Consultation Pack - Review of The Materials and Articles in Contact with Food (England) Regulations 2012

This report, on the second Post Implementation Review (PIR) of the 2012 Regulations, assesses the actual effect of the regulations ten years after they were enacted.

1. Executive Summary

1.1 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. The 2012 Regulations implemented the requirements of several European Union (EU) Directives, and provide for the execution and enforcement, in England, of several European Commission Regulations, including Commission Regulation (EU) No.10/2011 (the "Plastic Regulation").

1.2 The UK exited the EU at end of the transition period on 31st December 2020 and from that time EU legislation became part of Great Britain's retained EU law. This means Commission Regulation (EU) No. 10/2011 and several other EU Commission Regulations also became part of GB's retained EU law. Various legal provisions were made to ensure FCMs legislation remained operable after that date. To ensure the functioning of the market in Great Britain, legal provisions were made – The UK Internal Market Act 2020. Section 2 enables goods to maintain their compliance when moving between England, Scotland, and Wales so there are no legal barriers to trade between the three nations. There is a mutual recognition clause which permits free trade. Trade with Northern Ireland was initially covered by the Northern Ireland Protocol (NIP), and later from autumn 2023, the Windsor Framework.

1.3 This report on the second Post Implementation Review (PIR) of the 2012 Regulations, assesses the actual effect of the Regulations ten years after they were enacted. This has been done by collating evidence of the known views and experiences of key stakeholders and reassessing the baseline costs and benefits outlined in the associated impact assessment, particularly considering the changed status of the UK within Europe. 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 once directly applicable and now retained EU legislation. Therefore, the level of evidence is commensurate to the scale of the Regulations and their anticipated impact.

1.4 This report seeks to establish whether the objectives of the 2012 Regulations were achieved and currently remain relevant. It also looks at whether there have been any unintended effects on stakeholders resulting from the implementation of the 2012 Regulations and similarly on consumers' perspectives on the 2012 Regulations.

1.5 In line with the proportionate approach determined to be appropriate for the initial PIR, it was felt that a small-scale survey of affected stakeholders would help to understand the on-going effect of the legislation. This was 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 (OCLs). A confirmatory exercise was undertaken for this PIR to ascertain if the Regulations and their amendments remain pertinent and viable.

1.6 During the review of the 2012 Regulations, no strong evidence was obtained to suggest that the introduction of the Regulations has led to any negative or unintended consequences to stakeholders.

1.7 There was evidence that the 2012 Regulations achieved their objectives of protecting consumer health and providing for the execution and enforcement of the EU Regulations on FCM when in its original form, and this continues to be so following its amendments.

1.8 It should be noted that the 2012 Regulations were reviewed to fix inoperability's arising from the UK leaving the EU, once the transition period ended. The Regulations were, therefore, subject to amendment following EU exit, which are included below.

2. Introduction and Background

2.1 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 packaging, bottles, films and containers. There is also a wide range of paper and board products, laminates and metal and wooden containers. For example, 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.

2.2 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 cooked and served.

2.3 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 remains applicable as retained EU law and lays down the framework for the safety and suitability of all such materials and articles intended to come into contact with food.

2.4 The Framework Regulation requires that all FCM do not transfer chemicals into food in quantities that might be harmful to human health. It also requires that the quality of the food is not impaired. 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 and remain compliant to the safety provisions. These were also retained in national law after the UK's departure from the EU.

2.5 The 2012 Regulations brought together existing enforcement and implementation provisions for EU legislation on FCM into a single Statutory Instrument. A Statutory Instrument is a means of enacting laws of a technical nature. As a consequence of the departure of the UK from the EU a series of amendments were required to ensure it remained operable after the end of the Transitional Period (ended 31st December 2020).

2.6 The original Regulations for England have been amended as per the following individual amending Regulations (this also includes amendment(s) following the introduction of the Northern Ireland Protocol, to differentiate Great Britain from United Kingdom).

