Title: The Contaminants in Food (England) Regulations 2013	Post Implementation Review
PIR No: Click here to enter text.	**Date: 04/02/2019**
Original IA/RPC No: Click here to enter text.	**Type of regulation: Domestic**
Lead department or agency: Food Standards Agency	**Type of review: Statutory**
	Date measure came into force: 31/10/2013 Click here to enter a date.
	Recommendation: Keep
Contact for enquiries: **Mark Willis**	**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 provide for the execution and enforcement of the EU contaminants legislation, which set maximum levels for nitrate as a contaminant in certain crops; set maximum levels for the presence of coccidiostats and histomonostats in food; revoke the Mineral Hydrocarbons in Food England Regulations 1966, revoked and remade the provisions of the Erucic Acid in Food Regulations 1977 and introduced the use of ambulatory references. This resulted a consolidation of the Regulations into a single SI.

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

An initial small-scale survey with affected stakeholders was carried out to ascertain whether any significant unintended consequences of unforeseen burdens had been created as a result of the Regulations. This involved informal dialogue/communication with food industry, Trade Associations, Enforcement Authorities, Official Control Laboratories and Competent Authorities from some EU Members States. A Formal consultation was also carried out on the draft report.

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

The EU measures and the England SI have been effective in meeting its objectives of safeguarding consumers from the risk of chemicals that might otherwise have been present in food at levels that affect consumer health. The 2013 Contaminants Regulations also meet their objective of providing for the effective execution and enforcement of the EU provisions in removing non-compliant foods from the market. And the use of ambulatory provisions has simplified the national contaminants Regulations.

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 existing national legislation on chemical contaminants into a single SI and the introduction of ambulatory references would benefit industry by simplifying the rules. This was particularly the case with enforcement officers, who felt this was convenient and time saving to have a single point of reference, as this removed the necessity to keep up to date with partial amendments.

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

No. The Contaminants in Food Regulations provide for the execution and enforcement of the EU legislation on chemical contaminants in food, by revoking and consolidation existing national legislation into a single SI, and introducing the use of ambulatory references, 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 contaminants legislation they implement and as such industry is not subject to any potential burdens that may be associated with complying with the national measures (i.e. there is no 'gold-plating' of EU law); they merely provide for the execution and enforcement of directly applicable EU Regulations in England. 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 where contaminants are regulated under specific laws, or using the powers provided for in existing legislation. MS contacted informed that a Central Authority was responsible for regulations on contaminants (less formal food inspection teams at local level or formal regional enforcement bodies. There is no evidence to suggest that overall, burdens on UK businesses exceed those on businesses complying with equivalent enforcement Regulations in other MS

Post Implementation Review:

The Contaminants in Food (England) Regulations 2013

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. The Contaminants in Food (England) Regulations 2013[1] ("The 2013 Regulations") make provisions for implementing EU legislation on certain contaminants in food and for their enforcement. The 2013 Regulations revoked the Contaminants in Food (England) Regulations 2010[2] and remade them. The 2013 Regulations include the various provisions for contaminants in food which were covered by the previous Regulations and in addition included the following amendments:
    - set maximum levels for nitrate as a contaminant in certain crops
    - set maximum levels for the presence of coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed.
    - revoked the Mineral Hydrocarbons in Food Regulations 1966[3]
    - revoked and remade, the provisions of the Erucic Acid in Food Regulations 1977 as amended[4]
    - introduced ambulatory reference provisions to include the Articles of EC Regulation 1881/2006[5] (on contaminants) and the Articles and Annex of EC Regulation 124/2009[6] (on coccidiostats and histomonostats)
2. Thus, the changes to the Regulations were consolidated, resulting in a single Statutory Instrument.
3. This report on the post implementation review (PIR) of the 2013 Regulations assesses the actual effect of the Regulations, five years after they were enacted, principally by collating evidence of the known views and experiences of key stakeholders[7] and assessing the baseline costs and benefits outlined in the associated Impact Assessment. It is a light touch post implementation review based on the low impact estimated to arise from the Regulations in the original Impact Assessment (£0.07m EANDCB (equivalent annual net direct cost to business)),

[1] SI 2013 No. 2196

[2] SI 2010 No. 2228

[3] SI 1966 No. 1073

[4] SI 1982 No. 264

[5] OJ L 364, 20.12.2006, p. 5

[6] OJ L 40, 11.2.2009, p. 7

[7] Stakeholders in the food industry and Trade Associations as well as Local Authority enforcement officers, Port Health Officers and Public Analysts were informally consulted.

which have the main function of providing enforcement provisions for directly applicable EU legislation. Therefore, the level of evidence sourced is commensurate to the scale of the Regulations and their anticipated impact.

4. As a minimum, this report seeks to establish whether the objectives of the 2013 Regulations have been achieved. It also looks at whether there have been any unintended effects on stakeholders resulting from the implementation of the 2013 Regulations and how they are executed and enforced in other Member States.

5. In line with the light-touch approach determined to be appropriate for this PIR, it was felt that an initial small-scale survey of affected stakeholders would help to understand the effect of the legislation. In particular, to ascertain whether any significant unintended consequences or unforeseen burdens had been created as a result of their introduction. This exercise took the form of informal dialogue/communication with members of the food industry, Trade Associations, Enforcement Authorities, Official Control Laboratories and Competent Authorities from other EU Member States. Following this, a formal consultation was carried out on a draft report, but no further responses were received.

6. While the main focus of the PIR is the impact of the provisions for implementing and enforcement of the EU legislation (and not the process through which maximum levels are set in EU legislation), we did receive comments on the impact of the EU legislations themselves. These useful comments are presented separately as the focus of the PIR is on the implementation of the 2013 Regulations.

7. Feedback from the review of the 2013 Regulations indicates no suggestion that the introduction of the Regulations has led to any negative or unintended consequences on stakeholders.

8. Following consultation with industry, this PIR has found no new evidence to update the original IA’s cost estimates.

9. The PIR indicates that the Contaminants in Food (England) Regulations 2013 continue to meet their objectives of protecting public health by keeping contaminants at acceptable levels and providing for the execution and enforcement of the EU Regulations on contaminants in food. Whilst the UK remains in the transition period the, options for renewal, removal or replacement of the legislation are not directly actionable. The findings of this review will, however, help to inform future UK policy decisions on chemical contaminants in food.

10 Therefore, we recommend that the Contaminants in Food (England) Regulations 2013 are retained.

1. Introduction and Background

1.1 The term ‘Contaminants in Food’ refers to a range of chemicals not intentionally added to food, but present in food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination.

1.2 The Contaminants in Food (England) Regulations 2013 (“The 2013 Regulations”) make provisions for implementing the EU legislation on certain contaminants in food and for their enforcement. They revoked the Contaminants in Food (England) Regulations 2010 and remade them with necessary amendments. This took into account the provisions of Commission Regulations (EU) No 1258/2011[8] regarding maximum levels for nitrate in foodstuffs. In addition, they also made provisions for Regulation (EU) No. 610/2012[9] which amends Regulation (EC) No 124/2009, which sets maximum levels for the presence of coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed.

