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FOOD STANDARDS AGENCY CONSULTATION

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2012

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
January 10th 2012	3rd April 2012

Who will this consultation be of most interest to?

Businesses that manufacture, import, wholesale and/or retail materials and articles intended to come into contact with food, Port Health Authorities, Local Enforcement Authorities, consumers and others who may have in interest in the policy and legislation on food contact materials.

What is the subject of this consultation?

The proposed Materials and Articles in Contact with Food (England) Regulations 2012 which will provide for the execution and enforcement, in England, of European Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food ("the EU Regulation"). The proposed Regulations also revoke and re-enact nearly all food contact materials legislation within the Food Standards Agency's remit (with the exception of The Plastic Kitchenware (Conditions on Imports from China) England Regulations 2011)), into a single consolidated Statutory Instrument.

What is the purpose of this consultation?

To seek comments from industry, enforcement authorities, port health authorities, consumers and other interested stakeholders on the Materials and Articles in Contact with Food (England) Regulations 2012 and the associated draft Impact Assessment.

Responses to this consultation should be sent to:

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FOOD STANDARDS AGENCY
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Is an Impact Assessment included with this consultation?	Yes ☒	No ☐ See Annex A for reason.

INVESTOR IN PEOPLE

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.

POSITIVE ABOUT DISABLED PEOPLE

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2012

DETAIL OF CONSULTATION

1. We would welcome your comments on:

   - **The Materials and Articles in Contact with Food (England) Regulations 2012 ("the proposed consolidated Regulations") at Annex B**. These Regulations would provide for the execution and enforcement, in England, of Commission Regulation (EU) No. 10/2011[1] ("the new EU Regulation") at **Annex C** relating to plastic materials and articles intended to come into contact with food.

   - With the exception of The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011[2], the proposed consolidated Regulations will also revoke and re-enact all existing national legislation within the Food Standards Agency's (FSA) remit on materials and articles intended to come into contact with food, with necessary amendments; thus implementing and/or enforcing all EU food contact materials legislation in on one consolidated instrument. This is part of the FSA's intention to introduce a simplified system of food safety legislation in response to the Westminster Government's Red Tape Challenge initiative. We would welcome comments on this proposed consolidation.

   - Details of changes to the national legislation are discussed in paragraph 4 below.

   - **The draft Impact Assessment (IA) at Annex D.** We would particularly welcome comments and supporting evidence in respect of any cost implications that may arise from these proposals.

2. The Food Standards Agency in Scotland, Wales and Northern Ireland will be carrying out consultations on parallel but separate Regulations relating to those parts of the UK and associated draft Impact Assessments.

Background

3. The general principles governing the safety of all materials and articles intended to come into contact with foods are established in Commission Regulation (EC) No. 1935/2004[3] ("the framework Regulation"). The Framework Regulation lays down the framework of regulation for all materials and articles intended to come into contact with foods. The new EU Regulation is a specific measure within the meaning of Article 5(1) of the framework Regulation and establishes the specific rules for food contact plastics.

4. Until recently harmonised EU rules on plastic food contact materials were laid down by Commission Directive 2002/72/EC[4] (as amended). The new EU Regulation repeals Directive 2002/72/EC and all extant amendments on food contact plastics and consolidates the provisions at EU level that have applied from 1st May 2011.

[1] OJ Ref: L12m 15.1.2011, pg 1-89
[2] SI 2011 No. 1527
[3] OJ Ref: L338, 13.11.2004, pg 4-17
[4] OJ Ref: L220, 15.8.2002, p 18

The requirements of the Directive are implemented in England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009[5] ("the 2009 Regulations").

5. Furthermore, Directive 2002/72/EC was amended in January this year by Commission Directive 2011/8/EU/[6] which introduced restrictions on bisphenol A (BPA) in plastic infant feeding bottles. 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[7] as regards the restriction of the use of BPA in plastic infant feeding bottles; this 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, which take account of the restrictions on BPA in infant feeding bottles.

6. The amending European Regulation effectively brings the restrictions on BPA in infant feeding bottles, in line 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 1st June 2011, as regards the placing on the market and importation into the Union. Thus, ensuring continuity of the prohibition of BPA in infant feeding bottles.

