Title: THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2012	Impact Assessment (IA)
IA No: FOOD0027	**Date: October 2012**
Lead department or agency: FOOD STANDARDS AGENCY	**Stage:** Post Implementation
Other departments or agencies:	**Source of intervention:** EU
	Type of measure: Secondary legislation
	Contact for enquiries: Nasreen Shah, Tel: 020 7276 8538 Nasreen.shah@foodstandards.gsi.gov.uk

Summary: Intervention and Options

RPC: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£0.01m	£-0.12m	£-0.12	No	In/Out/zero net c

What is the problem under consideration? Why is government intervention necessary?

Chemical migration from food contact plastics can potentially affect consumer health. Consumers are unable to assess the risk involved when consuming a product because of the lack of knowledge of the chemical migration and production methods and therefore, cannot make informed choices about such risk. Government intervention is necessary to reduce the risk to consumer health from the migration of chemicals from materials and articles intended to come into contact with food. The proposed national legislation for the execution and enforcement of the new European Regulation on plastic materials and articles in contact with food provides for the continuation of consumer protection against food contamination by chemicals from which exposure could carry serious long-term and unacceptable risk to consumer health, particularly amongst more vulnerable people.

What are the policy objectives and the intended effects?

The purpose of these proposals is to meet three policy objectives:
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;
2. To provide for the execution and enforcement of the new EU Regulation that updates and replaces previous EU legislation in this area; and
3. To revoke, remake and consolidate almost all existing national legislation 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.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

1. Do Nothing – this option will not prevent the new EU Regulation applying in England as it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it.
2. Option 2 – provide for the execution and enforcement of the new EU Regulation
3. Option 3 – provide for the execution and enforcement of the new EU Regulation and simplify the vast majority of food contact materials legislation in a single statutory instrument. This option is the preferred option, as it meets the requirements of option 2 and will mean that stakeholders will only have to refer to one SI on food contact materials (except kitchenware Regulations which are specific to particular commodities).

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 06/2017

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Anna Soubry Date: 17.10.2012

Summary: Analysis & Evidence

Policy Option 1

Description: **Do Nothing**

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** N/A

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised costs by 'main affected groups'

There are no monetised incremental costs or benefits associated with this option. This is the baseline against which other options are assessed.

Other key non-monetised costs by 'main affected groups'

There are no non-monetised incremental costs or benefits associated with this option. This is the baseline against which other options are assessed.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised benefits by 'main affected groups'

There are no monetised incremental costs or benefits associated with this option. This is the baseline against which other options are assessed.

Other key non-monetised benefits by 'main affected groups'

There are no non-monetised incremental costs or benefits associated with this option. This is the baseline against which other options are assessed.

Key assumptions/sensitivities/risks **Discount rate (%)**

Failure to allocate adequate enforcement provisions in England will result in the UK being liable for EU infraction proceedings.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: N/A	**Benefits:** N/A	**Net:** N/A	No	IN/OUT/Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation only.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -0.13

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			Optional	
High			Optional	
Best Estimate	0.13		0	**0.13**

Description and scale of key monetised costs by 'main affected groups'

Industry, and Enforcement Authorities and Official Control laboratories will face one-off familiarisation costs as a result of the introduction of the new EU Regulation. For England only, these amount to Industry costs of £110,263 (an EAC of £12,810) and Public sector costs of £17,214 (an EAC of £2,000).

Other key non-monetised costs by 'main affected groups'

There are no non-monetised costs associated with the introduction of this measure.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

There are no monetised benefits associated with this option.

Other key non-monetised benefits by 'main affected groups'

There may be sampling and testing benefit to businesses associated with the provision of alternative testing regimes. As businesses will now be able to choose the most appropriate and cost effective testing regime to follow; costs savings may be made. We have no quantitative evidence at present about the likely savings in this area.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is uncertainty about the number of businesses affected by this proposal and the numbers used are likely to be a significant overestimate. As such, sensitivity analysis on business numbers has been provided at 80% and 50% of the maximum. The central estimate of 80% has been reported in the summary and main body of the document.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.013	**Benefits:** 0	**Net:** 0.013	No	IN/OUT/Zero net cost

Summary: Analysis & Evidence

Policy Option 3

Description: Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation and simplify nearly all food contact materials legislation in a single statutory instrument to fulfil the Government's Red Tape Challenge.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 1.04

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0.13		0	**0.13**

Description and scale of key monetised costs by 'main affected groups'

Industry, and Enforcement Authorities and Official Control laboratories will face one-off familiarisation costs as a result of the introduction of the new EU Regulation. For England only these amount to Industry costs of £110,263 (an EAC of £12,810) and Public sector costs of £17,214 (an EAC of £2000).

Other key non-monetised costs by 'main affected groups'

There are no non-monetised costs associated with the introduction of this measure

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0.14	**1.17**

Description and scale of key monetised benefits by 'main affected groups'

New entrants to Industry and Enforcement will benefit from simplification of the consolidation of the food contact materials and articles legislation. For Industry, benefits will equal £135,916 per year with a NPV over 10 years of £1,169,925. Public Sector benefits will equal £3,645 per year and a NPV of £31,372 over 10 years.

Other key non-monetised benefits by 'main affected groups'

There may be sampling and testing benefit to businesses associated with the provision of alternative testing regimes. As businesses will now be able to choose the most appropriate and cost effective testing regime to follow; costs savings may be made. We have no evidence at present about the likely savings in this area.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is uncertainty about the number of businesses affected by this proposal and the numbers used are likely to be a significant overestimate. As such, sensitivity analysis on business numbers has been provided to 80% and 50% of the maximum. The central estimate of 80% has been reported in the summary and main body of the document.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.013	**Benefits: 0.14**	**Net:-0.123**	No	IN/OUT/Zero net cost

Evidence Base (for summary sheets)

Problem under consideration

1. Unregulated chemical migration from food contact plastics may potentially create a cost to others such as the National Health Service, through detrimentally affecting consumer health. 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 choices about such risk. Government intervention is required to reduce the chronic and acute health risks to consumers arising from chemical migration from food contact materials into the food they eat and also to provide greater clarity in enforcement.

2. Providing for the execution and enforcement of the new EU Regulation provides for the continuation of consumer protection against exposure from chemicals that could migrate into food, which could carry serious long term and unacceptable risk to consumer health, particularly amongst vulnerable people. The new EU legislation updates and replaces all the existing rules on food contact plastics into a single European Regulation.

Rationale for intervention

3. To reduce the long term health risks to consumers in England arising from exposure to chemicals used in the manufacture of plastic food contact materials and articles that may migrate into food and to provide for the continuation of consumer protection against food contamination by chemicals from which exposure could carry serious long-term and unacceptable risk to consumer health. The effects of chemicals migrating from food contact materials and articles can be acute (e.g. primary aromatic amines (PAAs) and melamine migrating into food from plastic kitchenware), or long term.

4. PAAs are a family of compounds some of which are proven to be carcinogenic, while others are suspected carcinogens and could potentially pose a health risk to consumers. PAAs in materials and articles intended to come into contact with food may arise as a result of the presence of impurities or breakdown products.

5. Similarly, levels of formaldehyde have been released into foods that are higher than those authorised in EU legislation from melamine plastic kitchenware also originating in or consigned from China. There is evidence that formaldehyde can elicit immune effects such as hypersensitivity and contact dermatitis in sensitive individuals. The World Health Organisation (WHO) Concise International Chemical Assessment Document (CICAD, 2002) suggests that "the concentration of formaldehyde likely to elicit contact dermatitis reactions in hypersensitive individuals may be as low as 30 milligrams per litre".

6. The new EU Regulation, European Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, was published in the Official Journal[1] (OJ) of the European Communities on 15 January 2011. It has since been amended by Commission Implementing Regulations No. 321/2011, as detailed in paragraph 12 below, and No. 1282/2011. The new EU Regulation is a result of revocation and consolidation at EU level of all the existing rules on food contact plastics, from 12 Commission and Council Directives into a single European Regulation. The new EU Regulation continues to provide protection to consumer health from adventitious chemical migration from materials and articles with which food has intentionally been placed in contact. This latter point arises from improving technical and scientific knowledge that enables experts within the European Food Safety Authority (EFSA) to evaluate and re-evaluate risk to public health arising from the migration of chemicals from food contact materials.

7. The new EU Regulation came into force on 3 February 2011 and applies throughout the European Union (EU) from 1 May 2011. Government intervention is required to make national Regulations to provide for the execution and enforcement of the new EU Regulation in England, including:

   - designation of competent authorities for the purpose of the Regulation;
   - providing for offences of contravening certain provisions of the new EU Regulation and for defences against prosecution for committing an offence in particular circumstances; and
   - specifying the penalties that the Courts may impose upon conviction for an offence.

[1] OJ Ref L12, 15.1.2011, pg 1-89

8. The FSA is developing in England a simplified system of food safety legislation, including the consolidation of a number of Statutory Instruments as a Red Tape Challenge initiative. The consolidation proposed under Option 3, is part of this simplification.

9. Currently there are three separate principal SIs (and one amending SI), which contain the rules on food contact materials, which can be difficult for those that need to cross-refer to their various provisions; having all the rules in one SI will therefore benefit stakeholders.

