Post Implementation Review

The Materials and Articles in Contact with Food (England) Regulations 2012

Executive Summary

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.***

2. The Materials and Articles in Contact with Food (England) Regulations 2012 ("The 2012 Regulations") revoke, remake and consolidate all implementing and enforcement provisions on Food Contact Materials (FCM) that were previously contained in three Statutory Instruments.

3. The 2012 Regulations implement a number of EU Directives, and provide for the execution and enforcement, in England, of a number of Commission Regulations, including Commission Regulation (EU) No. 10/2011 ("the Plastic Regulation").

4. This report on the post implementation review (PIR) of the 2012 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 and assessing the baseline costs and benefits outlined in the associated impact assessment. It is a light touch PIR based on the low impact expected to arise from the 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 scale of the Regulations and their anticipated impact.

5. As a minimum, this report seeks to establish whether the objectives of the 2012 Regulations have been achieved. It also looks at: whether there have been any unintended effects on stakeholders resulting from the implementation of the 2012 Regulations, consumers' perspectives on the 2012 Regulations, and whether they are executed and enforced equally in other Member States.

6. In line with the light-touch approach determined to be appropriate for this PIR, it was felt that a 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 written consultations, and in some instances dialogue with Trade Associations, Enforcement Authorities and Official Control Laboratories.

7. During the course of reviewing the 2012 Regulations, no strong evidence was identified to suggest that the introduction of the Regulations has led to any negative or unintended consequences on stakeholders. This is supported by the comments received from the following three stakeholders during the

consultation; The Food & Drink Federation (FDF), the Food Service Packaging Association (FPA) and the Confederation of Paper Industries (CPI).

8. There is evidence that the 2012 Regulations continue to meet their objectives of protecting consumer health and providing for the execution and enforcement of the EU Regulations on FCM. Therefore, 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. The findings of this review will, however, help to inform future UK policy decisions on FCM.

1. Introduction and Background

1.1 The term food contact materials and articles (FCM) covers a broad range of goods. Among the most widely used materials are the many types of plastic used for bottles, films and containers. There is also a wide range of paper and board products, laminates and metal and wooden containers. Many modern forms of packaging will make use of a variety of these in a single packaging product to protect the foodstuff under the conditions expected during processing and transportation.

1.2 As well as materials used for packaging the food, others will be used in the equipment that prepares or processes the food. This equipment will bring the food into contact with many different types of surfaces made from, for example, metal, plastic, wood and rubber. There are also the food surfaces and preparation equipment used in the home such as crockery and cutlery, on which and with which food is served.

1.3 The general principles governing the safety of all materials and articles intended to come into contact with food are established in Regulation (EC) No. 1935/2004 of the European Parliament and of the Council ("the Framework Regulation"). This Regulation is directly applicable to the UK and lays down the framework for the safety of all such materials and articles intended to come into contact with food.

1.4 The Framework Regulation requires all FCM not to transfer chemicals into food in quantities that might be harmful to human health. In addition to the Framework Regulation, specific measures have been developed for some materials that come into contact with food to provide additional controls or as a result of a specific risk to health. For instance, the EU Regulation on plastic FCM lists the substances that plastic FCM can be made from and sets limits on the amounts that could potentially transfer into food and drink.

1.5 The Materials and Articles in Contact with Food (England) Regulations 2012 ("the 2012 Regulations") bring together existing enforcement and implementation provisions for EU legislation on FCM, into a single Statutory Instrument[1].

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 2012 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 policy review policy was introduced by the Government in 2011 for new English legislation derived from European law.

[1] with the exception of The Plastic Kitchenware (Conditions on Imports from China) England Regulations 2011. This provides enforcement powers for controls on the import of nylon and melamine kitchenware from the People's Republic of China and Hong Kong contained within Commission Regulation (EU) No 284/2011.

2.2 This report assesses the actual effect of the 2012 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 2012 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 2012 Regulations have been achieved. It also looks at: consumers' perspective on the 2012 Regulations; whether there have been any unintended impacts on stakeholders resulting from the implementation of the 2012 Regulations; and how the Regulations are executed and enforced in other Member States.