1.3 The 2013 Regulations also revoked the Mineral Hydrocarbons in Food Regulations 1966 (which were purely national and not EU-derived) and revoked and remade, the provisions of the Erucic Acid in Food Regulations 1977 as amended, thus consolidating the changes into one Statutory Instrument (SI). References to Articles and Annexes of Council Directive 76/621/EEC[10] and Commission Directive 80/891/EEC[11] on Erucic acid were also included.

1.4 They also introduced ambulatory reference provisions to include the Articles of Regulation 1881/2006 (previously only the Annex was included) and the Articles and Annex of Commission Regulation 124/2009. Thus, the changes to the Regulations were consolidated, resulting in a single Statutory Instrument.

Chemical Contaminants

1.5 Chemical contaminants can enter the food chain from multiple sources. Contamination can occur during primary production from various environmental sources including pollution and waste from factories, landfills, incinerators, fires and contaminated land and water (e.g. dioxins, halogenated organic compounds, heavy metals). Other pathways include, presence of natural toxins (erucic acid, cyanogenic glycosides), plant diseases (mycotoxins), contamination from weeds (plant toxins) and carry over from animal feed. Climatic conditions and seasonality will also influence these (e.g. increased production of mycotoxins in cereals and nitrates in green vegetables). Chemical contaminants can also enter the food chain at the secondary production stage; during cooking and processing

[8] OJ L 320, 3.12.2011, p. 15

[9] OJ L 178, 10.7.2012, p. 1

[10] OJ L 202, 28.7.1976, p. 35

[11] OJ L 254, 27.9.1980, p. 35

(e.g. acrylamide, 3-monochloropropanediol (3-MCPD) and polycyclic aromatic hydrocarbons), storage (e.g. mycotoxins) and transportation and handling. Time, temperature and humidity have an impact on their levels present in food.

1.6 The basic principles for managing risk from chemical contaminants (excluding residues[12]) are laid down in Council Regulation 315/93/EEC[13] which is the Framework Regulation. These can be summarised as:

- Food containing a contaminant at a level that could affect public health shall not be placed on the market
- Contaminant levels shall be kept as low as reasonably achievable (ALARA) following recommended good working practices
- Where appropriate, maximum levels must be set for certain contaminants in order to protect public health

1.7 Specific maximum levels for certain contaminants in food are laid down in Commission Regulation (EC) No 1881/2006. The legislation is based on scientific advice from the European Food Safety Authority (EFSA) and the principle that contaminant levels shall be kept as low as reasonably achievable following good working practices. Maximum levels have been set for a range of contaminants including nitrate, mycotoxins, metals and dioxins.

1.8 Since the framework EU Regulation requires that contaminants present in food are within toxicologically acceptable limits, the European Commission together with the Member States investigates whether limits should be set for additional contaminants and reviews the maximum limits for those contaminants and foods currently listed in the legislation. These are implemented as amendments to Commission Regulation (EC) No 1881/2006 (of which there are 28 to date).

Coccidiostats and Histomonostats

1.9 Coccidiostats and histomonostats are veterinary medicines authorised for use in animal feeds. The Veterinary Medicines Directorate (VMD) normally leads on any regulatory issues, such as maximum residue limits (MRLs) in formulated feeds and the resulting limits in food. The Commission was concerned about their possible carry-over into batches of feed that are not intentionally formulated with coccidiostats or histomonostats. Therefore, they have introduced legislation limiting the permissible amount of coccidiostats and histomonostats carried-over into feed, in order to reduce the resulting residue in food of non-target animals.

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12 The use of pesticides and biocides are regulated in the UK by the Health and Safety Executive (HSE) whilst the use of veterinary medicines in the UK is controlled and monitored by the Veterinary Medicine Directorate (VMD); these are not covered by the Contaminants in Food Regulations.

13 OJ L 37, 13.2.1993, p. 1

1.10 Commission Regulation (EU) No. 610/2012 (“Regulation 610/2012”) amending Regulation (EC) No. 124/2009, sets maximum levels for the presence of coccidiostats and histomonostats in food as the result of the unavoidable carryover (also known as cross-contamination into non-target feed), with a view to ensure proper functioning of the internal market and for the protection of public health. Regulation 610/2012 amended the provisions for Lasalocid Sodium, Maduramicin, Nicarbazin and Diclazuril in the Annex to Commission Regulation 124/2009.

Mineral Hydrocarbons in Food

1.11 The Mineral Hydrocarbons in Food Regulations 1966 (“the Mineral Hydrocarbons Regulations”) were revoked in the 2013 Regulations. The Mineral Hydrocarbons Regulations prohibited (except in the case of four specified exemptions) the use of any mineral hydrocarbons in the composition or preparation of food and the sale or import of any food containing any mineral hydrocarbons. In addition, the Mineral Hydrocarbons Regulations specified which mineral hydrocarbons could be used and included the specifications for each of the exceptions.

1.12 However, the Mineral Hydrocarbons Regulations were based on out-dated science and were too broad in scope by generally banning the sale or import of any food containing any mineral hydrocarbons, thereby having the unintended effect of banning the presence of residues of mineral hydrocarbons which could be tolerated under other EU legislation. Regulation (EC) No. 178/2002[14] of the European Parliament and of the Council of 28 January 2002 (“the General Food Law) was in place to ensure that food business operators had to manage the presence of unsafe levels of mineral hydrocarbons in food. Having consulted stakeholders on the use of mineral hydrocarbons in food and considered possible food safety issues, the FSA considered that the Mineral Hydrocarbons Regulations no longer served any practical function and the 1966 Regulations were revoked.

1.13 The European Commission has published a Recommendation to monitor the presence of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food (Commission Recommendation (EU) 2017/84[15]). The outcome of this monitoring may inform whether further specific controls are needed under food contact materials or contaminants legislation.

Erucic Acid in Food

1.14 Erucic acid - a natural plant toxin in vegetable oils - is a monounsaturated fatty acid, present in the oil-rich seeds of the *Brassicaceae* family of plants, particularly rapeseed and mustard. Previously, Council Directive 76/621/EEC (and read with Commission

[14] OJ L 31, 1.2.2002, p. 1

[15] OJ L 12, 17.1.2017, p. 95–96

Directive 80/891/EEC regarding the method of analysis for determining erucic acid levels) prescribes the levels of erucic acid in oils and fats intended as such for human consumption and in foods containing added oils and fats. The provisions of these Directives were implemented by the Erucic Acid in Food Regulations 1977 and amended by The Erucic Acid in Food (Amendment) Regulations 1982. The provisions of the 1977 Regulations as amended were revoked and consolidated in the Contaminants in Food Regulations 2013.