Policy objective/Intended Effect

10. The purpose of these proposals is to meet three policy objectives.

    I. 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.

    II. Providing national Regulations for the execution and enforcement by local authorities in England of the new EU Regulation. As well as the enforcement measures mentioned in paragraph 2, the proposed consolidated Regulations will link the new EU Regulation to provisions relating to sampling and analysis, powers of entry, etc.

    III. With regard to the third objective, as part of the FSA's response to the Government's Red Tape Challenge (RTC) exercise, we are seeking to revoke 4 sets of Regulations and consolidate into one SI nearly all existing national legislation on materials and articles intended to come into contact with food. The exception is the Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011[2]. These Regulations put in place additional import controls for plastic kitchenware originating from China and will be periodically reviewed by the European Commission, taking into account information received from Member States. This consolidation will make it more convenient for businesses and others that have to refer to the Regulations and obviate the need for cross-referencing between different sets of national Regulations – which is currently the case.

11. The England national Regulations being revoked are:

    I. The Plastic Materials and Articles in Contact with Food (England) Regulations 2009[3]

    II. The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011[4]

    III. The Materials and Articles in Contact with Food (England) Regulations 2010[5];

    IV. The Ceramic Articles in Contact with Food (England) Regulations 2006[6], which implement the provisions of Council Directive 84/500/EEC[7], as amended by Commission Directive 2005/31/EC[8]

Background – plastic food contact materials legislation

12. The general principles governing the safety of all materials and articles intended to come into contact with foods are established in Regulation (EC) No. 1935/2004[9] of the European Parliament and of the Council ("the framework Regulation"). This lays down the framework of regulation of all such materials and articles intended to come into contact with foodstuff. The new EU Regulation is a specific measure within the meaning of Article 5(1) of the framework Regulation and establishes the

[2] SI No. 2011/1527

[3] SI 2009 No. 205

[4] SI 2011 No. 231

[5] SI 2010 No. 2225

[6] SI 2006 No. 1179

[7] Council Directive 84/500/EEC on the approximation of laws of the Member States relating to Ceramic articles intended to come into contact with foodstuffs

[8] Commission Directive 2005/31/EC amending Council Directive 84/500/EEC, as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs.

[9] OJ Ref L338, 13.11.2004 pg 4-17

specific rules for plastic materials and articles intended to come into contact with foods. The new EU Regulation repeals Commission Directive 2002/72/EC[10] and all its amendments on plastic materials and articles intended to come into contact with foods. The Directive laid down the basic rules for the manufacture of plastic materials and articles; it has been the subject of substantial amendments spanning ten years. The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 implemented the provisions of Directive 2002/72/EC as most recently amended.

13. Furthermore, Directive 2002/72/EC was amended in late November 2010 by Commission Directive 2011/8(EU) which introduced restrictions on bisphenol A (BPA). These restrictions were not contained in the new EU Regulation, as this Regulation had already been published prior to the amending Directive 2011/8/EU. The Commission took steps to correct this by amending the new EU Regulation by Commission Implementing Regulation (EU) No. 321/2011[11] as regards the restriction of the use of bisphenol A (BPA) in plastic infant feeding bottles; the Regulation was published in the Official Journal of the European Communities on 2 April 2011 and came into force twenty days following its publication and applied throughout the EU. An amending entry was inserted in Table 1, of Annex I (substance number 151, namely, '2,2-bis(4-hydroxyphenyl)propane' (BPA), column 10 – restrictions and specifications), to the new EU Regulation to take into account the restrictions on BPA in infant feeding bottles.

14. The amending European Regulation effectively brings into line the restrictions on BPA in infant feeding bottles with the coming into force date of the new EU Regulation; and for those restrictions to remain in place and apply from 1st May 2011 as regards manufacture and from 1st June 2011 as regards the placing on the market and importation into the Union. This ensures continuity of the prohibition of BPA in infant feeding bottles.

Red Tape Challenge

15. In April 2011 the UK Government launched the Red Tape Challenge (RTC) initiative[12] with the purpose of getting comments from business and the public on the stock of legislation. On 6th May 2011 most of the FSA's legislation was published on the RTC website under the Hospitality Theme and remained on the site until 2 June 2011. The FSA is developing a simplified system of food safety legislation, including the consolidation of a number of domestic Statutory Instruments under the RTC. The consolidation proposed under Option 3, discussed in this Impact Assessment is part of this simplification.

Details of the four national Regulations being revoked following consolidation

16. The new EU Regulation consolidates requirements on food contact materials, making some adjustments to the requirements on plastics food contact materials, but leaving requirements on all other food contact materials unchanged. Policy option 2 provides for the enforcements of this new EU Regulation, whilst policy option 3 provides for the enforcement for the new EU Regulation and also consolidates national regulations into one single document.

17. With the exception of the Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011, which put in place specific import controls on plastic kitchenware from China (and Hong Kong), the proposed Materials and Articles in Contact with Food (England) Regulations 2012 will consolidate into one instrument nearly all national legislation on food contact materials and articles within the FSA's remit.

(1) The Materials and Articles in Contact with Food (England) Regulations 2010[13] ("the FCM Regulations")

The original FCM Regulations provide for the enforcement of three European Regulations and implement four Directives; these are:

i. Regulation (EC) No. 1935/2004/EC on materials and articles intended to come into contact with foodstuffs ("the framework Regulation");

ii. Regulation (EC) No. 2023/2006 on good manufacturing practice ("the GMP Regulation");

[10] OJ Ref L220, 15.8.2002, p.18

[11] Ref: OJ L87, 2.4.2011, p1

[12] http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/

[13] SI 2010 No. 2225

iii. Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with foodstuffs ("the AIM Regulation);

iv. Commission Directives 2007/42/EC on food contact materials and articles made from regenerated cellulose film (RCF[14]);

v. Council Directive 78/142/EEC relating to the use of vinyl chloride monomer (VCM) in food contact materials,

vi. Commission Directives 80/766/EEC on the methods for testing for vinyl VCM in food contact materials; and

vii. Directive 81/432/EEC method of testing migration of VCM from food contact plastics.

18. There is very little substantive difference in the way in which EU Regulations 1935/2004, 2023/2006 and 450/2009 will be enforced in the proposed consolidated Regulations as compared with how they are currently enforced in the original FCM Regulations; the provisions of all three Regulations remain intact and unchanged and there are no new or additional burdens on businesses from the proposed simplification. However, there will be minor textual changes to the proposed consolidated Regulations to take into account the revocation of the FCM Regulations, notably repealed Directives and cross-references to other SIs being removed, along with definitions of terms, such as 'plastics', that are now given in directly applicable EU legislation and no longer need to be transposed into national law.

Provisions for Regenerated Cellulose Film (RCF)

19. In relation to the implementation of Directive 2007/42/EC, the requirements for RCF are redrafted with minor amendments, which are designed to make the text closer to that of the Directive. There will be no new additional burden on business as a result of this legislation as it is intended to replace the repealed Directive 2002/72/EC; the new legislation sets out no new requirements for business; the changes of substance introduced by the new EU Regulation in relation to RCF are minor. Regenerated cellulose film with a plastic coating in contact with food had to comply with the requirements of Directive 2002/72/EC; the main difference here is that the new EU Regulation has direct effect in relation to the migration limits that apply to RCF with a plastic coating in contact with food. Again the provisions of Directive 2007/42/EC remain intact and there is unlikely to be any new or additional burden on business. Instead of carrying out testing in accordance with Commission Directive 2002/72/EC (which is now repealed by the new EU Regulation), testing will now be carried out in accordance with the new EU Regulation. All references to the repealed Directive have been removed and replaced by references to the new EU Regulation.

20. The proposed consolidated Regulations will not re-enact a number of provisions on RCF in the FCM Regulations, which are considered to be no longer necessary. The migration limits set out in regulation 11 of the FCM Regulations are now directly applied by the new EU Regulation, and past transitional provisions in regulation 12 are now considered obsolete; as they were time limited for which the time limit has now expired.

Provisions on Vinyl Chloride Monomer (VCM)

21. In relation to the Directives on VCM, the FCM Regulations implemented the provisions of Council Directive 78/142/EEC (this Directive predates Directive 2002/72/EC on the controls of the use of VCM in food contact plastics); although the new EU Regulation does not repeal this Directive, the migration limits however, are contained in Annex I, Table 1of the new EU Regulation. This is based on the view that Directive 78/142/EEC is now only applicable in the case of non-plastic materials and articles. As such some of its provisions have not been re-enacted in the proposed consolidated Regulations. Furthermore, the two Directives used to carry out analysis for VCM, namely 80/766/EEC and 81/432/EEC have been repealed by the new EU Regulation. Testing for VCM will now be carried out in accordance with Article 11 of Regulation (EC) No. 882/2004. There will be minor amendments to the provisions on VCM, to tie them into the requirements of the new EU Regulation. Again, there will be no new or additional burden on business from the proposed consolidation.

[14] Regenerated cellulose film is a thin sheet of film obtained from refined cellulose derived from wood or cotton that has not been recycled (it is mainly used to produce paperboard and paper; to a smaller extent it is converted into a wide variety of derivative products such as cellophane and rayon). Appropriate substances can be added to the body or surface of the material for technological reasons, but does not include synthetic casings of regenerated cellulose.