Amending Regulation	Effect on 2012 Regulations
The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019	Amendments to remove references pertaining to the EU.
The Food and Feed Hygiene & Safety (Misc. Amendments) (England) Regulations 2020	Regulation 4 amends to incorporate provisions for recycled plastics and restrictions on the chemical bisphenol A.
The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020	Regulation 16 amends The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 to differentiate Great Britain and United Kingdom.

2.7 At the time of this Post Implementation Review (PIR) further amendments were outstanding with regards to authorisation listing of substances in regenerated cellulose film and removal of the requirement to use the 'Do Not Eat' pictograph on active and intelligent materials. Consultations on these were undertaken in the summer of 2022. At the time of this publication these outstanding issues had been successfully resolved with their inclusion within The Food and Feed (Miscellaneous Amendments) Regulations 2022.

3. Purpose and Scope of the Report

3.1 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 PIR of the Regulations and set out the conclusions in a report within five years of the measure coming into force and within every five years thereafter. This statutory policy review policy was introduced by the Government in 2011 for new English legislation derived from European law. This is the second such review as the legislation has now been in force for a decade.

3.2 This report assesses the actual effect of the 2012 Regulations since the 2017 PIR (footnote 1) , 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.

3.3 This light-touch review is proportionate to the low impact the FSA believes to have arisen from the 2012 Regulations and which continues to be the case since the last review was published. The main function of the regulations is to provide the implementation of powers and enforcement for the EU derived legislation. Therefore, the level of evidence is commensurate to the anticipated impact of these Regulations, as confirmed in the first PIR.

3.4 This report seeks to establish whether the objectives of the 2012 Regulations continues to be achieved. It also looks at consumers' perspective on the 2012 Regulations and whether there have been any unintended impacts on stakeholders resulting from the implementation of the 2012 Regulation. Additionally, it looks at the impact of the amendments necessary to fix inoperability resulting from the UK departure from the EU.

3.5 The PIR on the 2012 Regulations relates to England alone as the other nations of the UK, Scotland, Wales and Northern Ireland do not have review clauses within their respective Regulations and are as such are not statutorily obliged to conduct a periodic review of their legislation.

This report -

a) reassesses the objectives of the 2012 Regulations and reviews the FSA impact assessment for the 2012 Regulations, revisits the baseline costs and benefits identified in the associated impact assessment and assesses the extent to which these costs and benefits have been realized.

b) provides an evidence-based evaluation of the extent to which those

objectives are being achieved.

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

d) examines how the legislation on FCM is executed and enforced and whether the implementation of the 2012 Regulations puts businesses at a disadvantage compared with the implementation in other countries.

e) whether the amendments required to maintain the provisions of the 2012 Regulations (footnote 2) have proved effective and are functioning adequately or need improvement.

3.6 Since departure from the EU, the European Commission has initiated a review of Commission Regulation (EC) 1935/2004, the underlaying legislation to the national Regulations. Whilst this is co-incidental, it seems timely that the national legislation is also re-evaluated to ensure it remains fit for purpose, and the opportunity taken to improve or replace it as necessary.

4. Objectives

4.1 The 2012 Regulations aim to meet the following policy objectives -

- 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. In addition, to protect consumer health from direct contact with articles associated with the consumption of food, such as cutlery.
- To provide for the execution and enforcement of the Plastics Regulation (see section 5 for additional detail).

4.2 It is not always possible to quantify or monetise the consumer health benefits of legislation that regulates the presence of unintended 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 develop as a result of long-term exposure. The approach to risk assessment of substances used in FCM considers both the short and long-term risks 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 health.

4.3 Thus, the primary aim of the 2012 Regulations is to protect consumer health by providing enforcement and implementation powers for FCM Regulations 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 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 or humidity level which may give it a shorter shelf-life.
- taint the food, by giving it an odd taste, aroma, colour, or texture, thereby making it less desirable.