2.4 This report on the 2012 Regulations relates to England only as the statutorily requirement to conduct a review of their legislation only extends to England. 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 2012 Regulations, revisits the baseline costs and benefits identified in the associated impact assessment[2], 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 FCM is executed and enforced in other Member States and whether the implementation of the 2012 Regulations puts businesses at a disadvantage compared with the implementation in other Member States.

3. Objectives and baseline costs of the 2012 Regulations

3.1 Objectives

The 2012 Regulations aim to meet three policy objectives:

[2] The impact assessment to accompany the 2012 Regulations is available here: http://www.legislation.gov.uk/ukia/2012/402/pdfs/ukia_20120402_en.pdf

- ❖ To protect consumer health from consumption of food containing harmful levels of chemicals migrating from materials and articles with which the food has intentionally been placed in contact;
- ❖ To provide for the execution and enforcement of Commission Regulation (EU) No. 10/2011 (The Plastic Regulation) which updates and replaces previous EU legislation in this area; and,
- ❖ To revoke, remake and consolidate existing enforcement and implementation provisions on materials and articles intended to come into contact with food into one set of Regulations, thus making it more convenient for businesses and others that have to refer to the Regulations.

3.2 **Baseline costs**

The estimated baseline costs and benefits anticipated for the enforcement of the 2012 Regulations were set out in the FSA impact assessment which accompanied the Regulations.

3.3 *Estimated* costs of familiarisation

It was estimated that: Industry, Enforcement Authorities (Local Authorities and Port Health Authorities) and Official Control Laboratories (OCLs) would face one-off familiarisation costs as a result of reading and familiarising themselves with the Plastic Regulation. The costs were estimated by multiplying the median hourly wage rate for each sector by the estimated time needed to assimilate and disseminate the information. This was then multiplied by the total number of businesses, authorities or laboratories.

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. The total one-off cost to enforcement authorities and OCLs in England affected by this proposal was estimated to be £17,214, which resulted in an EAC of £2,000 for a time period of 10 years. The total one-off cost to industry was estimated to be £110,263, which resulted in an EAC of £12,810 for a time period of 10 years.

3.4 *Actual* costs of familiarisation

The FSA has not identified any evidence to suggest that the familiarisations costs resulting from the 2012 Regulations were materially different from the estimates made in the published impact assessment. Consultation responses supported this view with all respondents confirming that they had not identified any other significant familiarisation costs. For proportionality the FSA has not attempted to undertake any further analysis of the actual familiarisation cost resulting from the 2012 Regulations.

3.5 *Estimated* simplification benefits of the 2012 Regulations

The 2012 Regulations revoke, remake and consolidate existing implementing and enforcement provisions on FCM that were previously contained in the following three Statutory Instruments:

(i) The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 as amended by the Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011

(ii). The Materials and Articles in Contact with Food (England) Regulations 2010;

(iii). The Ceramic Articles in Contact with Food (England) Regulations 2006,

3.6 It was assumed that new entrants to the industry and enforcement officers would benefit from simplification resulting from the consolidation of the FCM legislation. For industry, benefits were estimated at £135,916 per year with a net present value (NPV) over 10 years of £1,169,925. Benefits for enforcement authorities were estimated at £3,645 per year with a NPV of £31,372 over 10 years.

3.7 *Actual* simplification benefits

The average number of new FCM manufacturers and retailers over the period 2004-2009 in the Interdepartmental Business Register was used to estimate the number of expected new entrants of the relevant manufacturers and retailers that would benefit from simplification over a 10 year period from 2012 to 2022. The average actual number of new FCM manufacturers and retailers between 2010 to 2015 was slightly lower than estimated (around 12% lower). Although this means that the simplification benefits of consolidating the regulations to reduce familiarisation time may be slightly lower than estimated in 2012, the actual number of new entrants over the remaining years of the 10 year simplification period would be needed to draw comparisons with the estimated birth rate and estimated simplification benefits. It would be disproportionate for the purposes of this review to ascertain the actual number of new businesses that have benefited from simplification as the FSA does not collect data on new FCM manufacturers and it would be very time consuming to assess the relevance of this legislation to each business. Nevertheless, all the stakeholders we contacted during the course of this review welcomed the concept of consolidation and said that it reduces the need for constant cross-referencing which could make interpretation of the legislation more difficult.