7. The new EU Regulation was published in the Official Journal (OJ) of the European Union on 15th January 2011, is directly applicable throughout the EU and came into force on 3rd February and applies from 1st May 2011. It can be downloaded free of charge from the European Union website at:

http://eur-lex.europa.eu/JOIndex.do?year=2011&serie=L&textfield2=12&Submit=Search&_submit=Search&ihmlang=en

Changes to National Legislation Following Revocation and Consolidation

8. The proposed Materials and Articles in Contact with Food (England) Regulations 2012 will consolidate into one Statutory Instrument (SI) all the of national legislation on food contact materials and articles, within the FSA's remit except for The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011. These Regulations are intended as a short-term measure, which put in place additional import controls on polyamide and melamine plastic kitchenware from China. Apart from these Regulations at present the rules on food contact materials and articles are contained in three principal SI's and one amending SI', as indicted below:

- The Materials and Articles in Contact with Food (England) Regulations 2010 (see paragraphs 11-16).

[5] SI 2009 No. 205
[6] Ref: OJ L26, 29.1.2011
[7] Ref: OJ L87, 2.4.2011, p1

- The Ceramic Articles in Contact with Food (England) Regulations 2006 (see paragraphs 17 – 18); and
- The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 as amended by the 2011 Regulations (see paragraphs 19 - 22);

9. The consolidation being proposed is part of the FSA's response to the Westminster Government's Red Tape Challenge (RTC) initiative[8] launched in April 2011, with the purpose of getting comments from business and the public on the stock of legislation. On 6th May 2001 most of the FSA's legislation was published on the RTC under the Hospitality Theme and remained on the site until 2nd June 2011. In response to the RTC, the FSA will be developing a simplified system of food safety legislation, with the intention of making it easier for businesses and other stakeholders to find the legislation that affects them. This includes the consolidation proposed in this consultation.

10. Details of the four national measures on food contact materials and articles being consolidated and the European legislation they implement/enforce are provided in paragraphs 11 - 22 below.

Consultation question 1

a) 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?

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

11. The Materials and Articles in Contact with Food (England) Regulations 2010[9] ("the 2010 Regulations") provide for the enforcement of three European Regulations and implement the provisions of four Directives; these are:

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

    ii. Regulation (EC) No. 2023/2006[10] on good manufacturing practice ("the GMP Regulation");

    iii. Regulation (EC) No. 450/2009[11] on active and intelligent materials and articles intended to come into contact with foods ("the AIM Regulation");

    iv. Commission Directive 2002/42/EC[12] on food contact materials made from regenerated film (RCF);

    v. Council Directive 78/142/EEC[13] relating to vinyl chloride monomer (VCM) in food contact plastics;

    vi. Commission Directives 80/766/EEC[14] on the methods for testing for VCM in food contact plastics; and

[8] http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/
[9] SI 2010 No. 2225
[10] Ref: OJ L384 29.12.2006, pg 75
[11] Ref: OJ L135, 30.05.2009, pg 3
[12] Ref: OJ L172, 30.6.2007, pg 71-81
[13] Ref: OJ L44, 15.2.1978

vii. 81/432/EEC[15] method for testing migration of VCM from food contact plastics.

Enforcement provisions of Commission Regulations 1935/2004, 2023/2006 and 450/2009

12. The revocation of the 2010 Regulations will not change the way in which Commission Regulations 1935/2004, 2023/2006 and 450/2009, will be enforced in the proposed consolidated Regulations. The enforcement provisions of all three European Regulations remain intact and unchanged and there are no new or additional burdens on businesses or enforcement authorities from the proposed simplification. However, there will be minor textual changes to take into account the consolidation of the 2010 Regulations; the repealed Directives and cross-references to other SIs which will be removed along with the definitions of terms such as 'plastics', which stem from the plastics Directive.

Provisions for Regenerated Cellulose Film (RCF) and Vinyl Chloride Monomer (VCM)

13. In relation to the provisions for regenerated cellulose film (RCF) and the implementation of Directive 2007/42/EC; the provisions have been redrafted with minor amendments, which are closer to that Directive. The main difference here is that the new EU Regulation has direct effect in relation to the migration limits that apply to RCF. Again, the provisions of Directive 2007/42/EC remain intact and unchanged; there is unlikely to be any new or additional burden on businesses from the redrafted provisions. Instead of carrying out testing for compliance of RCF in accordance with Directive 2007/42/EC, testing will now be carried out in accordance with the new EU Regulation. All references in the proposed consolidated Regulations to the repealed Directive have been removed and replaced with references to the new EU Regulation.