1.15 Subsequently, action was taken by the European Commission, in order to simplify legislation, and since erucic acid is a contaminant according to the definition of the contaminant provided in Council Regulation (EEC) No 315/93, maximum levels for erucic acid were established in Regulation (EC) 1881/2006 as amended by Commission Regulation (EU) No 696/2014. Council Directive 76/621/EEC was repealed subsequently. Therefore, the reference to erucic acid in the 2013 Regulations will be removed in future.

Ambulatory Reference Provisions

1.16 The 2013 Regulations also introduced ambulatory reference provisions to include the Articles of Regulation 1881/2006 (previously only the Annex was included), the Articles and Annex of Commission Regulation 124/2009 and Commission Directives 76/621/EEC and 80/891/EEC on Erucic acid, as sometimes technical changes can be found in the former as well as the latter. Extending the use of ambulatory references to include Articles as well as Annexes therefore eliminates the need to introduce a new SI or amend the existing SI each time any of these Annexes or Articles is updated. This ensures the number of implementing instruments (in addition to the EU legislation) to which stakeholders such as business operators and enforcement authorities refer is kept to a minimum.

1.17 Thus, the Contaminants in Food (England) Regulations 2013 (“the 2013 Regulations”) brought together existing enforcement and implementation provisions for EU legislation on contaminants, coccidiostats and histomonostats in food as the result of the unavoidable carryover, into a single Statutory Instrument.

2. Purpose and Scope of the report

2.1 As part of the Government’s commitment to review provisions in secondary legislation that regulate businesses, the 2013 Regulations require the Food Standards Agency (FSA) to undertake a Post Implementation Review (PIR) of the Regulations and set out the conclusions in a report within five years of the measure coming into force. This statutory review policy was introduced by the Government in 2011 for new English legislation derived from European law.

2.2 This report assesses the actual effect of the 2013 Regulations, principally by collating evidence of the known views and experiences of key stakeholders and assessing the

baseline costs and benefits outlined in the associated Impact Assessment. This is a light touch review based on the low impact the FSA believes to have arisen from the 2013 Regulations, which have the main function of providing enforcement provisions for directly applicable EU legislation. Therefore, the level of evidence sourced is commensurate to the anticipated impact of these Regulations.

2.3 As a minimum, this report seeks to establish whether the objectives of the 2013 Regulations have been achieved, whether there have been any unintended impacts on stakeholders resulting from the implementation of the 2013 Regulations and how the Regulations are executed and enforced in other Member States. Owing to the highly technical nature of this subject, we have not directly sought consumer input to this review of the 2013 Regulations. This is based on our experience of seeking consumer views in the past on contaminants in food issues. Consumers, in general, prefer not to engage on technical detail of regulatory requirements, nor are they able to comment on business or local authority impacts of the regulations. Consumers are generally content to rely on the confidence that the Government will protect their interests in taking forward any legislative changes in this area. Nevertheless, consumer views on this review were welcomed and invited in the public consultation. No responses were received.

2.4 This report on the 2013 Regulations relates only to England as the requirement for review clauses does not extend to devolved areas of legislative competence, such as food and feed law in Scotland, Wales and Northern Ireland. Although the review is focused on England only, it is not anticipated that the conclusions of a similar review in the other nations in the UK would differ from this review.

2.5 This report:

a) restates the objectives intended to be achieved by the 2013 Regulations, revisits the baseline costs and benefits identified in the associated Impact Assessment[16], and assesses the extent to which these costs and benefits have been realised;

b) provides an evidence-based evaluation of the extent to which those objectives are being achieved;

c) assesses whether the objectives remain appropriate and, if they are, the extent to which they may be achieved within a framework that imposes less regulation; and

d) examines how the legislation on contaminants is executed and enforced in other Member States and whether the implementation of the 2013 Regulations puts businesses at a disadvantage compared with the implementation in other Member States.

2.6 Since the 2013 Regulations make provisions for implementing the EU legislation and for their enforcement, the focus of the review is on this aspect. It will not address the process through which maximum levels are set in EU legislation. Stakeholders are regularly updated and consulted on developing EU policy through various means including regular

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[16] The Impact Assessment to accompany the 2013 Regulations is available here: https://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/contam-regs-2013e.pdf

meetings, email updates and updates on the FSA's website[17]. Stakeholders have responded that they are satisfied with this aspect of the FSA's consultation process.

2.7 Previous versions of the Contaminants in Food Regulations have focussed on specific aspects of the amendments to the EU Regulations and have assessed their impact on providing enforcement powers as well as consumer safety. At the time of publication of the 2013 Regulations, the only additional amendment to EU Regulation 1881/2006 was the new maximum levels for nitrate in leafy vegetables. Stakeholders the FSA consulted had views on the Contaminants in Food Regulations in general and although they do not pertain specifically to the 2013 Regulations, their comments have been useful in understanding the costs and benefits to the industry and enforcement community to provide consumer protection. Therefore, although these comments do not strictly form a part of this review, they have been included separately.

3. Objectives and baseline costs of the 2013 Regulations

Objectives

3.1 In addition to the general objective of protecting public health by keeping contaminants at acceptable levels, the specific policy objectives and intended effects of the Contaminants in Food Regulations 2013 were set out as follows:

- To ensure that maximum levels set for nitrate in lettuce, spinach and rocket in England are sufficient to protect consumer health but are also achievable.
- To ensure that levels for coccidiostats and histomonostats in food in England are sufficient to protect consumer health by setting maximum levels for their presence in food resulting from the unavoidable carry-over in non-targeted feed.
- To revoke national legislation on mineral hydrocarbons in food and to revoke and remake, provisions currently contained in the Erucic Acid in Food Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.

3.2 The 2013 Regulations came into force in October 2013 and provide for the execution and enforcement, in England, of the provisions of the Contaminants Regulation. They provide offences under English law for contravening certain requirements of the Regulations and provide penalties which can be imposed for these offences.

3.3 Part 4 of the 2013 Regulations provides for the enforcement of the EU Regulations on Contaminants in Food and identifies those provisions of the EU Regulation which it constitutes an offence to contravene. The 2013 Regulations provide for penalties on conviction for an offence under these EU Regulations, specify the enforcement and competent authorities and also provide for the application of specified provisions of the Food Safety Act 1990 for the purposes of these Regulations. The day-to-day enforcement

[17] https://www.food.gov.uk/news-alerts/search/consultations

work of the 2013 Regulations is the responsibility of Local Authority (LA) enforcement officers and port health authorities (PHAs).

3.4 The Contaminants in Food Regulations 2013 make a consequential amendment to the Food Safety (Sampling and Qualifications) (England) Regulations 2013, the effect being to disapply the sampling and analysis provisions of those Regulations only to the extent that those matters are regulated by the EU instruments. These specific EU Regulations on methods of sampling and analysis (Commission Regulations (EC) No. 401/2006, 1882/2006, 333/2007 and 252/2012) are required to be used for the official control of levels of the substances covered by the Food Safety England Regulations 2013.