3.8 *Estimated* sampling and testing benefits

It was assumed that there would be additional benefits to industry as a result of the introduction of Article 19 of the Plastic Regulation. Article 19 recognises the use of internationally recognised scientific principles for the risk assessment of non-intentionally added substances (NIAS)[3] and non-listed substances. Although this benefit was not quantified, it was assumed that this would make it easier for businesses to comply with the new legislation as they would have the option of using alternative methods for risk assessment.

3.9 *Actual* sampling and testing benefits

There is no evidence of these benefits accruing from the introduction of Article 19 as many principles of risk assessment were in use prior to its introduction. However, we

[3] Non-intentionally added substances (NIAS) are chemical compounds that are present in a plastic material but have not been added for a technical reason during the production process. NIAS originate from either the break-down products of plastics, impurities in starting materials, or unwanted side-products.

understand from the industry that its introduction has raised the profile of the existing tools available for risk assessment and the issue of NIAS.

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

4.1 There are three main policy objectives which need to be assessed in order to ascertain whether the 2012 Regulations have met the intended objectives. These three objectives are discussed below.

Objective 1 - To protect consumer health from consumption of food containing harmful levels of chemicals migrating from materials and articles with which the food has intentionally been placed in contact

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 FCM. 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. The approach to risk assessment of substances used in FCM takes into account both the short and long term risk to health. Our approach has been to focus on the approaches to regulating FCM, such as setting limits on substances, which are likely to result in a reduction of human exposure and, ultimately, in a reduction of any negative effects on consumer safety.

4.3 Thus, the primary aim of the 2012 Regulations is to protect consumer health by providing enforcement and implementation powers for FCM Regulations and Directives which restrict, limit and in some cases prohibit substances that might potentially transfer from FCM into food (See Annex 1). The 2012 Regulations also have a deterrent effect, as businesses know that sanctions can be imposed by enforcement officers if they do not comply with the Regulations.

4.4 Article 3 of the EU Framework Regulation on FCM sets three general requirements. All materials and articles should be sufficiently inert so that under normal or foreseeable conditions of use they do not transfer their constituents to food at levels which could:

- endanger human health;
- bring about an unacceptable change in the composition of food, for example change its acidity level which may give it a shorter shelf-life;
- taint the food, by giving it an odd taste, aroma or texture, thereby making it less desirable.

4.5 The principles enshrined in the Framework Regulation apply to all FCM and are broad in their application. However, the Framework Regulation also provides for the adoption of specific measures on materials and articles. So far, specific measures have been adopted for the following FCM: plastics, recycled plastics, ceramics,

regenerated cellulose film, active and intelligent materials and certain epoxy derivatives.

4.6 Some specific measures, such as those covering plastics[4] and regenerated cellulose film[5], provide limits for substances that could transfer (migrate) into food. The use of migration limits (known as "specific migration limits") has therefore been an important mechanism in ensuring consumer safety. These limits have been established by the Commission and Member States, following a safety assessment by the European Food Safety Authority (EFSA) on the basis of toxicity data. They specify the maximum amount of substances migrating into food to ensure the safety of the final material.

4.7 Regulation (EC) No. 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food ("the GMP Regulation") is also broad in its application. This Regulation requires businesses to establish and document good practices and procedures, and to ensure that the manufacturing process is well controlled so that the FCM remains in conformity with any specifications given within the legislation.

4.8 The Framework and GMP Regulations ensure that there are general rules that apply to all FCM, thereby providing a high level of consumer safety. The Framework Regulation also provides a starting point for industry to produce their own material specific guidelines to support compliance with these Regulations. These guidance documents are often produced by individual trade associations representing the different industry sectors and are commonly made publically available.

4.9 Stakeholders we contacted during the course of this review informed us that the 2012 Regulations are meeting their objective of protecting consumers' health by providing:

- a framework that defines what is required for compliance to ensure consumer health
- clear provisions on what is required of each stakeholder at each stage to ensure the safety of the food in contact with the materials.