22. The proposed consolidated Regulations will re-enact the provisions on VCM, which were contained in regulation 8 but confine their application to non-plastic materials and articles, and will not re-enact regulation 9 of the FCM Regulations, for the reasons given above.

23. During the consultation, stakeholders were asked to comment on the omission of the content of regulation 8 and 9 of the current FCM Regulations from the proposed consolidated Regulations. We believed at the time that this content was no longer necessary, as the requirements for VCM were now covered by the new EU Regulation. However, following comments from stakeholders on the omission, a different approach has been taken and only regulation 9 has been omitted from the consolidated Regulations and regulation 8[15] will be re-enacted in the consolidated Regulations.

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

24. The proposed consolidated Regulations reproduce the requirements for ceramic articles intended to come into contact with food. The Ceramic Articles in Contact with Food (England) Regulations 2006 will be revoked and remade in the proposed consolidated Regulations. The provisions of Council Directive 84/500/EEC[16], which deals with the migration into food of lead and cadmium from ceramic articles intended to be brought into contact with food, were originally implemented in the United Kingdom, under powers in the Consumer Protection Act 1987, by the Ceramic Ware (Safety) Regulations 1988[17].

25. Regulation 9 and 10 of the proposed consolidated Regulations reproduces the operative provisions of the Ceramic Articles in Contact with Food (England) Regulations 2006[18], implementing Directive 84/2005/EEC. As the ceramics SI is no longer a standalone SI, references to the Directive are used more widely in the redraft implementing provisions. The definition of ceramic articles now resembles that of the Directive and references to antiques have been removed, as not relevant since they are already out of scope of the framework Regulation, which applies to all FCMs.

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

26. The 2009 Regulations implemented the provisions of Directive 2002/72/EC and all its amendments that are now repealed by the new EU Regulation. The Regulations also implemented the provisions of the two Directives relating to the testing for compliance of plastic materials and articles intended to come into contact with food (namely Directives 82/711/EEC, laying down the basic rules for testing migration of constituents and 85/572/EC, which contained the lists of food simulants[19] for migration testing). The new EU Regulation replaces Directive 2002/72/EC and also directly applies the testing rules contained in the other two Directives mentioned above so the provisions of these no longer need to be set out in the national legislation.

27. The 2009 Regulations also implemented the enforcement provisions of Commission Regulation (EC) No. 1895/2005 on the restrictions on the use of certain epoxy derivatives in materials and articles intended to come into contact with food[20]. The EC Regulation permitted the use of BADGE[21] in all food contact plastics, as well as adhesives and surface coatings, providing that any migration is with the SML of 9 milligrams per kilogram of food or food simulant, including the hydrolysed derivatives of BADGE. The EC Regulation permitted trade in the use of materials and articles containing BADGE throughout the EU from 1 January 2006 and re-affirmed the ban on the use of BFDGE[22] and NOGE[23].

28. The provisions for BADGE, BFDGE and NOGE are currently contained in regulation 12 of the 2009 Regulations. The enforcement of the EC Regulation will be carried over into the proposed consolidated Regulations with some textual changes. As the provisions of the EC Regulation have

---

[15] Note: the FSA will review this in the near future, as and when the Commission decides to repeal Council Directive 78/142/EEC and will take appropriate action.

[16] Ref: OJ L277, 20.10.1984

[17] SI 1988 No. 1647

[18] SI No. 2006 No. 1179 as amended by SI 2007 No. 2790

[19] Food simulants are materials intended to mimic the migration behavioural properties of foods. They are used in the laboratory to provide a conservative estimate of the amount of individual substances that may migrate from packaging into food.

[20] Ref OJ L302, 19.11.2005, pg 28-32

[21] 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether

[22] Bis(2,3-epoxypropyl) ethers

[23] Novolac glycidyl ethers

not changed, it is not anticipated that there will be a new or additional burden on business or enforcement authorities.

(4) The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011

29. The 2009 Regulations were amended recently to take account of the provisions of Commission Directive 2011/8/EC[24] (amending Directive 2002/72/EC) as regards the use of bisphenol A (BPA) in plastic infant feeding bottles. The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011[25] implemented the provisions of the Directive in England. The Directive prohibited the use of BPA in the manufacture of polycarbonate infant feeding bottles from 1st March 2011 and prohibited the placing on the market in, import into, the EU of polycarbonate infant feeding bottles manufactured using BPA from 1st June 2011. These Regulations will be revoked, together with the 2009 Regulations and their provisions in relation to BPA will be enforced in the proposed consolidation Regulations as part of the enforcement of the new EU Regulation.

Options Considered

OPTION 1 – Do Nothing – do not provide for the enforcement of the new EU Regulation

30. Under this option, the new EU Regulation would still be applicable in England and the rest of the UK. The Regulation has been applicable since 1st May 2011 and is already legally binding throughout the EU. In its current state however, enforcement authorities in England do not have the necessary powers to enforce its provisions, which could consequently have adverse impacts on public health. Offenders cannot currently be prosecuted and penalties cannot be imposed on those in breach of the new EU Regulation

31. This option would also leave the UK not fulfilling its Treaty obligations to put in place legislation to provide for the enforcement of EU law. This option does not provide for such enforcement, and may, lead to the UK being liable to infraction proceedings.

OPTION 2 – provide for the execution and enforcement of the new EU Regulation

32. This option provides for the execution and enforcement of the new EU Regulation and it will provide enforcement authorities with the necessary powers to enforce the new EU Regulation, but would mean there would be 4 separate SIs on food contact materials.

33. The new EU Regulation consolidates requirements on food contact plastics. This consolidation at the EU level will entail changes to plastics requirements whilst requirements for other food contact materials will remain unchanged. Option 2, which provides for the enforcement of this new EU Regulation, will therefore only impact on relevant UK businesses that operate in the plastics sector.

34. This is unlikely to change the compliance requirements for materials and articles other than plastics (i.e. metals, ceramics, paper and board etc), since in the EU legislation implemented by the national Regulations being revoked, (as indicated in Section (1), i, ii, iii, iv, vi and vii) those European provisions for other materials and articles remain intact and unchanged. There are no new or additional burdens on businesses from the consolidation in relation to the revoked national Regulations.

35. With regards to the new EU Regulation and the compliance requirements for food contact plastics, it must be emphasised that this Regulation replaces a previous Directive, namely Directive 2002/72/EC and its amendments and maintains the status quo, with some minor adjustments to take into account the replacement.

36. In response to the Government's Red Tape Challenge initiative, the FSA has committed to revoke and consolidate the majority of existing national legislation on materials and articles intended to come into contact with food. This option does not provide for this.

OPTION 3 – provide for the execution and enforcement of the new EU Regulation; revoke, remake, and consolidate nearly all food contact materials legislation in a single statutory instrument

37. This is the preferred option.

38. This option will provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the new EU Regulation in England. This

[24] Ref OJ L26, 29.1.2011, pg 11

[25] SI 2011 No. 231

ensures that enforcement authorities fulfil the requirement placed upon them and that the Courts can impose penalties that are in line with others elsewhere in food law.

39. This option will also meet the FSA's commitment in response to the Government's Red Tape Challenge (see paragraph 32 above) exercise to simplify the legislation on food contact materials and articles by revoking and remaking three existing principal national Regulations and one amending S.I. (detailed above in paragraph 6) into a single consolidated statutory instrument. This consolidation of existing domestic legislation means that instead of reading four pieces of legislation, entrants into the food contact materials sector will now only have to read one document. Option 3 will therefore impact on businesses in all food contact materials sectors. The Table below provides a brief summary of the options and affected businesses

Table1: Summary of options and affected businesses

	OPTION	DESCRIPTION	Affected Businesses
Option 1	Do Nothing,	This option would not provide for enforcement of the new EU Regulation introduced by the EU. The law would still be applicable in the UK (as it has been from 1st May 2011) however UK enforcement authorities do not currently have the necessary powers to enforce it.	N/A
Option 2	Provide for the execution and enforcement of the new EU Regulation	The new EU Regulation is a new regulation that consolidates existing European measures, by repealing at EU level, 12 Commission and Council Directives on food contact plastics into a single consolidated European Regulation (namely the new EU Regulation) and provides for the introduction of the text in Article 18 of the new EU Regulation, which recognises the use of internationally recognised scientific principles for risk assessment of non-intentionally added substances and non-listed substances. The amendments to the testing regime and risk assessment will make it easier for businesses to comply with the new legislation than the old as they will be given more choice and will have the advantage of using alternative methods.	**MANUFACTURERS** (including importers and processors) of food contact *plastic* products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment
Option 3	Provide for the execution and enforcement of the new EU Regulation; revoke, remake, and consolidate nearly all food contact materials legislation in a single statutory instrument	This provides all the benefits above but in addition consolidates 4 existing pieces of food contact materials legislation into one single SI	**MANUFACTURERS** (including importers and processors) of food contact *plastic* products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment In addition, **manufacturers** (including importers and processors) of all *other* food contact materials including *ceramics, aluminium, lead, zinc, tin and light metal* packaging, as well as **packaging** activities involving these materials; **RETAILERS** (including importers) of food and beverages, including retailers of food via markets and stalls;

Note: See Annex A1 for further details, including SIC Codes

Sectors Affected

Industry

40. Both options 2 and 3 set out in this Impact Assessment will affect UK manufacturers (including processors and importers) of *plastic* materials and articles intended to come into contact with food (including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of

processing equipment). The options will apply equally to all businesses in this sector regardless of size.