3.5 There are also a number of tools which provide support for the enforcement of the rules in place. The Rapid Alert System for Food and Feed (RASFF) enables Member States to report food that is not compliant with the relevant EU legislation to ensure that these are removed from the market. Audits and inspections carried out by DGSANTE - Directorate F (formerly the Food and Veterinary Office (FVO)) verify compliance in the Member States and beyond the EU. In addition, the European Commission has established a number of EU reference laboratories specialising in different types of food contaminants who carry out research in order to provide scientific advice and support on the sampling and analysis of various contaminants in food.

3.6 Most of those consulted during this review said that they were familiar with the 2013 Regulations and enforcement officers reported that although they did not refer to them very frequently (they consulted the EU regulations directly), they referred to the SI when they needed to clarify their powers in case of an offence or when there was a disagreement on implementation.

Costs and Benefits

3.7 The estimated costs and benefits anticipated for the enforcement of the 2013 Regulations were set out in the FSA Impact Assessment which accompanied the Regulations. The Impact Assessment for Contaminants in Food Regulations 2013 can be found at:

https://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/contam-regs-2013e.pdf

Estimated costs of familiarisation (initial Impact Assessment).

3.8 It was estimated that: Industry, Enforcement Authorities (Local Authorities (LAs) and Port Health Authorities (PHAs)) and Official Control Laboratories (OCLs) would face one-off familiarisation costs as a result of reading and familiarising themselves with the Contaminants in Food Regulation 2013.

3.9 The familiarisation costs presented in the 2013 Impact Assessment (IA) are summarised in Table 1 below. The costs were estimated by multiplying the median hourly wage rate by the estimated time needed to assimilate and disseminate the information. This was then multiplied by the total number of businesses, authorities or laboratories.

1: One-off familiarisation costs presented in 2013 IA				
ed Entity	iarisation Time per entity	per entity	Cost	
esses	urs • 45 minutes reading • 45 minutes dissemination	5	183	37
Authorities & Port Health Authorities	ours • 90 minutes reading • 45 minutes dissemination	5	94	8
			477	95

3.10 In order for one-off costs to be compared with annual costs on an equivalent basis across the entire time span of the policy, one-off costs were transformed into Equivalent Annual Costs (EAC) by dividing the one-off cost by an annuity factor. Equivalent annual costs are used to represent that upfront costs incurred in year one impose a greater burden on businesses than costs imposed gradually over a period of 10 years. The total one-off cost to industry was estimated to be £613,183, which resulted in an EAC of £71,237 for a time period of 10 years. The total one-off cost to enforcement authorities and OCLs in England affected by this proposal was estimated to be £20,294, which resulted in an EAC of £2,358 for a time period of 10 years.

Actual costs of familiarisation

3.11 Consultation with stakeholders in the industry indicated that while the approximate time taken to familiarise themselves with the SI for the 2013 Regulations (which do not specify the amendments in EU Regulations) had been estimated correctly, the time taken to read and understand the EU legislation would be substantially greater.

3.12 Those already familiar with the EU regulations would not require the 45 minutes, while those who are new to the system would need a considerably greater amount of time. It would take closer to 2 hours to read and understand the SI, with some considering the 45 minutes to be an underestimate of the resource required. A significant factor that needs to be considered is that often, new maximum levels are introduced, or existing ones amended in the EU Regulations and there is a need to refresh understanding of the EU Regulations, especially as product lines are changed and the regulations are amended, or new maximum levels introduced. This may take days or weeks to complete. The opinions of Enforcement Officers were similar, i.e. that the time taken for an unexperienced officer would be longer than 45 minutes. However, this related to familiarising with the EU Regulations. The time needed for understanding the SI would be in addition to that needed to actually equip the Officer with sufficient information to enforce the regulations with significantly more time required for the latter.

3.13 The original estimate of 45 minutes to read the EU legislation was less than the 2-hour estimate suggested by some stakeholders. If this estimate was used, the cost to Local Authorities (LAs) and Port Health Authorities (PHAs) would be higher. The total time taken to read and disseminate both the national and EU regulations would increase from 2 hours 15 minutes to 3 hours 30 minutes (1 hour 15 minutes longer). Using the hourly wage presented in the 2013 Impact Assessment of £20.74 the new cost per authority would be £72.59 (up from £46.65). The total cost to authorities would increase to £31,577 (from £20,294, an increase of £11,283). The Equivalent Annual Cost increases from £2,358 to £3,669.

3.14 It is acknowledged that these comments do not directly relate to the actual 2013 Regulations. It is also acknowledged that it is not possible to predict the number and nature of amendments to EU Regulations at the time of carrying out the Impact Assessment. Therefore, this is a static view. Following a formal consultation, the FSA did not receive any response to its request for comments in this area. There is therefore no new evidence to suggest the 2013 Impact Assessment did not accurately estimate the cost of this regulation.

Other costs and benefits of the 2013 Regulations

3.15 Stakeholders were asked whether there were any other one-off or ongoing costs and/or benefits or any other unintended consequences as a direct result of the 2013 Regulations that had not been included in the Impact Assessment.

3.16 All agreed that there have been no unintended consequences attributed to the 2013 Regulations. No financial burdens were identified except for the time and resources needed to refresh understanding of the EU regulations and how these may impact numerous product lines.

3.17 Stakeholders have also acknowledged the benefits of the simplification brought about by the 2013 Regulations. This single point of reference was particularly advantageous to enforcement officers as it was convenient and time saving, as this removes the necessity to keep up to date with partial amendments and it reduces the need for constant cross-referencing which can make interpretation more difficult. Trade associations and other industry stakeholders also agreed that the consolidation of regulations makes it more straightforward for businesses to find and implement statutory requirements. The revocation of the Mineral Oil Hydrocarbons Regulations has resulted in removing unintended restrictions in their use and in consistency with other EU Regulations.

Estimated sampling and testing benefits

3.18 At the time of publication of the 2013 Regulations, the only additional amendment to EU Regulation 1881/2006 was the new maximum levels for nitrate in leafy vegetables and it was assumed that the additional sampling, testing and analysis costs would be negligible as the additional sampling of rocket could be carried out at the same time as lettuce and spinach.

Actual sampling and testing benefits

3.19 There have been several amendments to the EU Regulation, with new maximum levels introduced for new foodstuffs as well as new contaminants. When asked for their views on this, stakeholders considered that proportionate testing at the point of entry is often seen as beneficial to the industry because it provides a safeguard that the commodity is of acceptable quality and mitigates losses due to non-compliance i.e. the consignment will be rejected and will not be delivered to the consignee. They also see the sampling at ports as a third-party audit.

3.20 Furthermore, the Regulations brought into focus emerging areas of concern with regards to the nature and levels of contaminants and these are taken seriously by industry. This extends to the rest of the food chain including farmers and importers. Inevitably, the industry has become more diligent in ensuring the integrity of the food chain. Although these benefits stem from the EU regulations that are being implemented by the 2013 Regulations, the national regulations create the shell that provides for the implementation of those EU regulations.