14. The proposed consolidated Regulations will not re-enact a number of provisions on RCF contained in the 2010 Regulations, which are considered to be no longer necessary. The migration limits set out in regulation 11 of the 2010 Regulations are now directly applied by the new EU Regulation, and the saving and transitional provisions in regulation 12 are now considered obsolete. This requirement related to transitional arrangements contained in the Materials and Articles in Contact with Food (England) Regulations 2005[16], which were time limited; that time limit has now expired.

Consultation question 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.

15. In relation to the provisions of the Directives on vinyl chloride monomer (VCM), the 2010 Regulations implemented the provisions of Directive 78/142/EEC on VCM, (which 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 are now contained in Annex II of that Regulation. This is based

[14] Ref: OJ L213, 16.8.1980
[15] Ref: OJ L 167, 24.6.1981
[16] SI 2005 No. 898

on the assumption (by the FSA) that Directive 78/142/EEC may now be redundant (though not repealed). As such, some of its provisions have not been re-enacted in the proposed 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 however, be minor amendments to the provisions on VCM, to tie them into the requirements of the new EU Regulation. Again, there is unlikely to be any new or additional burden on businesses from the proposed consolidation.

16. The proposed consolidated Regulations will not re-enact the provisions on VCM, which were contained in regulation 8 and 9 of the 2010 Regulations, due to the reasons given above.

Consultation question 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.

The Ceramic Articles in Contact with Food (England) Regulations 2006[17]

17. 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[18], 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[19].

18. Regulations 9 and 10, of the proposed consolidated Regulations reproduce the operative provisions of the Ceramic Articles in Contact with Food (England) Regulations, implementing Directive 84/500/EEC. As the ceramics SI is no longer a standalone SI, references to the Directives are used more widely in the redrafted implementing provisions. The definition of ceramic articles now resembles that of the Directive and references to antiques have been removed, which is not relevant as they are already out of scope of the Framework Regulation, which applies to all food contact materials and articles.

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

19. The Plastic Materials and Articles in Contact with Food (England) Regulations ("the 2009 Regulations") as amended, implemented the provisions of Directive 2002/72/EC and all its amendments (that have since been repealed by the new EU Regulation), together with the two Directives relating to the testing for compliance of plastic materials and articles intended to come into contact with foods (namely Directives 82/711/EEC, laying down the basic rules for testing for migration of constituents and 85/572/EC, which contained the lists of food simulants for migration testing).

[17] SI 2006 No. 1179
[18] Ref: OJ L277, 20.10.1984
[19] SI 1988 No. 1647

20. The 2009 Regulations also implemented the enforcement provisions of Commission Regulation (EC) No. 1895/2005[20] on the restrictions on the use of certain epoxy derivatives in materials and articles intended to come into contact with food. 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 within the Specific Migration Limit (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 1st January 2006 and re-affirmed the ban on the use of BFDGE[22] and NOGE[23].

21. 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 not changed, there will be no new or additional burden on business or enforcement authorities.

22. The 2009 Regulations were recently amended to take into account 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 prohibit the placing on the market in, import into, England of polycarbonate infant feeding bottles manufactured using BPA from 1st June 2009. These Regulations will be revoked, together with the 2009 Regulations and their provisions in relation to BPA will be enforced in the proposed consolidated Regulations as part of the enforcement of the new EU Regulation.

Consultation

Within Government

23. Other Government departments, including the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office and 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.

24. 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.

[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
[24] Ref: OJ L26, 29.1.2011, pg 11
[25] SI 2011 No. 231

25. Two informal consultations on the new EU Regulation were carried out; the first in 2004 and the second in 2009. Comments from the 2009 consultation were positive; industry welcomed the proposed consolidation of the European legislation on food contact plastics into a single European Regulation, simultaneously applicable in 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 not listed substances. This would result in industry possibly being able to use exposure-based risk assessment.