4.5 The principles enshrined in the Framework Regulation apply to all FCM regardless of their composition and are broad in their application. However, the Framework Regulation also provides

for the adoption of specific measures on materials and articles. Specific measures have been adopted for the following FCM - plastics, recycled plastics, ceramics, regenerated cellulose film, active and intelligent materials, vinyl chloride monomer and certain epoxy derivatives.

4.6 Some specific measures, such as those covering plastics and regenerated cellulose film (footnote 3), provide limits for substances that could transfer (migrate) into food. The use of migration limits (either “specific migration limits” for a given chemical or “overall migration limits” for general chemical substance levels) has therefore been an important mechanism in ensuring consumer safety. These limits were established by the Commission and EU Member States, following a safety assessment by the European Food Safety Authority (EFSA) on the basis of toxicity data. These limits were accepted in national legislation at the time of departure from the European Union but are subject to potential revision thereafter based solely upon a national assessment of their risk. These limits specify the maximum permissible amount of substances migrating into food so as to ensure the safety of the final material.

4.7 Retained 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 means to ensure 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 publicly available.

4.9 Stakeholders were contacted both during the 2017 review and for this review, which confirmed 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.

4.10 As well as safety an increasing emphasis has emerged on food quality, and the sustainability of food itself and of the materials expected to be in contact with it, especially its packaging. The 2012 Regulations have a significant role in this respect. Innovations must be safe but also demonstratively so and function effectively. This is a paramount requirement and supersedes any other consideration, such as to a materials sustainability or environmental impact.

4.11 Stakeholders we engaged with during the initial review in 2017, and the current review, indicated that these Regulations remain appropriate - they were not in favour of a non-regulatory regime, which they felt would be subject to different interpretations. Furthermore, they suggested that non-regulatory measures would not be as effective as the current legislation, which could have a negative impact on consumer safety as there would be no means of taking enforcement actions against businesses that do not comply with the law.

4.12 In 2014, views were sought on whether the current FCM measures in place were deemed sufficient. There was 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, cartonboard, coatings, inks, and adhesives.

4.13 Since 2014, several stakeholders have indicated their desire for an extension to the specific measures. These are reflective of the ones previously mentioned, with no adverse comment as to the current requirements, other than the duration for authorisations to be undertaken and

interpretations as to what may or may not be within scope of the existing provisions.

4.14 When considering the need for detailed, material specific measures, it is deemed important to carefully consider the justification for these against the cost of establishing and demonstrating compliance with these additional Regulations.

4.15 Introducing new specific measures on materials and positive lists of substances that can be used to make these materials is both time consuming and resource intensive and may not be necessary to fully ensure the safety of materials. The general principles within the Framework Regulation may be sufficient to maintain the desired level of safety and product quality. It should be noted that since the 2017 review no new specific regulations have been instituted in England nor have there been any in the EU.

4.16 There are wider considerations that come into play with the development of new materials - their economic viability is an essential requirement, but this can fluctuate markedly. The potential for such fluctuations to undermine the focus on safety is recognised and something that continues to bear scrutiny.

4.17 There is tacit recognition that in a time of limited resources for enforcement action to be undertaken, focus of the authorities must be on the most impactful risks, and as a consequence over the five years in question, controls have been primarily on plastics. This is due to their ubiquitous use in many food contexts, and their complex chemistry and associated potential risks.

5. Harmonised Controls on Food Contact Plastics

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

5.2 Part 6 of the 2012 Regulations provides for the enforcement of the Plastic Regulation and identifies those provisions of the retained EU legislation which constitutes an offence to contravene. The competent authorities for the purposes of certain provisions of the Plastic Regulation are designated in Regulation 15. (Generally speaking, these are the FSA, each food authority in its area, and each port health authority in its district).

5.3 The day-to-day enforcement of the 2012 Regulations is the responsibility of trading standards officers from local authorities and port health authorities (PHAs). Those consulted during the 2017 review said that they were familiar with the 2012 Regulations and occasionally referred to them. The PHAs that we contacted informed us that they frequently referred to the limits laid down in the associated Plastic Regulation.

