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

1.1 ***On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.***

1.2 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.

1.3 The 2013 Regulations 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 (S.I. 1993/1658);
(b) The Smoke Flavourings (England) Regulations 2005 (S.I. 2005/464);
(c) The Food (Suspension of the Use of E128 Red 2G Food Colour) (England) Regulations 2007 (S.I. 2007/2266);
(d) The Food Enzymes Regulations 2009 (S.I. 2009/3235);
(e) The Food Additives (England) Regulations 2009 (S.I. 2009/3238);
(f) The Flavourings in Food (England) Regulations 2010 (S.I. 2010/2817).

1.4 This light-touch PIR sets out the objectives of the consolidation exercise, the extent to which they have been achieved and whether they could be 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 are still relevant.

1.5 We are inviting further stakeholder views to increase the strength of our evidence on the implementation of 2013 Regulations.

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[1].

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 formal 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),

[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.

consumer groups, non-government organisations, enforcement bodies and 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 amount 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 Two respondents objected to the use of civil sanctions preferring the existing criminal approach. Guidance was introduced for local authorities on the use of civil sanctions shortly after this consolidation was published which addressed these concerns.

2.7 An impact assessment was not prepared as no significant impacts were identified as a result of the consolidation of existing requirements or the introduction of compliance notices. A view supported by the consultation responses, with no significant impacts identified by respondents.

3. Scope

3.1 As part of the Government's commitment to review provisions in secondary legislation 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, which have the main function of providing enforcement provisions for directly applicable EU legislation. The 2013 Regulations implement the enforcement provisions for directly applicable EU legislation, which are routinely considered and updated by the EU Commission - with input and agreement from Member States including the UK – these requirements are all considered to remain necessary and relevant. The FSA also believes that the England SI remains fully effective and fit for purpose, based on routine engagement and monitoring of UK official controls and enforcement. Therefore, the level of evidence sourced is commensurate to the scale of the 2013 Regulations and the associated impacts.

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 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)[2] 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)[3] have been achieved.

4.2 Stakeholder views, in addition to those provided during the initial exploration with key stakeholders, are now sought via public consultation.

4.3 It should be noted that minor amendments to the 2013 Regulations will be proposed through the draft Food Additives, Flavourings and Enzymes (EU Exit) Regulations 2019, to fix in-operabilities arising as a consequence of the UK leaving the EU. This is outside the scope of this PIR.

5. Budgeted and Actual Costs

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 initial consultation.

6. Questions Asked and Collated Responses

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

6.1 In the development of this report, an informal consultation was carried out by the FSA which included 46 stakeholders; three responses were received. The questions asked, and the responses received are listed below:

6.1.1 Has the consolidation of food additives, flavourings, enzymes, and extraction solvents into a single Statutory Instrument achieved its main goal and created a simplified system?

All three respondents agreed it has created a simplified system.

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.

6.1.2 Have there been any significant impacts, including economic impacts (costs/savings), or other intangible advantages and disadvantages following the introduction of the consolidated legislation?

Two respondents stated there were no significant impacts and the other was not aware of any.

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.

6.1.3 Has the introduction of compliance notices for non-food safety contraventions?

a) provided adequate consumer protection?

Two respondents stated that compliance notices provide adequate protection.

b) resulted in any additional costs or savings?

No comments were received.

c) introduced any other advantages and/or disadvantages?

One respondent noted that compliance notices provide FBOs with an opportunity to take corrective actions.

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.

6.1.4 Are the new civil sanctions appropriate and proportionate?

All respondents agreed that civil sanctions are appropriate.

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.

6.1.5 Additional comments

One comment was received 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 does not consider this comment to be within scope of the PIR but has noted the view for separate consideration.

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.

6.1.6 *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 towards incorporating further reliance on in food law in the future.

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.

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.

7.4 No consumer responses were received in relation to the Consolidated SI or through informal consultation on this draft PIR, but we would welcome any consumer views in response to this consultation.

8. Enforcement of the legislation in other EU Member States

8.1 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 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 their 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 the EU regulations in England. We welcome stakeholders' comments on this.

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?

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. 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.

9.2 To date, we have received no stakeholder responses representing alternative or contrasting views on this legislation. Stakeholder responses received have supported the FSA view and provided supporting evidence that 2013 Regulations are helpful in being combined into a single statutory instrument and the system has become more simplified.

9.3 Outside the scope of this review is the EU harmonised body of legislation relating to Food Additives, Flavourings, Enzymes and Extraction Solvents. Under the current regulatory framework, in which the UK still remains part of the European Union, options for renewal, removal or replacement are not directly actionable[4].

[4] On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union, and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future, once the UK has left the EU.

Annex I

Collated 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.

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