, or using the powers provided for in existing legislation. We do not believe there is any evidence of

unnecessary or disproportionate burdens in the enforcement of those EU regulations in England.

8.3 During the review of the 2013 Regulations, we have not come across any evidence that suggests the England implementation of the Regulations is materially different from the approach taken in EU Member States or has led to any unintended consequences that impact on stakeholders. Furthermore, there is no evidence that, overall, burdens on UK businesses complying with the 2013 Regulations exceed those on businesses complying with equivalent enforcement Regulations in EU Member States.

9. Conclusion

9.1 Overall, our considered view is that the 2013 Regulations continue to deliver reduced administrative burdens through the simplified presentation of a single SI in England. The England SI has the main function of implementing the enforcement of food safety requirements in relation to food additives, flavourings, enzymes and extraction solvents that were directly applicable prior to the UK's departure from the EU. The review supports our view is that the domestic instrument remains necessary, fully effective and fit for purpose.

9.2 Evidence gathered from stakeholder responses to the original 2013 consultation to consolidate the Regulations and in response to the FSA post implementation review support the FSA view on the impacts of the consolidated Regulations.

9.3 It is recommended that the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 are retained without the need for further amendment at this time, other than those proposed in order to fix inoperabilities in relation to the UK leaving the EU.

Annex I

List of Questions for Consultation

Q1. Do you agree with stakeholder responses to the preliminary consultation, that the consolidated SI created a simplified system? Please explain your response with evidence where possible.

Q2. Do you agree with stakeholder responses to the preliminary consultation, that there were no significant impacts resulting from the consolidated SI? Please explain your response with evidence where possible.

Q3. Do you agree with stakeholder responses to the preliminary consultation, that the introduction of compliance notices for non-food safety contraventions provide adequate consumer protection as well as opportunities [for food businesses] to take corrective action? Do you have any other views or comments in relation to the questions set out above in **6.1.3. a)**, **b)** and **c)**? Please explain your response with evidence where possible.

Q4. Do you agree with stakeholder responses to the preliminary consultation that the civil sanction introduced by the consolidated SI are appropriate and proportionate? Please explain your response with evidence where possible.

Q5. 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.

Q6. 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.

Q7: Do you have any views on the use of sanctions generally, or the inclusion of criminal sanctions, in The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013. Please explain your response with evidence where possible.

Q8: Do you have any views on whether the UK approach to enforcing The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations (2013) is significantly different from the approach taken by other Member States?

Annex 2. The EU Regulations enforced, and Directives implemented by, the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

Legal Reference	Official Journal Reference	Title
Regulation (EC) No 178/2002	OJ L 31, 1.2.2002, p. 1	Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Directive 2009/32/EC	OJ L 141, 6.6.2009, p.3	Directive 2009/32/EC on extraction solvents in the production of foodstuffs and food ingredients
Regulation (EC) No 2065/2003	OJ L 309, 26.11.2003, p. 1	Commission Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods.
Regulation (EC) No 1332/2008	OJ L 354, 31.12.2008, p.7	Commission Regulation (EC) No 1332/2008 on food enzymes
Regulation (EC) No. 1333/2008	OJ L 354, 31.12.2008, p.16	Commission Regulation (EC) No 1333/2008 on food additives (as read with Regulations 1129/2011, 1130/2011 and 231/2012)
Regulation (EC) No. 1334/2008	OJ L 354, 31.12.2008, p.15	Commission Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for in and on foods.
Regulation (EC) No 1129/2011	OJ L 364, 12.11.2011, p. 1	Commission Regulation (EC) No 1129/2011 amending Annex II to Regulation (EC) No. 1333/2008 by establishing a Union list of food additives.
Regulation (EU) No. 1130/2011	OJ L 295, 12.11.2011, p.178	Commission Regulation (EU) No. 1130/2011 amending Annex III to Regulation 1333/2008 on food additives by establishing a Union list of food additives, food enzymes food flavourings and nutrients.

Regulation (EU) No. 231/2012	OJ L267, 2.10.2012, p.162	Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333/2008