4. Assessment of the extent to which the objectives of the Regulations are being achieved

4.1 There are three specific policy objectives and intended effects of the Contaminants in Food Regulations 2013 which need to be assessed in order to ascertain whether the regulations have met the objectives. This is in addition to the general objective of protecting public health by keeping contaminants at acceptable levels. These objectives are discussed below.

General Objective - To protect consumer health by keeping contaminants at acceptable levels

4.2 It is not always possible to quantify or monetise the consumer health benefits of legislation that regulates the presence of unintentional chemicals in food, including chemical contaminants. This is because in most cases, the potential impacts of these chemicals on consumers are chronic, which means that any adverse effects only develop as a result of long-term exposure. Our approach has been to focus on the approaches to reduce exposure to contaminants by keeping levels as low as reasonably achievable. This is achieved by both regulatory and non-regulatory means, which will result in a reduction of human exposure and, ultimately, in a reduction of any negative effects on consumer health.

4.3 Thus, the primary aim of the 2013 Regulations is to protect consumer health by providing enforcement and implementation powers for EU Regulations on chemical contaminants in food and thereby restrict and limit substances that are potentially harmful to human health (See Annex 1). The 2013 Regulations also have a deterrent effect, as businesses know that enforcement action can be taken if they do not comply with the Regulations.

4.4 One of the risk management measures to control exposure to chemical contaminants is to set maximum levels for various contaminants in food. These limits have been established by the Commission and Member States, taking into consideration risk assessments carried out by the European Food Safety Authority (EFSA). These should be set at a strict level which is reasonably achievable by following good agricultural, fishery and manufacturing practices and take into account the risk related to the consumption of the food. This will ensure that measures are put in place by business to prevent and reduce the contamination as far as possible in order to protect public health.

4.5 In addition to these legal maximum levels, other non-regulatory measures such as guidance on preventing and reducing the levels of these contaminants in various foods have been developed both by the EC as well as the FSA. This is in addition to various guidance developed by the industry itself to control the occurrence of contaminants in food. Although these are not legally binding, food businesses are encouraged to follow these good agricultural and manufacturing practices, in order to keep the levels of contaminants in food as low as reasonably achievable. In addition to these, in some cases guideline levels, target levels or indicative levels have been agreed for certain contaminants. These are not legal limits but are trigger levels for further investigation. These measures are intended to reduce contamination at the source, before its entry into the food chain. The FSA has also provided consumption advice on the consumption of several foods in order to reduce consumer exposure to certain contaminants.

4.6 All the stakeholders contacted during the course of this review – from all sectors consulted, including the industry, the Enforcement Officers and Public Analysts - agreed that the 2013 Regulations are meeting their objective of protecting consumers' health by providing:

- a framework that defines what is required for compliance to ensure consumer health
- adequate powers for the enforcement of the EU regulations covering maximum levels and sampling, as well as the prevention of contaminated food from entering the UK market from abroad as evidenced by the rejection and removal of contaminated products from the market.

4.7 Some fairly broad and anecdotal examples (detailed below) were given to express concerns about the effectiveness of the regulations and the practical limitations in enforcement. These observations are useful and are noted for consideration in future communications and decisions.

- Although the larger Food Business Operators (FBOs) and major players in the food industry were up-to-date with the requirements of the 2013 Regulations, knowledge on contaminants was somewhat limited among smaller FBOs and the enforcement community. Contaminants were sometimes not listed in food safety management plans or HACCP system.
- Some were of the view that this is a very technical, scientific subject, requiring a lot of background knowledge, e.g. the meaning and relevance of hotspots and the dilution factors. Awareness needed to be increased and industry auditing bodies

and enforcement officers need to be trained in order to achieve this. Some enforcement officers wanted better training opportunities, expressing the need for time to be made available to attend courses on contaminants such as the Better Training for Safer Food (BTSF) initiative run by the European Commission. They also wished for better communication from the FSA on the availability of these courses.

- There was some difficulty in enforcement action for products that did not have maximum levels set (e.g. cassava) or how maximum levels were enforced for compound products.
- Resources available to the LAs in terms of funding and staff were limited and, in some cases, most of those resources are allocated to microbiological risks, as sampling requirements for contaminants are complex, time consuming, labour intensive and costly. This resulted in limited sampling and testing for contaminants.
- Some enforcement officers felt that if they could issue improvement notices (as is the case with hygiene regulations), it would give them the power to revisit the premises of offenders and take follow-up on action - to check on whether improvement action had been carried out.
- Additionally, it was suggested that the SI could be simplified at places and have links to EU regulations added in, to make its enforcement easier.

4.8 When asked about their opinion on whether non-regulatory measures had been successful in achieving the objectives of the Contaminants in Food Regulations, stakeholders had very positive views on their effectiveness. It was believed that sharing of information and knowledge is being handled very well by the FSA and this reflects on how measures to ensure food safety affect the UK industry. The example of T2 & HT2 toxin was provided as a very successful case study. The FSA had worked effectively with the industry in producing guidance on monitoring levels of T2 & HT2 toxin which was then the basis for the EU guidance document. A successful investigation was carried out when higher levels were detected during the 2014 harvest. It was established that the results did not indicate a risk to consumer health[18]. Similarly, the guidance and code of practice on seasoning spices was considered successful. Consumption advice was thought to be a useful tool with advice on fish with the aim to avoid excess exposure to mercury cited as a successful example. Advice on crab consumption due to cadmium was thought to be very effective as well. Finally, surveillance testing programmes covering heavy metals and mycotoxins helped to identify issues and focus resources on those issues in a more cost-effective manner.

4.9 In order to reduce levels of mycotoxin contamination at the source, the FSA has previously developed with key stakeholders three codes of practice for the farming industry on preventing and reducing mycotoxins, fusarium toxins and ochratoxin A. Some stakeholders expressed that these may benefit from being updated to include more mycotoxins (e.g. ergot alkaloids). They would also welcome more training on their use.

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[18] https://www.food.gov.uk/sites/default/files/media/document/fs102126execsum.pdf

4.10 Commenting on consumer advice for fish consumption, whilst acknowledging its usefulness, they felt that it could benefit from some revisions to ensure that all potentially significant sources of exposure are addressed.

4.11 On the whole, stakeholders agreed that the 2013 Regulations provide for the necessary enforcement action to control the presence of contaminant in food. The Regulations have ensured the continuation of consumer protection against exposure from chemical contaminants in food, which could potentially carry long term risks to consumer health.

Objective 1 - To ensure that maximum levels set for nitrate in lettuce, spinach and rocket in England are sufficient to protect consumer health but are also achievable.

4.12 In addition to the general objective of protecting consumer health from the presence of unacceptably high levels of chemical contaminants, the 2013 Regulations also included a specific objective with regards to the maximum levels for nitrates in green leafy vegetables. The EC Regulation on contaminants in food (EC) No. 1881/2006 includes maximum levels for nitrate in certain leafy vegetables. In some cases, despite developments in good agricultural practices, the maximum levels are exceeded. To give Member States time to comply, a temporary derogation was granted to certain Member States (including the UK) due to their respective climates, for the placing on the market of certain leafy vegetables, grown and intended for consumption in their territory with nitrate levels higher than the established maximum levels. The FSA worked with the industry to provide input on developing the industry codes of practice to minimise nitrate content of lettuce and spinach grown under protected cropping culture in the UK.