26. Any comments received from interested organisations have, where appropriate, been incorporated into the UK's negotiating line, as reflected in the new EU Regulation.

This Consultation

Purpose of the Consultation

27. The FSA is conducting this consultation to seek comments from interested parties and obtain their views on the proposal to make national Regulations to provide for the execution and enforcement of the new EU Regulation by enforcement authorities in England. We are also seeking comments on the FSA's proposal to revoke and re-enact the majority of national legislation on materials and articles intended to come into contact with food in a single consolidated instrument, under the Government's Red Tape Challenge exercise. The aim of this will be to reduce the number of national Regulations (from the current four to a single consolidate SI) on food contact materials that businesses and enforcement authorities have to refer to.

28. The key proposals on which this consultation seeks comments are as follows:

Key proposal:

- **To make national Regulations to provide for the execution and enforcement of the new EU Regulation;**
- **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;**
- **Specifying the penalties that the Courts may impose upon conviction for an offence; and**
- **To revoke and re-enact the majority of the national legislation on materials and articles intended to come into contact with food in a single consolidated instrument, in response to the Government's Red Tape Challenge initiative, which will reduce the number of national Regulations on food contact materials to which businesses and enforcement authorities have to refer to from four to a single instrument.**

29. Any comments that interested parties are able to provide in relation to the proposed Regulations would be gratefully received. We would be particularly keen to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage them to comment on all aspects of the proposal and its intended effect.

Consultation questions

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.

EU Guidance

30. The Commission will be producing guidance on the new EU Regulation in due course. The draft guidance is currently under discussion with Member States and once finalised, it will be published on the EU website at:

    http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

Other relevant documents

31. The following national Regulations on materials and articles intended to come into contact with food are available on the 'legislation.gov.uk' website at:

32. The Plastic Materials and Articles in Contact with Food (England) Regulations 2009
    http://www.legislation.gov.uk/uksi/2009/205/contents/made

33. The Materials and Articles in Contact with Food (England) Regulations 2010
    http://www.legislation.gov.uk/uksi/2010/2225/contents/made

34. The Ceramic Articles in Contact with Foodstuffs (England) Regulations 2006
    http://www.legislation.gov.uk/uksi/2006/1179/contents/made

35. The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011
    http://www.legislation.gov.uk/uksi/2011/231/contents/made

36. The European legislation on food contact materials mentioned in this document is available on the European Commission website at:
    http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

Responses

37. Responses are required by **3rd April 2012**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

38. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

Nasreen Shah
Regulatory Officer
Regulation and Business Support Team
Chemical Safety Division

Enclosed

Annex A: Standard Consultation Information

Annex B: The *draft* Materials and Articles in Contact with Food (England) Regulations 2012

Annex C: Commission Regulation (EU) No. 10/2011, on plastic materials and articles intended to come into contact with food

Annex D: Draft Impact Assessment

Annex E: List of interested parties

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex E. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: **http://www.berr.gov.uk/files/file47158.pdf** The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 — Duration of consultation exercises
Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 - The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 - Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 - Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

8. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex D.

10. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at:

    http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at:

    http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

    The questionnaire can also be used to update us about your existing contact details.

S T A T U T O R Y I N S T R U M E N T S

2012 No.

FOOD, ENGLAND

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

Made - - - -	***
Laid before Parliament	***
Coming into force - -	*Month 2012*

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Requirements for Regenerated Cellulose Film

PART 6

Requirements for Plastic Materials and Articles

PART 7

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PART 8

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PART 9

General and supplementary

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), 2(a) and (3), 31 and 48(1) of the Food Safety Act 1990(**a**), and now vested in him(**b**), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(**c**).

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for certain references to an EU instrument or to an Annex to an EU instrument specified in regulation 2(3) to be construed as references to that instrument or Annex as amended from time to time.

In accordance with section 48(4A) of the 1990 Act he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**d**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Preliminary

Title, application and commencement

1. These Regulations may be cited as the Materials and Articles in Contact with Food (England) Regulations 2012, apply in relation to England only and come into force on [----] 2012.

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

"Directive 84/500/EEC" means Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs(**e**)

"Directive 2007/42/EC" means Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs(**a**);

(**a**) 1990 c.16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c.51) and amended by Part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (2008 c.7).