41. Option 3 will additionally have an impact on any UK manufacturers, importers and retailers of *all other food contact material products*, including ceramics, aluminium, lead, zinc, tin and light metal packaging, as the simplification of the existing four Regulations extends beyond the plastics food contact materials industry.

42. We have used the Interdepartmental Business Register (IDBR) to identify which sectors and industries may be affected by the policy. The IDBR is a comprehensive register of UK businesses, covering 99% of UK economic activity. The data in the register is structured by the UK Standard Industrial Classification of Economic Activities (SIC 2007). Given the aggregate nature of the IDBR, it has been difficult to identify a precise subsector that will be affected by the policy. This means that the sectors identified and used in the analysis will be larger (in terms of number of businesses affected) than number affected by the policy. For example "manufacture of plastic packing goods" SIC 22.22 refers to all plastic packaging manufacture not exclusively those in contact with food. In order to minimise the impact of these uncertainties we have provided sensitivity analysis around the final costings (sector size of 50% and 80%, respectively, of the actual sector size in the available data), see Annex Table A3. The central estimate of 80% (which remains conservative) is used to calculate the best estimate of the costs and benefits.

Manufacturers

43. For Option 2, affected parties will be limited to the plastics food contact materials manufacturing sector, as the new EU Regulation entails changes to existing plastic requirements. (Requirements on food contact materials other than plastics (e.g. ceramics, metals, paper) remain unchanged).

44. For Option 3, the main businesses that will be affected are all manufacturers of materials and articles that are intended to come into contact with food; including manufacturers of *plastics, ceramics, aluminium, lead, zinc, tin and light metal packaging, as well as packaging activities* involving these materials. This is because nearly all the national Regulations on food contact materials and articles will be revoked and consolidated into a single Statutory Instrument. Having the national rules on FCMs in one document will assist businesses that in the past would have had to refer to several pieces of legislation in order to show compliance of their products.

Importers

45. Importers of materials and articles that are intended to come into contact with food are likely to be affected by the proposed consolidated Regulations. The IDBR does not, however, separate out importers and we are unable to present results for importers separately. However, importers are included in the classification of the other sectors identified (i.e. manufacturers, processors and retailers).

Retailers

46. Option 2 will have no impact on retailers. For option 3, businesses affected include retailers of food and beverage products, including supermarkets, food stalls, food markets, as well as retail of food and beverages in specialised stores.

Summary of businesses affected

47. Table 2 below summarises the businesses affected by Option 2 and 3. See Annex A1 for a more detailed list including SIC codes.

Table 2: Summary of Businesses Affected

Option 2		Option 3	
Manufacturers (including processors and importers)	Food contact *plastic* products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment	Manufacturers (including processors and importers)	Food contact *plastic* products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment
			All other food contact materials manufacturers including *ceramics, aluminium, lead, zinc, tin and light metal packaging*, as well as packaging activities involving these materials
		Retailers	Retailers of food and beverages,

		(including importers)	including retailers of food via markets and stalls

48. This Impact Assessment is for businesses in England only and all costs and benefits will be provided for England. However, as the FSA is a UK wide body and changes to the legislation in England may require similar changes to be enacted in each of the devolved administrations we have provided analysis for the UK; tables 3 and 4 below summarise the distribution across the UK of the sectors that are affected by the proposed consolidated Regulations. A more detailed description of the SIC codes is provided in Annex A1

49. As detailed above there remains uncertainty as to the number of affected businesses using IDBR SIC classification. As such the number of businesses set out in tables 3 and 4 below represents 80% of the maximum number of potentially affected businesses (full sensitivity analysis can be found in the Annexes).

Table 3a: Option 2: Sectors Affected by the Regulation, by Country

	England	Wales	Scotland	NI	UK
Plastic Manufacturers	2,112	108	100	84	2,404

Source: IDBR 2011, for details and SIC codes see Annex 1

Table 3b: Option 2: Sectors Affected by Country and Firm Size

	Micro	Small	Medium	Large	Total
England	1,409	506	165	32	2,112
Wales	72	26	8	2	108
Scotland	67	24	8	1	100
NI	56	20	7	1	84
UK	1,604	576	188	36	2,404

Source: IDBR 2011, for details and SIC codes see Annex 1

50. Table 4 below summarises the sectors that are affected under Option 3 by the Regulation:

Table 4a: Option 3: Sectors Affected by the Regulation, by Country

	England	Wales	Scotland	NI	UK
Manufacturer plastics	2,112	108	100	84	2,404
Manufacturer other	744	44	52	20	860
Retail	35,140	1,996	3,848	1,472	42,456
Packaging activities	888	40	56	24	1,008
Total	38,884	2,188	4,056	1,600	46,728

Source: IDBR 2011, for details and SIC codes see Annex 1

Table 4b: Option 3: Sectors Affected by Country and Firm Size

	Micro	Small	Medium	Large	Total
England	34,943	3,388	443	110	38,884
Wales	1,966	191	25	6	2,188
Scotland	3,645	353	46	11	4,056
NI	1,438	139	18	5	1,600
UK	41,992	4,072	532	132	46,728

Enforcement Authorities

51. Enforcement Authorities (EAs) and official control laboratories (OCLs) will also be affected by this policy as they will be required to read and familiarise themselves with the new EU Regulation. Table 5 below shows the number of enforcement authorities that are affected by the Regulation. This includes Local Authorities (LAs) Port Health Authorities (PHAs) and OCLs:

Table 5: Number of LAs, PHAs and public OCLs in each UK Country

	England	Wales	Scotland	NI	UK
No LAs	354	22	32	26	434
No PHAs	39	1	n/a	n/a	40
No. OCL labs	19	5	4	1	29
Total	**412**	**28**	**36**	**27**	**503**

Source: FSA internal data

Option Appraisal

Costs

OPTION 1 – Do Nothing – do not provide for the enforcement of the new EU Regulation or the consolidation of existing national legislation

52. There will be no incremental costs or benefits to businesses or consumers as a result of this option. This is the baseline against which the other options are appraised.

53. A risk of not intervening is that we will fail to address the initial rationale for market intervention for the previously repealed 2002/72/EC plastic contact materials legislation; thus, potentially allowing for the detrimental effect of chemical migration into food from food contact materials. We will also be foregoing an opportunity to reduce the regulatory burden on businesses, through consolidation of existing legislation without compromising consumer health.

54. Another risk with this option is that the UK would not meet its Treaty obligations to provide for the enforcement of EU law and may therefore, lead to the UK being liable to infraction proceedings.

OPTION 2: Provide for the Execution and Enforcement of the new EU Regulation

COSTS OPTION 2

Costs to Enforcement Authorities

Familiarisation (One-Off Cost)

55. There will be a one-off cost to Enforcement Authorities (EAs) for reading and familiarising with the new Regulations. Local Authorities (LAs) and Port Health Authorities (PHAs) are responsible for enforcing food safety and food hygiene legislation in their respective areas and as such, will need to be aware of the legislative changes. In addition, there will also be a one-off cost to Official Control Laboratories (OCLs) for reading and familiarising with the changes to testing requirements.

56. Familiarisation costs are quantified by multiplying the time it will take for an official to familiarise himself (herself) with the Regulations by the wage rate of the official and the number of enforcement authorities or laboratories affected.

57. For LAs and PHAs, either an Environmental Health Officer (EHO) or a Trading Standards Officer (TSO) will be required to familiarise themselves with the new enforcement provisions. In order to account for the differences across enforcement authorities[26], wage rates for both TSOs and EHOs are used to produce a range of values for hourly pay. As the lower bound we have used the median hourly wage of an EHO (£20.46[27]) and as the upper bound the median hourly wage rate of a TSO (£21.01[28]). This gives us a central estimate of £20.74. For all sensitivity analysis, see Annex A2.

58. For OCLs we have used an ASHE median wage estimate for a science and technology professional of £18.54 which increases to £24.10 when adjusted for overheads[29].

59. We assume that one enforcement officer per EA and one science professional per OCL is required for familiarisation. Consultation responses has indicated that it will take one hour per officer to

[26] Note that TSOs or EHOs may be responsible for enforcing this legislation depending on resource in each local authority

[27] Wage rates obtain from the Annual Survey of Household Earnings (ASHE), 2011, All Employees, Median hourly wage rate of "Environmental Health Officers" http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-235202. This includes an overhead of 30% (15.74*1.3=20.46).

[28] Wage rates obtain from the Annual Survey of Household Earnings (ASHE), 2011, All Employees, Median hourly wage of "Inspectors of factories, utilities and trading standards" http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-235202 . This includes an overhead of 30% (16.16*1.3=21.01).

[29] SCM guidance indicates that wage rates should be uprated by 30% to account for overheads http://www.bis.gov.uk/files/file44503.pdf

familiarise themselves, and further one hour to disseminate this information within their organisation[30].