Objective 2 - To provide for the execution and enforcement of the Plastic Regulation; which updates and replaces previous EU legislation in this area

4.10 The 2012 Regulations came into force in November 2012 and provide for the execution and enforcement, in England, of the provisions of the Plastic Regulation. They provide offences under English law for contravening certain requirements of the Regulations and provide penalties which can be imposed for these offences.

4.11 Part 6 of the 2012 Regulations provides for the enforcement of the Plastic Regulation and identifies those provisions of the EU Regulation which it constitutes an offence to contravene. The competent authorities for the purposes of certain provisions of

[4] Commission Regulation 10/2011
[5] Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

the Plastic Regulation are designated in Regulation 15. (Generally speaking, these are the Food Standards Agency, each food authority in its area, and each port health authority in its district).

4.12 The day-to-day enforcement work of the 2012 Regulations is the responsibility of environmental health practitioners from local food authorities and port health authorities (PHAs). Those consulted in the course of this review said that they were familiar with the 2012 Regulations and referred to them, although not very frequently.

4.13 The PHAs that we contacted informed us that they refer to the Plastic Regulation frequently, using the limits laid down in the Plastic Regulation (in conjunction with the plastic kitchenware regulations)[6] to reject non-compliant consignments of plastic kitchenware imported from China. One Authority informed us that financial constraints meant that their focus was on carrying out enforcement where the mechanisms for them to recover the cost of enforcement exist, such as in the plastic kitchenware regulations.

4.14 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 FCM that are not compliant with the relevant EU legislation to ensure that products are removed from the market. Inspections of the Food and Veterinary Office (FVO) verify compliance in the Member States and beyond the EU. In addition, the Joint Research Centre (JRC), which is the European Commission's science and knowledge service, carries out research in order to provide independent scientific advice and support to policy development on FCM.

4.15 While the industry agrees that the 2012 Regulations provide for the execution and enforcement of the Plastic Regulation, it is clear from our consultation that they would like to see greater enforcement of FCM legislation in the UK, particularly for imported products.

4.16 However, local enforcement authorities employ a risk-based approach to enforcing FCM legislation, with a proportionate level of priority being accorded to areas where the highest risk is involved. In the UK, the focus in recent years for FCM has been on the risk to health from non-compliant kitchenware products imported from China and Hong Kong. Local authorities work closely with business operators to ensure safety, for example by passing on educational material to new businesses.

4.17 On the whole, providing for the enforcement of the Plastic Regulations has ensured continuation of consumer protection against exposure from chemicals that could migrate into food, which could potentially carry long term risks to consumer health.

Objective 3 - To revoke, remake and consolidate almost all existing enforcement measures on materials and articles intended to come into contact with food into one set of Regulations, thus making it more convenient for businesses and others that have to refer to the Regulations

[6] Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011

4.18 The 2012 Regulations meets objective 3 by revoking three previous Regulations:

(1) The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 as amended by the Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011;

(2) The Materials and Articles in Contact with Food (England) Regulations 2010;

(3) The Ceramic Articles in Contact with Food (England) Regulations 2006

4.19 The 2012 Regulations also satisfies Objective 3 by consolidating into one Statutory Instrument the FCM enforcement provisions which were contained in the three revoked Regulations.

4.20 Most of the enforcement authorities we spoke to felt that they had benefited from having one piece of legislation as it reduces the need for constant cross-referencing which can make interpretation more difficult. Trade associations we contacted agreed that the consolidation of regulations makes it more straightforward for businesses to find and implement statutory requirements.

5. Assess whether the objectives remain appropriate, and 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 Plastic Regulation, and provide the benefits of simplification which have been brought about as a result of the consolidation of existing enforcement measures.

5.2 Stakeholders we engaged with in the course of this review were unanimous in their view that the 2012 Regulations remain appropriate and were not in favour of a non-regulatory regime, which they felt would require significant levels of education and be subject to different interpretations.

5.3 They suggested that non-regulatory measures would not be as effective as the current legislation and could have an impact on consumer safety as there would be no means of taking action against businesses that do not comply with the law.