4.13 Following an assessment by the European Food Safety Authority (EFSA) which compared the risk and benefits of exposure to nitrate from vegetables, it was concluded that in most cases the estimated exposure to nitrate from vegetables is unlikely to result in appreciable health risks; therefore, the recognised beneficial effects of consumption of vegetable prevail. Commission Regulation (EU) No. 1258/2011 ("the nitrate Regulation") was published amending maximum levels for nitrate in foods in Regulation (EC) No. 1881/2006. It set (permanent) higher, achievable levels than those initially set for lettuce and spinach across the EU. It also sets maximum levels for rocket, where a risk has been identified.

4.14 The nitrate Regulation also specified that Member States shall monitor nitrate levels in vegetables which may contain significant levels, in particular green leafy vegetables, and communicate the result to EFSA on a regular basis. The FSA commissioned a surveillance programme where the nitrate levels in samples of domestic and imported lettuce, spinach, rocket and other leafy green vegetables are monitored[19]. This programme has been in place since January 2009, allowing monitoring of nitrate levels in green leafy vegetables and to ensure that the maximum levels are achievable. The monitoring results have been submitted annually to EFSA as required by the legislation. Results show good compliance with the maximum levels, ensuring consumer protection, indicating that Objective 2 of the Regulations have been met. Where maximum limits have

[19] https://www.food.gov.uk/research/research-projects/nitrate-monitoring-in-spinach-and-lettuce-surveillance-programme

been exceeded, the grower will examine and/or review aspects of their agricultural practices that could have contributed to the results.

Objective 2 - To ensure that levels for coccidiostats and histomonostats in food in England are sufficient to protect consumer health by setting maximum levels for their presence in food resulting from the unavoidable carry-over in non-targeted feed.

4.15 The stakeholders we consulted all acknowledged that their knowledge of this issue was limited. The food industry considered it relevant to feed, and usually samples of feed, rather than food, were analysed for their presence. Although classified as feed additives, most of these chemicals are veterinary medicines, manufactured by pharmaceutical companies and regulated as such by the Veterinary Medicines Directorate. However, when the substance in question has been unavoidably transferred (carried) from one feed product in which it is used as an authorised additive to another feed product where its use is not authorised (non-targeted feed) during manufacture, it is considered an undesirable substance as a result of 'carry over' or' 'cross contamination'. Enforcement action will then be carried out by Local Authority enforcement officers.

4.16 Feed manufacturers were aware of the requirements (maximum levels for their presence in food) but their approach would be to control the levels in the feed, complying with Directive 2002/32/EC on undesirable substances in feed, section VII: authorised feed additive in non-target feed following unavoidable carry-over. Factors they considered were carry-over as well as cross contamination and cleaning procedures. Some enforcement officers reported testing samples of imported food, but UK-produced food was perceived generally as safe in that respect.

4.17 Generally, compliance in feed was monitored rather than levels of coccidiostats and histomonostats actually present in food. Most stakeholders did not use the 2013 Regulations for this purpose.

Objective 3 - To revoke national legislation on mineral hydrocarbons in food and to revoke and remake, provisions currently contained in the Erucic Acid in Food Regulations 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations 2013.

4.18 As a part of the Government's Red Tape Challenge (RTC) programme the FSA has delivered a number of initiatives[20], including developing a simplified system of food safety legislation. This involved the consolidation and revocation (where they are no longer required for consumer protection) of a number of domestic Statutory Instruments. The revocation of the Mineral Hydrocarbons in Food Regulations 1966 and the revocation and remake of the Erucic Acid in Food Regulations 1977 were part of this simplification.

[20] http://www.food.gov.uk/enforcement/regulation/betregs/red-tape-challenge/

4.19 *The Mineral Hydrocarbons Regulations:* Following stakeholder consultation and considering EFSA's scientific opinion, the FSA concluded that the Mineral Hydrocarbons Regulations no longer served any practical function; an equivalent level of public health protection was achieved by newer legislative controls on mineral hydrocarbons in EU legislation on food additives and contaminants, and by the General Food Law (Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 ("General Food Law"). Thus, the FSA considered that revocation of these national regulations would not alter the level of consumer protection. The revocation of the Mineral Hydrocarbons Regulations therefore removed redundant legislation and was non-controversial in terms of food safety.

4.20 *The Erucic Acid in Food Regulations 1977* ("the 1977 Erucic Acid Regulations") and its amending Regulations were revoked and remade in the Contaminants in Food Regulations 2013. The provisions for erucic acid were brought into one SI, thereby simplifying existing legislation.

4.21 In 2014, the European Commission during their own efforts to simplify legislation, consolidated EC legislation on erucic acid. The maximum levels for erucic acid as laid out in Council Directive 76/621/EEC were included in the main contaminants Regulation (EC) 1881/2006, as amended by Commission Regulation (EU) No 696/2014 (erucic acid is a contaminant according to the definition of contaminants provided in Council Regulation (EEC) No 315/93). Council Directive 76/621/EEC was repealed subsequently. There were no changes in the substance of the legislation and no new burdens were anticipated.

4.22 The revocation of the 1977 Erucic Acid Regulations and inclusion in the 2013 Regulations, have therefore resulted in simplification of legislation whilst ensuring consumer safety.

Ambulatory Reference Provisions

4.23 The 2013 Regulations introduced ambulatory reference provisions to include the Articles of Regulation 1881/2006 (previously only the Annex was included), the Articles and Annex of Commission Regulation 124/2009 and Commission Directives 76/621/EEC and 80/891/EEC on erucic acid, as sometimes technical changes can be found in the former as well as the latter. Extending the use of ambulatory references to include Articles as well as Annexes have avoided the need to introduce a new SI each time any of these Annexes or Articles is updated.

4.24 Unequivocally, stakeholders responded that the ambulatory references used in the SI simplified the use of these regulations. This was particularly the case with enforcement officers, who thought it was convenient and time saving to have a single point of reference, as this removes the necessity to keep up to date with partial amendments and it reduces the need for constant cross-referencing which can make interpretation more difficult. Trade associations and other industry stakeholders we contacted agreed that the consolidation of regulations makes it more straightforward for businesses to find and implement statutory requirements. That said, it was also made clear that they only rarely consulted the national regulations as they tended to refer directly to the EU regulations.

General comments about regulations on contaminants in food:

4.25 While stakeholders acknowledged that the main purpose for the 2013 Regulations (and the previous versions) was to make provisions for the implementation and enforcement of EU Regulations in domestic legislation, they had some general comments to make about the provisions of the EU Regulations.

4.26 These general comments, while they do not apply specifically to the national contaminants in food Regulations, have given useful insight into the practical issues faced by industry and the enforcement community in implementing and enforcing the EU Regulations.