60. For LAs and PHAs, this results in a lower bound familiarisation cost of £40.92 (£20.46*2*1), an upper bound familiarisation cost of £42.02 (£21.01*2*1) and a central (mid-point) estimate of £41.47 (£20.74*2*1), per authority. For OCLs the familiarisation cost per authority is £48.20. Multiplying the cost per authority by the number of authorities (see Table 5), taking into account the wage differences between PHAs/LAs and OCLs, results in a total familiarisation cost to UK enforcement of **£21,055**. Table 6 below summarises the familiarisation costs by country.

Table 6: Central Estimate of One-Off Familiarisation Costs (£) per LA, PHA and OCL, by Country

Option 2	England	Wales	Scotland	NI	UK
Cost LAs	£14,680	£912	£1,327	£1,078	£17,998
Cost PHAs	£1,617	£41	£0	£0	£1,659
Cost OCL labs	£916	£241	£193	£48	£1,398
Total	£17,214	£1,195	£1,520	£1,126	£21,055

Notes: Totals may not sum due to rounding
Costs are estimated by uplifting wage rates by 30% to account for overheads; this means the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in rounding error.

61. 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 are transformed into Equivalent Annual Costs (EAC) by dividing the one-off cost by an annuity factor.[31]

62. The total one-off cost to enforcement authorities and OCLs in England affected by this proposal is estimated to be £17,214 which yields an equivalent annual cost of £2000 for a time period of 10 years. Table 7 shows the breakdown of EACs by UK country:

Table 7: Familiarisation Equivalent Annual Costs (£) to Enforcement Authorities by UK country

Option 2	England	Wales	Scotland	NI	UK
EAC	£2,000	£139	£177	£131	£2,446

Notes: Totals may not sum due to rounding

Costs to Industry

Familiarisation (One-Off Cost)

63. Under Option 2, there will be a one-off cost to industry for reading and familiarising with the new consolidated EU Regulations. The only businesses affected under this Option are manufacturers of plastic packaging goods and other plastic products that are intended to come into contact with food. The new EU Regulation is specific to materials and article manufactured from plastic. We have assumed that it is the plant production manager that will be responsible for familiarisation. Familiarisation costs are quantified by multiplying the time it will take for the manager to familiarise himself (herself) with the Regulations by the wage rate of the manager and the number of officials that will be required to familiarise themselves.

64. The median hourly wage rate of a production manager is £26.10[32]. We assume that one production manager per plant will be required for familiarisation. Consultation have responses indicated that familiarisation will take in total two hours, one hour for familiarisation and another hour to disseminate the information within the organisation. This results in a total familiarisation cost per business of £52.21. Multiplying this with the total number of businesses (see Table 3), results in a

[30] This assumption (1+1 hour) is supported by the majority of consultation responses and we have therefore decided to go for the consensus. To note is however that two enforcement authorities indicated that two hours may not be enough if staff needs to fully understand the changes and internal documents or procedures would need to be updated – however no alternative estimates were provided.

[31] The annuity factor is essentially the sum of the discount factors across the time period over which the policy is evaluated. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left(\frac{1}{1+r_i} \right)$$

.

[32] Wage rates obtain from the Annual Survey of Household Earnings (ASHE), 2011, All Employees, Median hourly wage rate of "Production Manager"http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-235202
. This includes an overhead of 30% (20.08*1.3=26.10).

total familiarisation cost to the plastic manufacturing industry in England of £110,263. Table 8 presents total familiarisation costs by firm size and UK country:

Table 8: One-Off Familiarisation Costs (£) to UK Plastics Manufacturers, by Firm Size and UK Country

Option 2	Micro	Small	Medium	Large	Total
England	£73,570	£26,419	£8,623	£1,651	£110,263
Wales	£3,762	£1,351	£441	£84	£5,638
Scotland	£3,483	£1,251	£408	£78	£5,221
NI	£2,926	£1,051	£343	£66	£4,385
UK	£83,742	£30,072	£9,815	£1,879	£125,508

Notes:
1. Totals may not sum due to rounding.
2. Due to the aggregated nature of IDBR, some subsectors covered by the analysis will be larger than the actual subsection covered by the policy. The IDBR does not disaggregate data by sector, business size and country simultaneously. These categorisations are therefore estimated based on the proportion of businesses in each country, for each size of business.
3. Costs are estimated by uplifting wage rates by 30% to account for overheads; this means the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in rounding error.

65. As explained in paragraph 53 above, one-off costs need to be annualised. Table 9 below shows the EAC by UK country:

Table 9: Annual Equivalent Costs (£) to the Plastic Manufacturing Industry, by UK Country

Option 2	England	Wales	Scotland	NI	UK
EAC	£12,810	£655	£607	£509	£14,581

Note: Totals may not sum due to rounding

BENEFITS OPTION 2

Benefits to Enforcement Authorities

Simplification Benefits (Ongoing Benefit)

66. There may be potential benefits to enforcement authorities as a result of the simplification of the new EU Regulation. Any new entrant to an EA or OCL would have to only familiarise with a single European Regulation, namely the new EU Regulation, instead of numerous Directives. However, the Regulation will also involve additional complexities associated with the sampling and testing regime and alternative risk assessment allowance, we assume that any benefit in familiarisation time from simplification will net to zero on average. This assumption is supported by stakeholders. As such, no quantification is provided here.

Benefits to Industry

Cost Efficiency in Testing Regime

67. There may be additional benefits to Industry as a result of introducing this new EU Regulation. Businesses currently have to comply with the existing testing regime set out before the introduction of the new EU Regulation, which is entirely prescriptive and does not allow for alternative testing methods to be used. The new EU Regulation does allow for alternative testing methods to be used which provides for alignment in regimes across all EU member states. The option of using alternative methods should allow businesses more choice which will enable use of the most cost effective methods available and result in simplifying compliance demonstration in all EU member states simultaneously. The new EU Regulation also recognises the use of internationally approved scientific principles for risk assessment of non-intentionally added substances and non-listed substances; this allows industry to use exposure based risk assessments which they cannot currently do. Informal consultation indicates that Industry welcomes the introduction of the new EU Regulation.

Sampling and Testing Benefits

68. As detailed above, businesses will potentially be able to reap benefits from being able to use alternative testing methods for their products. This will allow compliance with the law to be assessed using potentially cheaper/more cost effective means. At this stage it is difficult to estimate how large these benefits are likely to be as increased competition across Europe may reduce prices currently charged by laboratories for testing.

Simplification Benefits

69. There also may be potential benefits to businesses as a result of simplification of the new EU Regulation. Any new entrant in the market would have to only familiarise with a single European Regulation, namely the new EU Regulation, instead of numerous Directives. However, because there are additional complexities associated with the sampling and testing regime and alternative risk assessment allowance we assume that any benefit in familiarisation time from simplification will net to zero on average from the additional complexities. As such, no quantification is provided here.

Benefits to Consumers

Public Health Benefits

70. The potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles, to the food itself, would also be minimised if fewer non-compliances are found. Whilst the potential health benefits are difficult to quantify, they are likely to include the risk of illness through long-term exposure to substances that can migrate and may be associated with various adverse effects on human health (as indicated in paragraphs 3-5 above).

Summary of Costs and Benefits to England under Option 2

71. Table 10 below shows a summary of total costs and benefits to England under Option 2. As can be seen, the option yields a total cost £127,477 (PV over ten years). To note is that there are also health benefits from this option (see paragraph 63), although we have been unable to quantify them.

Table 10: Summary of Costs under Option 2 to England (£)

Option 2	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/p.a.	NPV
One-Off Costs: Familiarisation													
Enforcement	£17,214	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,214	£2,000	£17,214
Industry	£110,263	£0	£0	£0	£0	£0	£0	£0	£0	£0	£110,263	£12,810	£110,263
Total Costs	£127,477	£0	£0	£0	£0	£0	£0	£0	£0	£0	£127,477	£14,810	£127,477

Note: Totals may not sum due to rounding

OPTION 3 – provide for the execution and enforcement of the new EU Regulation; revoke and consolidate all food contact materials legislation into a single statutory instrument

COSTS OPTION 3

Costs to Enforcement Authorities

Familiarisation (One-Off Cost)

72. There will be a one-off cost to EAs and OCLs for reading and familiarising themselves with the changes to plastics requirements in the new EU Regulation, following the consolidation at EU level of all the legislation on food contact plastics. The familiarisation costs under Option 3 will be the same as under Option 2; these are reported in Table 6.

73. In addition, under Option 3, the domestic legislation on food contact materials will be consolidated into one document, thereby providing for the enforcement of the new EU Regulation and consolidation of nearly all the other food contact materials national legislation. We do not, however, envisage that this consolidation in itself will result in any additional costs or need of additional familiarisation; enforcement authorities will already be familiar with the regulations as the consolidation does not change the provisions of the consolidated Regulations, but merely puts all the provisions into one single Statutory Instrument.

Costs to Industry

Familiarisation (One-Off Costs)

74. As set out in option 2, manufacturers of plastic articles and materials that are intended to come into contact with food will be required to familiarise themselves with the new EU Regulation and it's enforcement provisions; i.e. the changes to the plastics requirements. The one-off familiarisation costs to *plastics* manufacturers will be the same under Option 3 as under Option 2, see Table 8, with the corresponding EACs in Table 9. As these tables show, the total familiarisation cost to England is £110,263, whilst the corresponding number for the UK is £125,508. The EACs are £12,810 for England and £14,581 for the UK.