5.4 In a 2014 stakeholder views were sought on whether the current FCM measures in place are sufficient. There was general consensus among stakeholders that there was a need for further regulation in areas where there are no specific measures. They suggested that the priorities for further Regulation are paper, board, coatings, inks and adhesives. However, when considering the need for detailed, material specific measures, it is important to carefully consider the justification for these against the cost of establishing and demonstrating compliance with these additional Regulations. Introducing new specific measures on materials and positive lists of substances that can be used to make these materials is time consuming and may

not always be necessary to ensure the safety of materials. The principles in the Framework Regulation may be sufficient for this.

6. Examination of :

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

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

a) Enforcement of the legislation in other EU Member States

6.1 In England (and throughout the UK) harmonised legislation is enforced by means of Statutory Instruments which provide penalties and enforcement powers for infringements. We contacted a range of Member States in the course of this review to ascertain how FCM legislation is executed and enforced in their countries.

6.2 The approach to enforcement is similar in the Member States we contacted where FCM are regulated under specific laws, or using the powers provided for in existing legislation. Three of the four Member States we contacted said that the FCM Regulations are enforced at a local level. As in the UK, enforcement of FCM is targeted, based on the level of risk associated with it. Two of the four Member States we contacted informed us that that they go beyond the EU Regulations. One explained that they regulate paper, rubber, metal, glass, textiles, wood & cork, coatings, pigments & colourants: the other regulates polymeric materials and substances, both at a national level.

6.3 The Framework Regulation stipulates that sanctions for infringement should be effective, proportionate and dissuasive. 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.

6.4 In 2016 the Joint Research Centre published an EU-wide review of FCM for which there are no specific measures at EU level[7]. One of the key issues identified was that practical implementation and enforcement is impeded by the lack of access to or availability of testing methods to test compliance with legislative limits.

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 other EU Member States

[7] Non-harmonised food contact materials in the EU Regulatory and market situation baseline study final report: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study

6.5 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. There is no evidence that the 2012 Regulations has led to 'gold-plating' of EU law, which is where national legislation exceeds the requirements of EU legislation. Five of the measures enforced by the 2012 Regulations are EU Regulations and as such are directly applicable. The other three measures are European Directives which contain specific provisions which have been transposed into national law.

6.6 The Framework Regulation on FCM 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. The UK does not have any national rules over and above those of the EU harmonised legislation and as such is not subject to any potential burdens that might be associated with complying with national measures. In areas where there is no harmonised legislation, businesses must demonstrate compliance with the Framework Regulation, in particular, the provisions of Article 3 (see paragraph 4.4). Most other Member States have some form of national measures[8]. For example, France, Germany, Spain, Croatia, Italy and the Netherlands have national measures on adhesives, while Belgium, the Czech Republic, Germany, Greece, France, Italy, the Netherlands and the Slovak Republic have national measures on paper and board.

6.7 However, in relation to conformity and application a number of 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 Member States enforce the current EU FCM rules to the full extent, whereas others only partially enforce the rules, leaving industry at a cost disadvantage where enforcement is comprehensive. Overall, the main comments received from the three stakeholders during the consultation said that the enforcement of the EU Regulations and the implementation of EU Directives on FCM didn't lead to extra burdens on businesses than the implementation in other Member States.

7. Consumers' perspective

7.1 The FSA has a dedicated FCM electronic mailbox for queries from consumers and industry from which it is able to draw out consumers' views on FCM. Questions from consumers are commonly on the safety of certain chemicals or specific materials, particularly those that have received media attention; and on the safety of reusing food packaging.

7.2 Consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed

[8] With the exception of Malta, Luxembourg, Lithuania, Latvia, Cyprus, Estonia and Hungary, Ireland and Slovenia.

choices about such risk. They are rarely interested in the 2012 Regulations as such, though confirmation that there is comprehensive legislation to protect consumer health from the migration of chemicals from FCM is usually well received.

7.3 The FSA biannual public attitudes trackers[9] of May 2016 and November 2016 did not report on any particular concerns on FCM when respondents were prompted about food safety.

7.4 Little distinction is made between the national and the European FCM legislation when issues are raised by consumers. At the European level, the consumer view reported by the European Parliament is that the lack of EU specific measures for some FCM has a negative effect on consumer trust, and that the current EU rules are insufficient to ensure traceability in the supply chain[10].