(**d**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468 with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

(**e**) OJ No. L277, 20.10.1984, p.12, amended by Commission Directive 2005/31/EC (OJ No. L110, 30.4.2005, p.36).

"Regulation 1935/2004" means Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC(**b**);

"Regulation 1895/2005" means Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food(**c**);

"Regulation 2023/2006" means Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food(**d**);

"Regulation 450/2009" means Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food(**e**);

"Regulation 10/2011" means Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food(**f**)

"authorised officer" means any person, whether or not an officer of the authority having responsibility for execution and enforcement under regulation 14, who is authorised by that authority in writing to act in matters arising under these Regulations;

"food authority" does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple) nor a port health authority;

"port health authority" means —

(a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984(**g**) by section 7(1) of that Act), the Common council of the City of London; and

(b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act;

"preparation" includes manufacture and any form of treatment or process, and "prepare" shall be construed accordingly.

(2) Expressions used in these Regulations and in Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 or Regulation 10/2011 bear the same meaning in these Regulations as they bear in those Regulations.

(3) Any reference to Regulation 2023/2006 or to an Annex to Directive 2007/42/EC or Regulation 10/2011 is a reference to that Regulation or that Annex as amended from time to time.

Scope

3. The provisions of these Regulations do not apply to those materials and articles specified in sub-paragraphs (a), (b) and (c) of Article 1(3) of Regulation 1935/2004.

(**a**) OJ No. L172, 30.6.2007, p.71. This Directive repealed and consolidated without further amendment Commission Directive 93/10/EEC as last amended by Commission Directive 2004/14/EC.
(**b**) OJ No. L338, 13.11.2004, p.4, amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).
(**c**) OJ No. L302, 19.11.2005, p.28.
(**d**) OJ No. L384, 29.12.2006, p.75, amended by Commission Regulation (EC) No.282/2008 (OJ No. L86, 28.3.2008, p.9).
(**e**) OJ No. L135, 30.5.2009, p.3.
(**f**) OJ No. L12, 15.1.2011, p.1 as last amended by [*DN: update close to consultation date*]
(**g**) 1984 c.22.

PART 2

General Requirements for Materials and Articles

Offences of contravening specified provisions of Regulation 1935/2004

4.—(1) No person may place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food any material or article that does not comply with the requirements of Article 3(1) (general requirements) or Article 4(1),(2),(3) or (4) (special requirements for active and intelligent materials and articles).

(2) No person may place on the market any material or article that does not comply with the requirements of Article 3(2), 4(5) or (6) or 15(1),(3),(4),(7) or (8) as read with 15(2) (labelling).

(3) Any person who contravenes paragraph (1) or (2) or Article 11(4) or (5) (Community authorisation) or 17(2) (traceability) is guilty of an offence.

(4) In this regulation a reference to a numbered Article is a reference to that Article in Regulation 1935/2004.

Offence of contravening Article 4 of Regulation 2023/2006

5. Any person who fails to comply with the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.

Competent authorities for the purposes of Regulation 1935/2004 and Regulation 2023/2006

6.—(1) The following bodies are designated as the competent authorities for the purposes of the provisions of Regulation 1935/2004 specified below —

(a) in respect of Articles 9 and 13, the Food Standards Agency; and

(b) in respect of Articles 16(1) and 17(2), the Food Standards Agency, each food authority in its area and each port health authority in its district.

(2) The competent authority for the purposes of Article 6(2) and 7(3) of Regulation 2023/2006 is each food authority in its area.

PART 3

Requirements for Active and Intelligent Materials and Articles

Offences of contravening specified provisions of Regulation 450/2009

7.—(1) Subject to the transitional provisions contained in Article 14 of Regulation 450/2009, any person who places on the market any active or intelligent material or article which does not comply with the requirements of Article 4 of that Regulation is guilty of an offence.

(2) Any person who fails to comply with the requirements of Article 13 (requirements relating to supporting documentation) of Regulation 450/2009 is guilty of an offence..

Competent authorities for the purposes of Regulation 450/2009

8. The competent authorities for the purposes of Article 13 of Regulation 450/2009 are the Food Standards Agency, each food authority in its area and each port health authority in its district.