75. Under Option 3, all the domestic regulations on food contact materials are consolidated into one document. We do however not envisage any familiarisation costs to manufacturers other than those in the plastics sector (see previous paragraph), as there are no changes in the regulations on other food contact materials (e.g. ceramics, aluminium, etc.); they are just consolidated into one document.

76. However, new entrants (manufacturers, retailers and importers) in those sectors will potentially realise benefits from simplification; these are quantified in next section.

BENEFITS OPTION 3

Benefits to Enforcement Authorities

Simplification Benefits (Ongoing)

77. Under Option 3, there will be benefits accruing to simplification. The consolidation of the existing domestic legislation on food contact materials into one statutory instrument means that instead of reading four pieces of legislation, EAs and OCLs will now only have to read one document.

78. We assume that the simplification will lead to a reduction in the time it takes for new entrants into an EA/OCL to familiarise themselves with the legislation. We assume this will lead to a time reduction from two hours to one, an assumption that is supported by the majority of stakeholders[33].

79. At present we have been unable to assess the number of EAs that will be able to benefit from the simplification. Instead we have used an approximation based on the number of newly registered EHOs (inspectors in LAs and PHAs) per annum[34]. Based on the average of the per annum number of new EHOs between 2007 and 2010, we assume that, on average, there will be 212 new EHOs per annum in the UK.

80. For PAs (inspectors in OCLs), data from HPA indicates that OCLs employ less than 1 new PA per year, and we have therefore excluded this from the analysis since we envisage that the benefits would be negligible.

81. To estimate these simplification benefits we multiply the wage rate (central estimate) for a TSO/EHO (£20.74) by one hour and the number of EHOs that are affected (212). This yields a total annual benefit to the UK of £4,396. Splitting this number across the devolved administrations by proportions of LAs and PHAs in each country yields a per annum benefit to England of £3,645; with a per annum benefit to Wales of £213; an annual benefit to Scotland of £297 and annual benefit to Northern Ireland of £241, as outlined in Table 11 below.

Table 11: Annual Benefits (£s) to UK LAs and PHAs

Option 3	England	Wales	Scotland	NI	UK
Annual Benefit	£3,645	£213	£297	£241	£4,396

Note: data provided by CIEH has been split across the Devolved administrations by proportions of LAs and PHAs in each country (see table 5).

82. In order to assess the benefits over the life time of this policy it is standard HM Treasury practice to sum costs/benefits over a period of 10 years and discount to obtain the present value of these costs and benefits. Discounting adjusts for the general principle that people prefer to receive goods/services now to later.[35] The ongoing benefits are set out in table 12 below.

[33] To note is however that one enforcement authority believed that this was an overestimate. No alternative estimates were however provided.

[34] Data provided by CIEH

[35] Discounting is a technique used to compare costs and benefits that occur in different time periods. It is a separate concept from inflation, and is based on the principle that, generally, people prefer to receive goods and services now rather than later. This is known as 'time preference'.

Table 12: Ongoing Simplification Benefits (£) to England LAs and PHAs over 10 years

Option 3	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Benefit	NPV
Ongoing Benefit: Simplification												
EAs	3,645	3,645	3,645	3,645	3,645	3,645	3,645	3,645	3,645	3,645	36,446	31,372

Benefits to Industry

Simplification Benefits (Ongoing)

83. Under Option 3, there will be benefits accruing from simplification. The consolidation of existing domestic legislation on food contacts materials into one statutory instrument (SI) means that instead of reading four pieces of legislation, businesses will now only have to read one document. We assume that these benefits will only accrue to *new market entrants* as existing businesses will already have made themselves familiar with the existing legislation (sunk costs[36]).

84. *New entrant businesses* affected by this proposal are entrants in the following sectors: manufacturers and retailers of articles and materials that are intended to come into contact with food, including manufacturers, processors and importers of plastics, ceramics, aluminium, lead, zinc and tin, as well as packaging activities involving these products. We also envisage that retailers will incur a simplification benefit as they will also need to be familiar with the required standards of the products they choose to sell and the products they use to package the food they sell.

85. We assume that the simplification will lead to a reduction in the time it takes for new entrants to become familiar with the legislation. We assume this will lead to a time reduction from two hours to one. We further assume that it is the production manager that benefits from this simplification. The median hourly wage rate of a production manager is £26.10[37]. Additionally, we assume that the legislation will impact on 1 production manager per firm.

86. To get an estimate of the new entrants of the relevant manufacturers and retailers we have used the ONS Business Demography dataset (2010)[38]. The data in this dataset is only available at the UK level. To account for this we have used the proportion of IDBR businesses affected in each sector and UK country, to produce numbers on lower levels of aggregation. We have taken the average birth rate over the period 2004 to 2009 for all manufacturers and retailers of food contact materials. This includes importers of food contact materials as IDBR do not report importers as a separate category. Table 13 below shows the average birth rate of these businesses.

87. Note that in order to maintain consistency across estimation of costs and benefits, as well as to take into account the uncertainties around businesses affected, we have assumed a **central estimate of 80%** of the identified sectors will be affected by this proposal (for a full discussion see Paragraph 35).

Table 13: Average Per Annum Enterprise Birth in UK Food Contact Materials Industry

	Micro	Small	Medium	Large	Total
England	4,679	454	59	15	5,207
Wales	263	26	3	1	293
Scotland	488	47	6	2	543
NI	193	19	2	1	214
UK	5,623	545	71	18	6,257

Note: Totals may not sum due to rounding

[36] Costs of goods and services that have already been incurred and are irrevocable should be ignored in an appraisal. They are 'sunk costs'. What matters are costs about which decisions can still be made. However, this includes the opportunity costs of continuing to tie up resources that have already been paid for. http://www.hm-treasury.gov.uk/d/green_book_complete.pdf

[37] Wage rates obtain from the Annual Survey of Household Earnings (ASHE), 2011, All Employees, Median hourly wage rate of "Production Manager" http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-235202 . This includes an overhead of 30% (20.08*1.3=26.10).

[38] http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-229177

88. To calculate the simplification benefits to UK food contact materials industry, we multiply the number of new businesses per annum (see Table 13) with the time benefit per business (£26.10). Table 14 shows the total simplification benefits by firm size and UK country to manufacturers, processors, packagers and importers of food contact materials and retailers of food and beverages:

Table 14: Ongoing Simplification Benefits (£) to UK Food Contact Materials Industry by Firm Size and UK Country

	Micro	Small	Medium	Large	Total
England	£122,141	£11,844	£1,547	£384	£135,916
Wales	£6,873	£666	£87	£22	£7,648
Scotland	£12,741	£1,235	£161	£40	£14,177
NI	£5,026	£487	£64	£16	£5,593
UK	£146,780	£14,233	£1,860	£461	£163,334

Note: Totals may not sum due to rounding

89. The benefits above provide a static disaggregation of first year ongoing annual savings. In order to assess the benefits over the life time of this policy it is standard HM Treasury practice to sum costs/benefits over a period of 10 years and discount to obtain the present value of these costs and benefits. Discounting adjusts for the general principle that people prefer to receive goods/services now to later.[39]

90. Table 15 below provides the profile of annual benefits over a 10 year period for England only.

Table 15: Ongoing Benefits to Business of Simplification – England Only (£s)

Option 3	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	NPV
Ongoing Benefit: Simplification												
Industry	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£1,359,163	£1,169,925

Summary of Costs and Benefits to England under Option 3

Table 16 below shows a summary of all costs and benefits to England under Option 3. As can be seen, Option 3 provides a total net benefit to the UK of £1,073,820 (PV over a period of ten years). The corresponding net benefit to UK business is £1,059,662 (PV over a period of ten years).

Table 16: Summary of Additional Benefits under Option 3 to England (£)

Option 3	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/ P.A	NPV
One-Off Costs: Familiarisation													
Industry	£110,263	£0	£0	£0	£0	£0	£0	£0	£0	£0	£110,263	£12,810	£110,263
Enforcement	£17,214	£0	£0	£0	£0	£0	£0	£0	£0	£0	£17,214	£2,000	£17,214
Total	£127,477	£0	£0	£0	£0	£0	£0	£0	£0	£0	£127,477	£14,810	£127,477
Ongoing Benefit: Simplification													
Industry	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£1,359,163	£135,916	£1,169,925
Enforcement	£3,645	£3,645	£3,645	£3,645	£3,645	£3,645	£3,645	£3,645	£3,645	£3,645	£36,446	£3,645	£31,372
Total	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£1,395,609	£139,561	£1,201,297
Total Net Benefit													
Total	£12,084	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£139,561	£1,268,133	£124,751	£1,073,820
Business	£25,653	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£1,248,900	£123,106	£1,059,662

[39] Discounting is a technique used to compare costs and benefits that occur in different time periods. It is a separate concept from inflation, and is based on the principle that, generally, people prefer to receive goods and services now rather than later. This is known as 'time preference'.