5.4 Whilst industry agrees that the 2012 Regulations provide for the execution and enforcement of the Plastic Regulation, it was clear in the 2017 PIR consultation that they would have liked to have seen greater enforcement of FCM legislation in England, particularly for imported products. Conversations with industry have confirmed that this general attitude regarding enforcement has been maintained.

5.5 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 for FCM has been on the risk to health from non-compliant melamine and polyamide kitchenware products imported from China and Hong Kong. This has evolved of late into action with regards to the use of non-authorised substances of botanical origin (bamboo, rice husks wheat straw and such like) as additives in food contact plastics. Local authorities work closely with business operators to ensure safety, for example by passing on

educational material to new businesses.

5.6 Overall, 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 and wellbeing.

5.7 The objective of this report, to confirm the continued appropriateness of the legislation after a further five-year period after implementation, remains a valid exercise to ensure that it continues to protect human health and provide for the enforcement of the Plastic Regulation. Whilst a review such as this does not preclude further developments of the legislation, it does give a measure of reassurance that it currently functions at a reasonable level to achieve the desired aim of consumer protection.

6. Impacts

Baseline costs

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

Estimated costs of familiarisation

6.2 It was estimated that Industry, Enforcement Authorities (Local Authorities and Port Health Authorities) and OCLs would face one-off familiarisation costs for reading and understanding the Regulations. 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.

6.3 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 period of 10 years.

Actual costs of familiarisation

6.4 For reasons of proportionality, we have not sought to ascertain the actual familiarisation costs as these one-off costs have already been incurred. We do not envisage that the actual familiarisation costs were significantly higher or lower than anticipated in our assessment in 2012. This is borne out by comparison with costings for the subsequent amendments and associated legislation with regards to exit from the EU. The familiarisation costs of the subsequent amendments to the legislation and pertinent legislation covered under its general provisions were estimated.

6.5 Although there were no comments from enforcement bodies on the costs associated with the familiarisation costs of the Regulations there was consensus from industry stakeholders that familiarisation costs were proportionate and there was no evidence to suggest any additional burdens for enforcement.

The Food and Feed Imports (Amendment) (EU Exit) Regulations 2019

6.6 Only part of the Food and Feed Imports (Amendment) (EU Exit) Regulations 2019 (paragraphs 18-26) apply to FCMs). The associated direct cost for businesses has been calculated by applying the 2017 median annual wage for production managers and directors” of £22.05 and uprating it by 20% to account for overheads. Multiplying this wage rate with the

expected familiarisation time gives an estimated total one-off cost to businesses of £5.7m. After adjusting for inflation and applying a discount rate of 3.5% as per HMT Green Book guidance, this translates to an Equivalent Annual Net Direct Cost to Business (EANDCB) of approximately £600,000 (costing for the entire set of Regulations).

The Materials and Articles in Contact with Food (Amendment)(EU Exit) Regulations 2019

6.7 The associated direct cost for businesses has been calculated by applying the 2017 median annual wage for “production managers and directors” of £22.05 and uprating it by 20% to account for overheads. Multiplying this wage rate with the expected familiarisation time gives an estimated total one-off cost to businesses of £5.7m. After adjusting for inflation and applying a discount rate of 3.5% as per HMT Green Book guidance, this translates to an Equivalent Annual Net Direct Cost to Business (EANDCB) of approximately £600,000.

The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020

6.8 An impact assessment was not produced for this instrument, which the FSA certified as being below the de minimis threshold of +/- £5m equivalent annual net direct cost to business.

The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020

6.9 For England only, the amount to Industry costs of £104,150.04 (an Annual Equivalent Cost of £12,099.66) and Public-sector costs of £15,673.46 (an Annual Equivalent Cost of £1,820.87).