PART 4

Requirements for Ceramic Articles

Interpretation of this Part

9. In this Part —

(a) "ceramic article" means an article within the meaning of Article 1(2) as read with 1(3) of Regulation 1935/2004 which —

(i) is manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added,

(ii) is first shaped and the shape thus obtained permanently fixed by firing, and

(iii) may be glazed, enamelled and/or decorated; and

(b) any reference to a numbered Article or Annex is a reference to that Article in or Annex to Directive 84/500/EEC.

Limits for lead and cadmium and declaration of compliance

10.—(1) The quantities of lead or cadmium transferred from a ceramic article must not exceed the limits laid down in Article 2(4) as read with Article 2(3) and (5).

(2) Unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium, compliance with paragraph (1) is to be determined by testing and analysis in accordance with Annex I and Annex II respectively.

(3) No person may place on the market a ceramic article that does not comply with the requirements of paragraph (1) as read with paragraph (2).

(4) A person who places on the market a ceramic article that is not yet in contact with food must provide a written declaration complying with paragraph (5) to accompany the article at the marketing stages up to and including the retail stage.

(5) The declaration must be issued by the manufacturer or by a person established within the EU who placed the ceramic article on the market and must contain the information laid down in Annex III.

(6) A person who manufactures or, in the course of a business, imports into the EU/[EEA] a ceramic article shall on request make available to [an authorised officer/the competent authority] appropriate documentation to demonstrate compliance with the requirements of paragraph (1) including —

(a) the results of analysis carried out;

(b) the test conditions; and

(c) (i) the name and address of the laboratory that performed the testing, or

(ii) evidence that the materials used to make the ceramic article did not contain lead or cadmium.

(7) Paragraphs (4),(5) and (6) do not apply to a ceramic article which is second-hand.

PART 5

Requirements for Regenerated Cellulose Film

Interpretation of this Part

11.—(1) In this Part —

(a) "regenerated cellulose film" (or "RCF") means a thin sheet material obtained from refined cellulose derived from unrecycled wood or cotton, with or without the addition of suitable substances, either in the mass or on one or both surfaces, but does not include synthetic casings of regenerated cellulose;

(b) "URCF" means uncoated regenerated cellulose film;

(c) "CRCF" means coated regenerated cellulose film with coating derived from cellulose; and

(d) "PRCF" means coated regenerated cellulose film with coating consisting of plastics.

(2) This Part applies to RCF which —

(a) constitutes a finished product in itself; or

(b) is part of a finished product containing other materials,

and is intended to come into contact with food or, by being used for that purpose, does come into contact with food.

(3) Except in regulation 12(3), any reference in this Part to a numbered Annex is a reference to that Annex to Directive 2007/42/EC.

Controls and limits

12.—(1) URCF and CRCF may be manufactured using only the substances or groups of substances listed in Annex II and subject to the restrictions set out in that Annex but, by way of derogation, substances other than those listed in Annex II may be used when these substances are employed as —

(a) dyes and pigments; or

(b) adhesives,

provided that there is no trace of migration of the substances, detectable by a validated method, into or on to foodstuffs.

(2) PRCF may be manufactured, prior to coating, using only substances or groups of substances listed in the first part of Annex II and subject to the restrictions set out in that part.

(3) The coating to be applied to PRCF may be manufactured using only substances or groups of substances listed in Annex I to Regulation 10/2011 and subject to the restrictions in that Annex.

(4) Materials and articles made of PRCF must comply with Article 12 as read with Articles 17 and 18 of Regulation 10/2011.

(5) Printed surfaces of RCF must not come into contact with foodstuffs.

(6) Any material or article made of regenerated cellulose film that is not by its nature clearly intended to come into contact with food must, at a marketing stage other than the retail stage, be accompanied by a written declaration attesting that it complies with the legislation applicable to it.

(7) Where special conditions of use are indicated, the material or article made of RCF must be labelled accordingly.

(8) No person may place on the market any RCF which has been manufactured in contravention of the requirements of paragraphs (1) to (4), or which fails to comply with paragraphs (5),(6) or (7).