CONSULTATION

Within Government

91. Other Government departments, including the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office and the Department of Environment, Food and Rural Affairs were kept informed of the progress throughout the negotiations relating to the new EU Regulation, through regular progress reports. To date no adverse comments have been received from any Department.

Wider consultation

92. During the course of negotiations with the Commission, FSA officials have frequently conveyed information to interested organisations, including, industry, research institutes, consumer groups, enforcement bodies, public analysts and others with an interest in policy issues related to food contact materials. Consultations on the harmonised rules on food contact plastics have been conducted in seven recent years; 2002, 2004, 2005, 2006, 2007, 2008 and 2009 when the rules on food contact plastics were last amended.

93. Two informal consultations on the proposed new EU Regulation were carried out; the first in 2004 and the second in 2009. Industry welcomed the proposed consolidation of the plastics legislation into a single European Regulation, simultaneously applicable all Member States, noting that the process of compliance demonstration would become much simpler. They also welcomed the introduction of the text in Article 18 of the new EU Regulation, which recognises the use of internationally recognised scientific principles for risk assessment of non-intentionally added substances and non-listed substances. This would result in industry possibly being able to use exposure-based risk assessments.

94. Any comments received from interested organisations have, where appropriate, been incorporated into the UK's negotiating line.

Formal Public Consultation

95. The FSA conducted a formal public consultation from 10th January to 3rd April 2012[40], seeking comments on the draft consolidated instrument and associated *draft* Impact Assessment. Eighty two stakeholders were consulted on these proposals; these included, food industry organisations, sector specific organisations, consumer groups, non-government organisations, enforcement authorities, including port health authorities, public and independent laboratories and others with an interest in food contact materials legislation were consulted. The consultation questions can be found at Annex A5.

96. In total 9 responses were received; two from Port Health Authorities (PHAs), one from the Trading Standards Institute, one from the Government Chemist and five from industry.

97. Whilst comments focused mainly on the estimated costs associated with the consolidated Regulation as reflected in the Impact Assessment (IA), there were however, a number of comments on the draft Regulations, from both industry and port health authorities. These were primarily on drafting detail and have been acted upon where necessary.

Summary of Comments

98. Stakeholders were asked whether the proposed consolidated food contact materials (FCM) Regulations would make it easier for businesses and other stakeholders to find the legislation that affected them and if new entrants to the FCM sector would benefit from these proposals. Enforcement authorities and industry were generally in support of the proposed consolidation of nearly all the FCM national legislation into a single statutory instrument. They also agreed that new entrants to the FCM sector will benefit from the consolidation of several pieces of legislation. However, the trade association representing the ceramics sector felt that it will not make it easier for their members, as they would still need to refer to the two different documents rather than one.

99. Stakeholders were also asked to comment on the omission of regulations 11 and 12 and regulations 8 and 9 of the current 2010 Regulations from the proposed consolidated Regulations, as they are no longer considered necessary or have become obsolete. Enforcement bodies agreed that regulations 11 and 12 and 8 and 9 were no longer necessary and could be omitted from the consolidated Regulations. However, whilst industry agreed that regulations 11 and 12, and regulation 9 could be

[40] http://www.food.gov.uk/news/consultations/consulteng/2012/materialsarticlesfoodregs2012eng

omitted, they felt that the omission of regulation 8 may prevent the FSA or enforcement bodies from taking action against businesses placing goods on the market and requests that the FSA reconsider the removal of the legal limits transposed from Directive 78/142/EEC, which are currently laid down in regulation 8.

100. Following comments from stakeholders on the omission, a different approach has been taken and only regulation 9 has been omitted from the consolidated Regulations and regulation 8[41] will be re-enacted in the consolidated Regulations in a modified form – it will only apply to non-plastic FCMs.

101. Stakeholders were asked to comment on the FSA's assessment of the businesses identified as being affected by each of the options in the IA, and whether the businesses identified adequately captured all those that are likely to face an impact. Although industry agreed that the assessment was an accurate reflection, they felt that perhaps end-users, such as fillers and food packers should also be included; as it would affect the food packers using plastic materials as well as industry, since they need compliance documentation from their suppliers. If these categories were included, the number of businesses affected by the proposals is likely to increase from the number identified in Table 4 of the IA.

102. Comments received from enforcement bodies indicated that 2 hours was a reasonable estimate for familiarisation and for the dissemination of information on the Regulations. But it was felt that more time may be required for internal procedures/document changes, should these be required and staff may need further time to understand the changes. Even when legislation is simplified, there is a familiarisation cost for enforcement bodies. Consideration needs to be given as to what is covered by the new legislation and which legislation previously covered it. The enforcement bodies agreed that there will be no familiarisation benefit from the simplification of the legislation.

103. Stakeholders were asked to provide evidence to support their views in relation to additional costs over and above their commercial activities of the proposed Regulations; however, none were able to quantify the additional costs in their comments or provide evidence to support their views.

104. A full summary of the comments received in response to the consultation will be published on the FSA's website in due course.

Enforcement

105. The purpose of The Materials and Articles in Contact with Food (England) Regulations 2012 is to provide enforcement authorities, e.g. Environmental Health Officers, Trading Standards Officers and Port Health Officers with the necessary powers to ensure that businesses are complying in England with the provisions of the new EU Regulation that apply to them.

Simplification

106. The FSA is taking the opportunity under the Government's Red Tape Challenge initiative to simplify the majority of the legislation on materials and articles, by revoking and remaking nearly all national food contact materials legislation in a single set of Regulations. This will make it easier for businesses and others that have to refer to the Regulations to use them and minimise the burden on industry and enforcement authorities. An earlier simplification of the regulation of food contact materials legislation was carried out in February and March 2006.

Statutory Review

107. The FSA is required to carry out a review every five years on the way in which EU legislation for which the FSA has enforcement oversight is implemented and enforced in other Member States. This review period begins when the proposed consolidated Regulations that are the subject of this Impact Assessment come into force. In carrying out the review, the FSA is required to produce a report that will assess whether the Regulations achieved their intended objectives. The report will also assess if these objectives could be achieved by means that impose less Regulation.

Specific Impact Tests

Competition Assessment

108. We fully considered the questions posed in the Office of Fair Trading (OFT) competition assessment test[42] and conclude that the preferred policy option on the proposed Regulations that

[41] Note: the FSA will review this in the near future, as and when the Commission decides to repeal Council Directive 78/142/EEC and will take appropriate action.

[42] http://www.oft.gov.uk/shared/_oft/reports/comp_policy/oft876.pdf

enforce the new EU Regulation are unlikely to hinder the number or range of businesses or the ability of operators to compete. As such, these proposals are unlikely to significantly affect competition. The proposals do not contain a strong competition element or any significant new or additional burden. This is not expected to result in any reduction or change in businesses operating in this area, nor in their competitiveness or incentive to compete. The EU legislation is directly binding on all Member States and the businesses that trade within them. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Small Business Impact Test

109. With over 98 per cent of businesses affected by this legislation are micro or small businesses; the costs and benefits set out in the IA reflecting the impact on these businesses. We do not consider the impact on small businesses to be significant.

Sustainability

110. Impacts under the three pillars of sustainable development (environment, economic and social) have been and continue to be considered in the preparation of this Impact Assessment. Option 3 is the preferred option as it provides enforcement authorities the necessary powers for the execution and enforcement of the new EU Regulation. This option is also more sustainable as businesses and enforcement authorities will benefit from having one set of Regulations containing all the provisions on materials and articles that they need to refer to (except in the special case of plastic kitchenware imported from China), instead of three separate sets of Regulations. The potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles to the food itself would also be minimised.

Race/Gender/Disability Equality Issues

111. The FSA envisages that the proposal will have no impact on race, gender or disability equality.

Annexes

112. **Annex A1:** Summary of Affected Industries.

Industry	SIC Code
Manufacturing: Food Contact Plastics	
Manufacture of plastic packing goods	2222
Manufacture of other plastic products	2229
Manufacturing: Other Food Contact Materials	
Manufacture of other articles of paper	1729
Manufacture of hollow glass	2313
Manufacture of ceramic household art.	2341
Manufacture of ceramic products	2349
Aluminium production	2442
Lead, zinc and tin production	2443
Manufacture of light metal packaging	2592
Packaging	
Packaging activities	8292
Food Retailers	
Retail of food, beverages	4711
Retail of fruit, vegetables	4721
Retail of meat	4722
Retail of fish	4723
Retail of bread	4724
Retail of beverages	4725
Retail Other Food	4729
Retail via stalls and markets of food	4781
Total	

113. **Annex A2:** Sensitivities of One-Off Familiarisation Costs (£) under Different Wage Rates (Central, Low or High) per LA, PHA and OCL, by Country (Option 2 and 3)

Country	England	Wales	Scotland	NI	UK
No LAs	354	22	32	26	434
No PHAs	39	1	n/a	n/a	40
No OCLs	19	4	7	2	35
Familiarisation Cost LAs					
Low	14,874	900	1,310	1,064	17,761
Central	14,680	912	1,327	1,078	17,998
High	14,847	924	1,345	1,092	18,235
Familiarisation Cost PHA					
Low	1,596	41	n/a	n/a	1,637
Central	1,617	41	n/a	n/a	1,659
High	1,639	42	n/a	n/a	1,681
Familiarisation Cost OCL					
Central	916	241	193	48	1,398
Total (Low)	**16,999**	**1,182**	**1,502**	**1,112**	**20,796**
Total (Central)	**17,214**	**1,195**	**1,520**	**1,126**	**20,055**
Total (High)	**17,428**	**1,207**	**1,537**	**1,141**	**21,314**

Notes: The central OCL estimate is included in each of the totals
Totals may not sum due to rounding
Costs are estimated by uplifting wage rates by 30% to account for overheads; this means the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in rounding error.