Estimated Cost of the Primary Legislation and its Amendments

Provision	Estimated Cost to Industry	Annual Equivalent Cost	Estimated Cost to Enforcement	Annual Equivalent Cost
The Materials and Articles in Contact with Food (England) Regulations 2012	£110,263	£12,810	£17,214	£2,000
The Food and Feed Imports (Amendment) (EU Exit) Regulations 2019 (in part only)	<£5,700,000	<£600,000	-	-
The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019	£5,700,000	£600,000	-	-
The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (in part only)	£104,150	£12,100	£15,673	£1,821

7. Examination as to how the legislation is executed and enforced

7.1 To put these findings into perspective, the total number of regulations relative to the number of relevant FCMs regulations for the legislation given above are provided below:

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

- 31 regulations, all relevant.

The Food and Feed Imports (Amendment) (EU Exit) Regulations 2019

- 84 regulations of which 9 are relevant.
- This is difficult to compare, as this is for all businesses and not just FCM ones.

The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019.

- 80 regulations & 3 schedules, of which all relevant.

The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020

- 8 regulations and 5 schedules of which 1 regulation relevant.

7.2 It should be noted that the calculations are either for just FCM businesses or for all food businesses, thereby accounting for the wide discrepancies for the industry figures.

Stakeholder Consultations

7.3 As a follow up to the initial consultation for the legislation, and for the 2017 review, a further consultation was undertaken.

Q1. We invite stakeholders to provide evidence if they believe that familiarisation costs (below) incurred have increased or decreased since 2017, and as to what has accounted for this change? Please provide evidence to support your view(s)

It was assumed in the previous PIR 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.

Actual simplification benefits

7.4 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 actual average number of new FCM manufacturers and retailers between 2010 to 2015 was slightly lower than estimated (approximately 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.

7.5 For the period 2017 to 2022 a comparison is not viable because of the covid pandemic, departure from the European Union and the economic impact of the war in Ukraine, which all had unforeseen detrimental effects on trade. With the contraction of the market this decade it is assumed that the number of FCM manufacturers and retailers will have proportionately fallen in line with the general economy.

7.6 During the period of the pandemic, it is known that there was a 6.5% reduction in the number of small to medium enterprises in the UK overall (footnote 4). As wage inflation has been minor

during the five years of this current review period (approximately 3% per annum) it is not expected that familiarisation costs will have increased by any significant amount above that previously considered.

7.7 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 disproportionately time consuming to assess the relevance of this legislation to each business. All the stakeholders we contacted during the first 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.

Q2. To account for the departure from the European Union several amendments were required to maintain the 2012 Regulations, which have yet to be rationalised and consolidated. Has this had a negative impact, and would a revision of the legislation to simplify it be of material benefit, or is the status quo adequate?

Estimated sampling and testing benefits

7.8 It was originally assumed that there would be additional benefits to industry from the introduction of Article 19 of the Plastics Regulation. Article 19 recognises the use of internationally recognised scientific principles for the risk assessment of non-intentionally added substances (NIAS) 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.

Actual sampling and testing benefits

7.9 Whilst there is no direct evidence of these benefits accruing from the introduction of Article 19 as many principles of risk assessment were in use prior to its introduction, it raised the profile of the existing tools available for risk assessment and the issue of NIAS.

7.10 Since the initial PIR, the subject of NIAS has become more pronounced within the plastics industry, as noted in conferences attended by FSA officials. The driver for this interest is the recycling of plastics and the concept of the functional barrier used to preclude chemical migration from plastics used in connection with the Plastic Packaging Tax, introduced on 1 April 2022 (footnote 5). The previous benefit mentioned above can be considered timely in this respect.

7.11 The assessment of NIAS (footnote 6) has become increasingly important due to the desire to expand the recycling of FCMs on a like-for-like basis. The prohibition of chemicals classified as carcinogenic, mutagenic or toxic to reproduction (CMR) in such materials is an issue that has increasing been needed to be addressed, for example with regards to environmental recovered plastics destined for recycling (“Ocean Bound Plastics”), and the use of functional barriers to restrict migration from hidden layers. This aspect of the legislation has come to increasing prominence in the past decade, and more so in the current assessment period of this PIR.