4.27 There was agreement that the EU Regulations and therefore the implemented national legislation provided assurance in terms of food safety and provided a level playing field for everyone. Other benefits include safeguarding the interests of the industry and increased confidence in the food chain, production of safer food as a result of the implementation of the regulations, improved practices and better education. It also provided the industry with a standard that they could work to and specify as a requirement with their suppliers. Stakeholders were generally happy with the consultation processes followed by the FSA when EU Regulations were being negotiated, giving them the opportunity to raise any issues they might have.

4.28 Again, referring to the EU Regulations and the timing provided for the industry to adapt, one comment was made that the period to implement change may not always be sufficient, e.g. when maximum levels for ochratoxin A in dried fruits were first introduced there was no transition period.

4.29 In terms of costs, there is a general feeling that analytical tests for contaminants were more expensive and sampling for due diligence by the industry as well as sampling by enforcement authorities would be costly (for example compared to microbiological testing). This is mainly the due to nature of analysis for contaminants and is not specific to the 2013 Regulations. Whilst it is not stipulated that businesses must undertake analysis on all batches of food, it is ultimately their responsibility to manage all known risks and as part of due diligence undertake appropriate testing or use other options to seek reassurance that products are compliant.

4.30 Some enforcement officers - especially smaller LAs - were concerned about funding available for sampling and analysis of contaminants. Sometimes, the lack of training hinders enforcement. They were also concerned with funding required for re-training and purchase of equipment when maximum levels or sampling protocols change. However, sampling plans and budgets are the responsibility of individual LAs. It would be expected that local intelligence would be used to decide on these, depending on the industries and food produced/available in their jurisdiction; it would not come under the central remit of the FSA.

4.31 Commenting on the complexity of the SI itself, large retailers who are responsible for several product lines and who need to consider multiple risks expressed a preference for a less complex SI as this would relieve some of the burden on them. Some suggestions included inclusion of direct links to EU regulations, and mirroring of the SI with the EU regulation with most of the information on one webpage for ease of finding everything, including tables for maximum levels, etc. Another suggestion that was viewed to be very

helpful was to have a searchable database - the facility to search by contaminant to find the maximum level or by product to see what contaminants could be present. This would be particularly beneficial to suppliers as it would help them identify potential contaminant risks for different products with different ingredients. Simplification of the SI was thought as beneficial to SMEs as well, as they do not have access to technical resources provided by trade associations.

4.32 In summary, the comments so far suggest that the 2013 Regulations meet the following objectives 1 to 3 by:

- protecting consumer health by keeping contaminants at acceptable levels and setting maximum levels for various contaminants - including nitrate, coccidiostats and histomonostats
- The revocation of the Mineral Hydrocarbons in Food Regulations 1966.
- The revocation and remaking of the Erucic Acid in Food Regulations 1977.

5. Assess whether the objectives remain appropriate, if so, the extent to which they can be achieved within a framework that imposes less regulation

5.1 The three objectives listed in paragraph 3.1 of this report remain appropriate insofar as they continue to protect human health, provide for the enforcement of the Contaminants Regulation, and provide the benefits of simplification which have been brought about as a result of the ambulatory references.

5.2 Stakeholders we engaged with in the course of this review were unanimous in their view that the 2013 Regulations remain appropriate and provide adequate powers for the execution and enforcement of the EU contaminants regulations. These are useful in providing the legal basis for taking action against businesses that do not comply with the law. They also indicated that these harmonised Regulations provide a level playing field across the board, safeguarding industry's interests. Benefits included the increased confidence due to the production of safer food as a result of the implementation of the regulations, improved practices and better education.

5.3 Stakeholders were also in agreement that in addition to the regulatory measures provided in the 2013 Regulations, non-regulatory measures used were also effective in providing safety to consumers by reducing exposure to various contaminants. Consumption advice, provision of guidance on good agricultural and good manufacturing practices were effective in achieving these objectives.

6. Examination of:

a) how the legislation is executed and enforced in EU Member States, and:

b) whether the UK's implementation leads to extra burdens on businesses than the implementation in Member States

a) Enforcement of the Legislation in EU Member States

6.1 In England as well as in Scotland, Wales and Northern Ireland, harmonised legislation is enforced by means of Statutory Instruments which provide penalties and enforcement powers for infringements. We contacted a number of Member States (Spain, the Netherlands and Denmark kindly responded to our consultation) in the course of this review to ascertain how contaminants legislation is executed and enforced in their countries. Information available online regarding enforcement approaches in Member States (Germany and Czech Republic) were also considered.

6.2 The approach to enforcement is similar in the Member States we contacted where contaminants are regulated under specific laws, or using the powers provided for in existing legislation. The Member States we contacted said that a Central Authority was responsible for regulations on contaminants with either formal regional enforcement authorities or less formal local food inspection teams implementing and monitoring at a local level. Official controls for contaminants are laid out in the country's Multi Annual National Control Plan and the results published.

6.3 As in the UK, enforcement of Regulations on contaminants is targeted, based on the level of risk associated with it.

6.4 The Framework Regulation on contaminants allows Member States to adopt their own national specific measures for those areas of legislation that are not harmonised at EU level, provided they comply with the rules of the Treaty on the Functioning of the European Union. Each Member State is responsible for the enforcement of EU law within its own legal system, ensuring enforcement measures are adopted before any specified deadlines, and ensuring conformity with the law and its correct application.

6.5 There are no additional regulatory requirements in the UK that go beyond the EU regulations on contaminants in food. Some Member States have national legislation providing additional requirements for certain contaminants in foodstuffs that are not regulated under Regulation (EC) No 1881/2006. Additional maximum levels are in place for certain commodities - for example, ochratoxin A in pig liver, figs, nuts and liquorice, mycotoxins in tiger nuts, heavy metals in edible salt. Other examples of regulation at a national level include aflatoxins, ochratoxin A, nitrates, pyrrolizidine alkaloids, opium alkaloids, halogenated solvents (tetrachloroethene, trichloroethane, trichloromethane) and non-dioxin like polychlorinated biphenyls (PCBs) in foodstuffs that are not regulated under Regulation (EC) No 1881/2006.

6.6 As in the UK, we identified that in other Member States these sanctions may range from fines or penalties to imprisonment, confiscation or destruction of non-compliant goods at the company's expense, the closing down of premises, and other penalties.

6.7 When asked about their experience of intra-community trade with regards to these Regulations, Member States did not indicate anything special, but highlighted the importance of harmonised legal limits to have a fully functioning internal market. Their view was that since contaminants in foods are harmonised with EU Regulations, trade was functioning smoothly.

6.8 The use of flexibilities to make the implementation of EU Regulations less burdensome was discussed. Some Member States indicated that they were open minded about the use of flexibilities as long as the methods did not impose a risk for the consumers. For example, specific risk assessments were made on non-compliant findings by toxicologists to assess the need for issuing consumer warnings and to decide on the extent of product withdrawal from the market. The use of action limits for contaminants that do not have maximum levels was also mentioned - findings above action limits were followed up by specific evaluations according to Article 14 of the 'General Food Law' (Regulation (EC) No. 178/2002).