Annex A3: Sensitivities of Sector Size (option 3)

Table A3.1: Total Cost to Business under Option 2 (England)

Option 2	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/p.a.	NPV
Sensitivity Scenario													
80% of businesses (central)	£110,263	£0	£0	£0	£0	£0	£0	£0	£0	£0	£110,263	£12,810	£110,263
100% of businesses	£137,829	£0	£0	£0	£0	£0	£0	£0	£0	£0	£137,829	£16,012	£137,829
50% of businesses	£68,915	£0	£0	£0	£0	£0	£0	£0	£0	£0	£68,915	£8,006	£68,915

Table A3.2: Net Cost to Business under Option 3, Central Scenario (80%) (England)

Option 3	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/ P.A.	NPV
One-Off Costs: Familiarisation													
Industry	£110,263	£0	£0	£0	£0	£0	£0	£0	£0	£0	£110,263	£12,810	£110,263
Ongoing Benefit: Simplification													
Industry	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£1,359,163	£135,916	£1,169,925
Net Benefit	£25,653	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£135,916	£1,248,900	£123,106	£1,059,662

Table A3.3: Net Cost to Business under Option 3, (80% of businesses) (England)

Option 3	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/ P.A.	NPV
One-Off Costs: Familiarisation													
Industry	£137,829	£0	£0	£0	£0	£0	£0	£0	£0	£0	£137,829	£16,012	£137,829
Ongoing Benefit: Simplification													
Industry	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£1,698,954	£308,901	£1,462,406
Net Benefit	£32,066	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£169,895	£1,561,125	£292,888	£1,324,577

Table A3.4: Net Cost to Business under Option 3, (50% of businesses) (England)

Option 3	Year 0	1	2	3	4	5	6	7	8	9	Total Cost	EAC/ P.A.	NPV
One-Off Costs: Familiarisation													
Industry	£68,915	£0	£0	£0	£0	£0	£0	£0	£0	£0	£68,915	£8,006	£68,915
Ongoing Benefit: Simplification													
Industry	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£849,477	£84,948	£731,203
Net Benefit	£16,033	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£84,948	£780,562	£76,942	£662,289

Annex A4

The European Food Safety Authority (EFSA) is responsible for carrying out risk assessments and gives its opinions on substances used in the manufacture of food contact plastics based on risk assessment dossiers, submitted by industry seeking approval for use of a particular substance. These opinions are given on the basis of protection of public health from any harmful substances that may arise from the consumption of food into which the substance may have migrated. Any resulting limits contained in EFSA's opinions have margins of safety to ensure that the health of consumers who may eat contaminated foodstuffs would not be affected over their lifetime. The resulting European Commission proposals reflect these safety margins when determining the level of a substance that may be allowed to migrate into food. The Commission regularly amends these technical limits and refines definitions of categories used for limiting migration as scientific understanding of the substances and their health effects improves. Some substances that are deemed to be an unacceptable risk to consumer health in any quantity, particularly among vulnerable people, may be prohibited for use.

The new EU Regulation reflects improved scientific knowledge of particular chemicals in relation to human health and changes the lists of substances that may be used in manufacturing food contact plastics. Some substances may be removed from the Union list of permitted monomers[43] and additives either because satisfactory data has not been submitted by applicants for completion of the necessary risk assessment by EFSA, or because the risk assessments have deemed that the substance should no longer be used.

[43] Monomers are small molecules that can become chemically bonded to other monomers to form a polymer.

Annex A5

Consultation Questions

1a). Stakeholders are asked to comment on the proposed consolidation of the food contact materials SIs. Will this make it easier for businesses and other stakeholders to find the legislation that affects them?

1b). Will new entrants to the food contact materials and articles sector benefit from these proposals?

2). Stakeholders are asked to comment on the omission of regulations 11 and regulation 12 of the current 2010 Regulations from the proposed consolidated Regulations as they are not longer considered necessary or have become obsolete. If you disagree with this assessment, please provide evidence to support your view.

3). Stakeholders are asked to comment on the omission of the content of regulations 8 and 9 of the current 2010 Regulations from the proposed consolidated Regulations. We believe this content is no longer necessary, the requirements for VCM now being covered by the new EU Regulation. If you disagree with this assessment, provide evidence to support your views.

4). Stakeholders are asked to comment on the changes to the national Regulations, in particular the way in which the proposed consolidated Regulations have been re-drafted following revocation and re-enactment of the three principal national Regulations and one amending Regulation on food contact materials and articles into a single Statutory Instrument.

We would also welcome comments on the proposed Regulations, in so far as they relate to the provisions for enforcement of the new EU Regulation, defences and penalties.

We would also welcome comments on any likely costs to be incurred in implementing the enforcement proposals.

Stakeholders are asked to comment on the likely savings and benefits accruing to the consolidation of the national Regulations in a single set of Regulations.

5). Table 1 on page 12 of the Impact Assessment sets out the businesses that we have identified as being affected by each of the options. We welcome comments on whether the businesses identified adequately capture all those that are likely to face an impact. If agree or disagree with this assumption, please provide evidence to support your views.

6). It is our assumption that 39,276 businesses in England will be affected by this proposal. We invite stakeholders to comment on whether our assessment for the number and type of affected businesses, is a reasonable assessment? If you agree or disagree with this assessment, please provide evidence to support your response.

Specifically:

a). Are the sectors affected as displayed in the tables an accurate representation?

b). Will option 2 affect only manufacturers of plastic food contact materials?

7). It is our assumption that LAs, PHAs and OCLs will be affected by this proposal. We invite stakeholders to comment on whether this is a reasonable assessment? If you agree or disagree, please provide evidence to support your response.

8). It is our assumption that it will take EAs and OCLs one hour to familiarise themselves and one hour to disseminate the proposed consolidated Regulations to other members of staff within the organisation. We invite EAs and OCLs to comment on whether our assessment is a reasonable one; please provide evidence to support your response.

9). It is our assumption that there is a familiarisation cost for businesses associated with the proposed consolidated Regulations. We invite businesses to comment on our estimate of one hour for familiarisation and a further one hour for dissemination to key staff within the organisation of the new

Regulations a reasonable assessment? If you agree or disagree with this assessment, please provide evidence to support your response.

10). It is our assumption that there will be no familiarisation benefit for new EHOs/TSOs or public analysts employed by Local authorities as any benefit from simplification will be cancelled out by increased testing and risk assessment options. We welcome views on this; please provide evidence to support your response.

11). It is our assumption that there is a sampling and testing benefit to businesses as a result of changes to the new EU Regulation. We would welcome views from business on:

a) Current sampling and testing costs to ensure product compliance with the law

b) The anticipated savings from making use of alternative sampling and testing methods.

Please provide evidence to support your response.

12a). It is our assumption that there will be no familiarisation benefit for new EHOs/TSOs or public analysts employed by Local authorities as any benefit from simplification will be cancelled out by increased testing and risk assessment options. We welcome views on this; please provide evidence to support your response.

b). We would also welcome views on whether the benefits set out here are an accurate representation of the benefits to industry; please provide evidence to support your response.

13a). It is our assumption that it will take EAs and OCLs one hour to familiarise themselves and one hour to disseminate the proposed consolidated Regulations to other members of staff. We invite EAs and OCLs to comment on whether our assessment is a reasonable one; please provide evidence to support your response.

b). It is our assumption that EAs and OCLs will not have to familiarise themselves with the new simplified and consolidated legislation as they will be informed by the FSA via standard updates that no materials difference to their enforcement practice is required as a result of this simplification. We invite EAs and OCLs to comment on whether this assumption is reasonable; please provide evidence to support your response.

14a) It is our assumption that there is a familiarisation cost for businesses associated with the proposed consolidated Regulations. We invite businesses to comment on our estimate of an hour for familiarisation and a further an hour for dissemination to key staff within the organisation of the proposed consolidated Regulations a reasonable assessment? If you agree or disagree with this assessment, please provide evidence to support your response.

b). It is our assumption that businesses will not have to familiarise themselves with the new simplified and consolidated legislation as they will be informed by the FSA that no material difference to their enforcement practice is required as a result of this simplification. We invite Industry to comment on whether this assumption is reasonable; please provide evidence to support your response.

15). It is our assumption that there is a simplification benefit for businesses associated with the proposed consolidated Regulations. We invite businesses to comment on:

a) our estimate of a time reduction from two hours to one as a result of this simplification measure.

b) the number of new market entrants in this sector.

If you agree or disagree with these assessments, please provide evidence to support your response.

16). Do you agree with our assumption that there will not be a significant impact on small businesses as a result of this legislation a correct assumption? If you agree or disagree with this assessment, please provide evidence to support your response.