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

Enforcement of the legislation

8.1 In England, (and Scotland, Wales, and Northern Ireland) harmonised legislation is enforced by means of Statutory Instruments, which provide penalties and enforcement powers for infringements. These are for enacting laws of a particularly technical nature. This is a well-established form of governance and is deemed proportionate to the need for controls within this

area.

8.2 One of the key issues identified in an EU-wide review of FCM in 2016 by the Joint Research Centre (the EU Commission's science and knowledge service) 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. This continues to be an issue that concerns industry and the enforcement authorities, with the FSA liaising with the UK National Reference Laboratory (NRL) for the development of analytical tools to assist enforcement authorities and aid industry.

8.3 In relation to conformity and application, several stakeholders have stated their belief that there is an inconsistent approach to the enforcement of the Regulations. With the focus on only a small number of harmonised materials, it is a matter of concern that other product types may either be gaining an unfair commercial advantage with less onerous requirements and limited enforcement - or issues are going unrecognised. However, there is a compensating factor that a lack of prescriptive measures allows some sectors to develop their own comprehensive guidance that caters for the specific challenges inherent with a material type. This has given a measure of flexibility that has benefited such sectors, whilst providing a structure through which compliance can be assured.

8.4 Consequently, it can be asserted that the Framework Regulations are functioning satisfactorily as they encourage industry to seek its own, pertinent, guidance - the driver being to safeguard the reputation of the whole industry and thereby its individual member companies. The role of the authorities in this is to provide sufficient support to ensure the guidance is fit for purpose and can form the basis to a more utilitarian suite of legislation as required.

Q3. The first 5-year review was carried out in 2017 - the recommendation was to retain the 2012 Regulations as they are fit for purpose. We would welcome stakeholder views as to whether this remains the case.

Q4. Previously concerns were raised as to the inconsistent level of enforcement, we welcome views as to whether this remains a concern and on any perceived shortcomings in the system.

Consumers' perspective

8.5 The FSA has a dedicated FCM electronic mailbox (foodcontactmaterial@food.gov.uk) for queries from consumers and industry from which it can 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. These themes have been consistent over the period, though following withdrawal from the EU the practical implications of that action came to predominate.

8.6 Consumers are able to assess some risk when using a FCM or article – i.e., when cutlery is rusty, the enamel pan is chipped, the ceramic glaze is crazed or worn, however, they are unable to determine the level of chemical migration and will not have full information on the production methods used in its manufacture. Therefore, they cannot make informed choices about such risk. They are rarely interested directly in the 2012 Regulations as such, though confirmation that there is comprehensive legislation to protect consumer health from the migration of chemicals from FCM, when informed, is usually well received.

8.7 Little distinction was made prior to departure from the EU between the national and the European FCM legislation when issues were raised by consumers. At the European level, the consumer view reported by the European Parliament was that the lack of EU specific measures for some FCM had a negative effect on consumer trust, and that the EU rules were insufficient to ensure traceability in the supply chain.

8.8 The Materials and Articles in Contact with Food (England) Regulations 2012 provide for the enforcement of the FCM Framework Regulation, in June 2022, the European Commission issued a working document on the effectiveness of that Regulation. This raised some issues that are concurrent to the English legislation. Whilst the overall protective nature of the provisions is beneficial for stakeholders, the complexity of provisions such as the plastics regulation are still an issue of concern. Health benefits are expected to exceed the costs of enforcement.

- "…costs to industry are estimated to be around 3% (EUR 3 billion [€ 3 billion = £2.61 billion in 2023]) of the total turnover, composed of administrative costs (~1%) and compliance costs (~2%), including applications for EU authorisation of substances, although these are considered prohibitive for SMEs. Costs for non-plastic sectors however vary significantly, with certain sectors, including paper and board, facing higher costs. The likely cause of this is multiple risk assessment and testing requirements due to the lack of specific rules, although the relevance of other factors – including lost market opportunities – could not be sufficiently quantified."