8. Conclusion

8.1 The 2012 Regulations meet their objective of safeguarding consumers from the risk of chemicals that might otherwise have migrated into food at levels that affect human health (Section 4). Some specific EU measures on FCM provide specific migration limits which restrict, limit and in some cases ban substances that might migrate into food. The Framework regulation also provides safeguards for non-harmonised materials, requiring that all FCM should be safe and not influence food in a negative way.

8.2 The 2012 Regulations also meet their objective of providing the enforcement provisions for the Plastic Regulation (paragraph 4.12). There is evidence from Port Health Authorities that the provisions in the Plastic Regulation are enforced (in conjunction with the Kitchenware Regulations) to remove non-compliant kitchenware from the market. Nevertheless, while industry agree that that the 2012 Regulations provide for the execution and enforcement of the Plastic Regulation, they would like to see more enforcement of FCM, both at the borders and locally, particularly to ensure compliance for products from third countries.

8.3 The 2012 Regulations met their objective of consolidating nearly all existing FCM enforcement provisions into one statutory instrument. They simplified existing regulations in this area by consolidating the requirements of three regulations (paragraph 4.18). Key industry stakeholders informed us that the consolidation has simplified and added clarity to the national FCM regulations. There was a general consensus that it reduces the need for constant cross-referencing and makes it more straightforward for businesses to find and implement statutory requirements.

8.4 During the course of reviewing the 2012 Regulations, we have not come across any evidence that suggests they have led to any negative unintended consequences that impact on stakeholders. This is supported by the comments received from the

[9] https://www.food.gov.uk/science/research/ssres/publictrackingsurvey

[10] European Parliament resolution of 6 October 2016 on the Implementation of the Food Contact Materials Regulation (EC) No 1935/2004: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2016-0384+0+DOC+PDF+V0//EN

following three stakeholders during the consultation; The Food & Drink Federation (FDF), the Food Service Packaging Association (FPA) and the Confederation of Paper Industries (CPI). Nevertheless, the high cost of analytical testing to smaller businesses was alluded to by some stakeholders. Also, the administrative burden of keeping the required documentation was mentioned. There was no evidence that, on the whole, burdens on UK businesses to comply with the 2012 Regulations exceed those on businesses complying with equivalent enforcement Regulations in other Member States.

8.5 Though this review does not examine the use of sanctions in the Materials and Articles in Contact with Food (England) Regulations 2012, 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 Materials and Articles in Contact with Food (England) Regulations 2012 continue to meet their objectives of protecting consumer health and providing for the enforcement of EU Regulations and the implementation of EU Directives on FCM. Therefore, 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[11].

9.2 We recommend that the Materials and Articles Regulation Contact with Food (England) Regulations 2012 are retained.

[11] 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 1. The EU Regulations enforced, and Directives implemented by, the Materials and Articles in Contact with Food (England) Regulations 2012

Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food	The principle underlying this Regulation (also known as the Framework Regulation) is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health, or to bring about an unacceptable change in the composition of the food, or a deterioration in its organoleptic properties.
Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.	This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. It establishes the rules for plastic materials and articles to be applied for their safe use.
Commission Regulation (EC) No. 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food	This Regulation requires that businesses establish and document good practices and procedures. It elaborates the general requirement from the Framework Regulation in relation to GMP. This Regulation applies to all sectors and to all stages of manufacture, processing and distribution of FCM, but not the production of the starting substances used in the manufacture of FCM.
Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food	This Regulation establishes the specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.
Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials	This Regulation prohibits the use of two substances (BFDGE[12] and NOGE[13]) in materials and articles intended to come into contact with food. It also provides

[12] Bisphenol-F DiGlycidyl Ether
[13] novolac glycidyl ethers

and articles intended to come into contact with food	maximum limits for the use of BADGE[14] and its derivatives.
Council Directive 78/142/EEC on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs	This Directive limits the presence and migration of vinyl chloride monomer in and from materials and articles intended to come into contact with foodstuffs.
Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs	This Directive regulates the possible migration of lead and cadmium from ceramic articles which, in their finished state, are in contact or are intended to come into contact with foodstuffs.
Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs	This Directive lays down a list of substances authorised in the manufacture of regenerated cellulose film (RCF), as well as quantities not to be exceeded so as to protect consumers' health.

[14] Bisphenol-A DiGlycidyl Ether