6.9 In summary, the approach to implementation and enforcement of EU Regulation on contaminants in other Member States are similar to the UK. There is no evidence that the 2013 Regulations have led to 'gold-plating' of EU law, which is where national legislation exceeds the requirements of EU legislation (as observed in some Member States). The measures enforced by the 2013 Regulations are EU Regulations and as such are directly applicable.

b) Examination of whether UK's implementation of EU Directives and enforcement of EU Regulations leads to extra burdens on businesses than the implementation and enforcement in EU Member States

6.10 Stakeholders view the UK implementation of EU Regulations as being fair and appropriate with actions taken by the FSA, being risk based and proportionate. The availability of clear guidance was also highlighted as a positive for the UK which may not be the case in other Member States. Industry stakeholders also positively highlighted the good working relationship with the FSA and the consultations and updates provided with regards to setting of EU legislation. The handling of enforcement by the Local Authority Officers was perceived positively as well. In certain cases - for example the testing for aflatoxins - UK standards and capabilities were more advanced than in some other MSs (anecdotal evidence provided by some suggested that this has resulted in imports being directed to other EU countries in the past, but no current issues or concerns were raised).

6.11 The UK does not have any national rules over and above those of the EU harmonised legislation on contaminants and as such the industry is not subject to any potential burdens that might be associated with complying with national measures. As mentioned above, there is no evidence of 'gold-plating' of EU law, when national legislation exceeds

the requirements of EU legislation. The measures enforced by the 2013 Regulations are EU Regulations and as such are directly applicable.

6.12 With regards to employing flexibilities to make the implementation of EU Regulations less burdensome, stakeholders were of the view that the use of non-regulatory measures were effective in providing the industry with guidance to reduce contaminant levels, while ensuring consumer safety. The provision of consumption advice (lead shot in game, mercury in fish, arsenic in rice drinks) as well as target or guideline levels for various contaminants was effective in helping businesses work towards reducing the levels without the burden of a regulatory measure. This is somewhat a different approach to some Member States who consider it easier to enforce when legal limits are in place.

6.13 In relation to conformity and application, some stakeholders believe that there is an inconsistent approach to the enforcement of the EU Regulations across Member States. There is a perception from some stakeholders that while some Member States enforce the current EU contaminants regulations fully, others only partially enforce the rules, leaving industry at a cost disadvantage where enforcement is comprehensive. However, these claims relate to anecdotal evidence only, and no evidence has been provided to substantiate these claims.

6. Consumers' perspective

7.1 The FSA routinely engages with consumers on the presence of contaminants in food. An FSA dedicated electronic mailbox for consumers and industry contaminants queries is available from which we are able to monitor consumers' views. Questions from consumers are commonly focused on the safety of certain chemicals or consumption of specific foodstuffs, particularly those that have received media attention. Questions are also raised on the process and effectiveness of regulatory measures in place.

7.2 However, research carried out by the FSA on consumer perspectives on chemical contaminants in food[21] indicated that in general, consumers have low awareness and understanding of chemical contaminants in food. Despite this, results from this study suggested that consumers would pay attention to Government advice, and on the whole, were trusting of Government advice on food.

7.3 This research also indicated that consumers considered this a highly technical area and would prefer receiving information about chemicals that are present in food only when the risks were particularly salient or dangerous, or there were clear actions consumers could take to avoid or reduce risk. Too much information about chemicals would risk overwhelming consumers, and participants were uncomfortable with learning about chemicals that they felt they could do little to avoid. Overall, current advice was considered to be clear and useful.

7.4 We did not receive specific comments or views on the 2013 Regulations from consumers.

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21 https://www.food.gov.uk/sites/default/files/consumer-understanding-of-food-risk-chemicals.pdf and https://www.food.gov.uk/sites/default/files/chemicalscontaminants.pdf

8 Conclusion

8.1 The 2013 Regulations meet their objective of safeguarding consumers from the risk of chemicals that might otherwise have been present in food at levels that affect human health (Section 4). Feedback from stakeholders shows that it is perceived that these Regulations provide for a fair, harmonised enforcement of EU Regulations, while being proportionate and ensuring consumer safety.

8.2 The 2013 Regulations also meet their objective of providing the enforcement provisions for the Contaminants Regulation (paragraph 3.1). There is evidence from Port Health Authorities and Local Authority enforcement officers that the provisions in the 2013 Regulation are enforced to remove non-compliant foods from the market. Nevertheless, while the enforcement authorities and industry agree that the 2013 Regulations provide for the execution and enforcement of the EU Regulation on contaminants; because of the complexity and resource-intensive nature of the sampling requirements for contaminants and since funding and staff available to the LAs were limited, it resulted in limited sampling and testing for contaminants.

8.3 It was clear that stakeholders almost always refer to the original EU Regulations which are complex to understand and implement. They would like a database containing food products and related risks from various chemical contaminants.

8.4 Industry stakeholders informed us that the provision of the ambulatory reference has simplified the national contaminants in food regulations. There was a general consensus that it reduces the need for constant cross-referencing and makes it more straightforward for enforcement officers and businesses to find and implement statutory requirements.

8.5 During the course of reviewing the 2013 Regulations, we have not come across any evidence that suggests they have led to any negative unintended consequences that impact on stakeholders. Nevertheless, the high cost of analytical testing to smaller businesses was alluded to by some stakeholders. There was no evidence that, on the whole, burdens on UK businesses to comply with the 2013 Regulations exceed those on businesses complying with equivalent enforcement Regulations in other Member States.

8.6 Though this review does not examine the use of sanctions in the Contaminants in Food (England) Regulations 2013, the FSA is considering how to reduce reliance on criminal sanctions and will be consulting on moving towards civil sanctions in existing regulations in due course

9. Recommendations

9.1 There is evidence that the Contaminants in Food (England) Regulations 2013 continue to meet their objectives of protecting public health by keeping contaminants at acceptable levels and providing for the execution and enforcement of the EU Regulations on

contaminants in food. Therefore, during the transition period, options for renewal, removal or replacement are not directly actionable[22].

9.2 It is recommended that the Contaminants in Food (England) Regulations 2013 are retained.

[22] 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.

Annex 1. The EU Regulations enforced, and Directives implemented by, the Contaminants in Food (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
Regulation No 315/93 (EEC)	OJ L 37, 13.2.1993, p.	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.
Regulation (EC) No 1881/2006	OJ L 364, 20.12.2006, p. 5	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.
Regulation (EC) No 401/2006	OJ L 70, 9.3.2006, p.12	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the sampling methods and the methods of analysis for the official control of the levels for mycotoxins in foodstuffs.
Regulation (EC) No 333/2007	OJ L 88, 29.3.2007, p.29	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Regulation (EC) No 1882/2006	OJ L 364, 20.12.2006, p. 25	Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs
Regulation (EU) 2017/644	OJ L 92, 6.4.2017, p. 9–34	Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014