8.9 Whilst the system was deemed effective for the harmonised materials (principally in reference to plastics) it was noted that other materials have issues attaining compliance due to varied national provisions in EU Member States. This is an issue the UK is conversant with and is also addressing, in a proportionate and sustainable manner.

8.10 This reflects some of the comments made to the first PIR of the English legislation. While industry agreed that that the 2012 Regulations provides for the execution and enforcement of, for example, the Plastic Regulation, they stated that in time they would like to see more enforcement of FCM, both at the borders and locally, particularly to ensure compliance for products from third countries.

8.11 As a consequence of the trade disruption from 2020 due to the covid pandemic it has not been possible to make a direct comparison with regards to the earlier period. In many ways the FCM market has fundamentally changed this decade due to the rise of on-line shopping and home delivery of fresh, preserved, preprepared and take-away foods.

9. Conclusion

9.1 The 2012 Regulations continue to meet their objective of safeguarding consumers from the risk of chemicals that might otherwise have migrated into food at levels that affect human health or diminish its quality. Some specific retained EU measures on FCM provide specific migration limits which restrict, limit and in some cases prohibit substances that might migrate into food. The Framework Regulations also provides safeguards for non-harmonised materials, requiring that all FCM should be safe and not interact with food in a negative way. This view was supported by the respondents to the first PIR.

9.2 The 2012 Regulations also continues to meet their objective of providing for the enforcement of the Plastics Regulation. There is evidence from PHA's that the provisions in the Plastics Regulation are enforced (in conjunction with the Kitchenware Regulations) to remove imported non-compliant kitchenware from the market. This is subject to its own PIR reappraisal, which will be carried out separately but alongside the review for the 2012 Regulations.

9.3 The 2012 Regulations met their initial objective of consolidating nearly all existing FCM enforcement provisions into one statutory instrument. Key industry stakeholders originally informed us that the consolidation has simplified and added clarity to the national FCM regulations, and this remains the case.

9.4 While reviewing the 2012 Regulations in 2017, we did not identify any evidence that suggests they 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.

Also, the administrative burden of keeping the required documentation was mentioned. The FSA remains mindful of these issues as it looks to the evolution of further regulatory developments in light of the socio-economic changes experienced by the country since the start of this decade.

9.5 There is ongoing evidence that the Materials and Articles in Contact with Food (England) Regulations 2012 and its subsequent amendments continues to meet their objectives of protecting consumer health and providing for the enforcement of retained EU Regulations on FCM.

9.6 Consideration has been made, and continues to be made, as to whether the 2012 Regulations could be improved or superseded, and whether the level of regulation remains proportionate. This review forms part of that on-going process. Indications are that whilst the burdens they impose are manageable and provide a reasonable level of consumer protection, further work is desirable, particularly in light of the socio-economic changes within the country.

Annex I

The retained EU Regulations enforced, and Directives incorporated by transposition by, the Materials and Articles in Contact with Food (England) Regulations 2012 are -

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
- Commission Regulation (EC) No. 2023/2006 of 22 December 2006
- on good manufacturing practice for materials and articles intended to come into contact with food.
- Commission Regulation (EC) No. 450/2009 of 29 May 2009, on active and intelligent materials and articles intended to come into contact with food.
- Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
- Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- Council Directive 78/142/EEC of 30 January 1978 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 & Commission Directive 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs.

1. 2017 Post Implementation Review of The Materials and Articles in Contact With Food (England) Regulations 2012

2. Impact Assessment for The Materials and Articles in Contact With Food (England) Regulations 2012

3. Commission Regulation (EU) No. 10/2011 on food contact plastics and Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

4. Business population estimates for the UK and regions 2021: statistical release

5. Part 2 (Sections 42 to 85): Finance Act 2021, The Plastic Packaging Tax (Descriptions of Products) Regulations 2021, HMRC Guidance on Plastic Packaging Tax

6. 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.