PART 6

Requirements for Plastic Materials and Articles

Interpretation of Part 6 and Schedule

13. In this Part and in the Schedule any reference to a numbered Article or Annex is a reference to that Article of or Annex to Regulation 10/2011.

Offences of contravening specified provisions of Regulation 10/2011

14.—(1) Subject to the transitional arrangements set out in Article 22(4) and (5) and 23, any person who places on the market a plastic material or article that fails to comply with a requirement of Regulation 10/2011 specified in column 1 of the Schedule is guilty of an offence.

(2) Any person who fails to comply with the second sentence of Article 8 or, subject to transitional arrangements set out in Article 22(1),(2) and (3), with Article 16 (requirements to make specified information available to competent authorities on request) is guilty of an offence.

Competent authorities for the purposes of Regulation 10/2011

15. The competent authorities for the purposes of Regulation 10/2011 are —

(a) in respect of Article 8, the Food Standards Agency, each food authority in its area and each port health authority in its district; and

(b) in respect of Article 16(1), the Food Standards Agency.

PART 7

Requirements for certain epoxy derivatives

Restrictions on the use of certain epoxy derivatives (BADGE, BDGE and NOGE)

16.—(1) In this Regulation —

(a) any reference to a numbered Article or Annex is a reference to that Article or Annex in Regulation 1895/2005; and

(b) paragraphs (2) and (3) are subject to Article 1(3) (exception relating to certain storage containers and pipelines).

(2) Subject to Article 6(1),(2) (transitional provisions) and (4) (labelling requirements), no person may place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food —

(a) any material or article in contravention of Article 3 (prohibition on BFDGE) or Article 4 (prohibition on NOGE); or

(b) any material or article that fails to comply with the restrictions contained in Article 2 as read with Annex I (specific migration limit for BADGE and certain of its derivatives).

(3) Subject to Article 6(3) (transitional provisions relating to materials and articles brought into contact with food before 1st January 2007), no person may place on the market any material or article which fails to comply with the requirements of Article 5 (obligations regarding the provision of a written statement when marketing materials or articles containing BADGE or its derivatives).

(4) Any person who contravenes paragraph (2) or (3) is guilty of an offence.

Competent authorities for the purposes of Regulation 1895/2005

17. The competent authority for the purpose of Article 6(4) (person to whom date of filling must be disclosed) is each food authority in its area and each port health authority in its district.

PART 8

Enforcement

Offences and penalties

18.—(1) Any person who —

(a) contravenes the provisions of regulation 10(3) or (4) or 12(8);

(b) (i) intentionally obstructs any person acting in the execution of Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009, Regulation 10/2011 or these Regulations,

(ii) without reasonable excuse, fails to provide any assistance or information that person may reasonably require, or

(iii) fails to comply with regulation 10(6); or

(c) in purported compliance with any requirement mentioned in sub-paragraph (b), knowingly or recklessly supplies information that is false or misleading in any material particular,

is guilty of an offence.

(2) Any person guilty of an offence under these Regulations is liable —

(a) in the case of an offence mentioned in paragraph (1)(a) or (c) or in regulation 4(3), 5, 7(1), 14(1) or 16(4) —

(i) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both, or

(ii) on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 3 months or both; and

(b) in the case of an offence mentioned in paragraph (1)(b) or in regulation 7(2) or 14(2), on summary conviction to a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 on the standard scale or both.

(3) Nothing in paragraph (1)(b) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate them.

Enforcement

19.—(1) Each food authority in its area and each port health authority in its district shall execute and enforce —

(a) Regulation 1935/2004, Regulation 450/2009, Regulation 1895/2005 and Regulation 10/2011; and

(b) except in relation to the provisions referred to paragraph (3), these Regulations.

(2) The Food Standards Agency may also execute and enforce the provisions of —

(a) Articles 16(1) and 17(2) of Regulation 1935/2004; and

(b) Article 13 of Regulation 450/2009.

(3) Each food authority in its area shall execute and enforce the provisions of Regulation 2023/2006 specified in regulation 5.

Offences by corporate bodies or Scottish partnerships

20.—(1) Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of —

(a) any director, manager, secretary or other similar officer of the body corporate, or

(b) any person purporting to act in such a capacity,

that individual as well as the body corporate shall be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

(2) Where an offence under these Regulations which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a partner, that partner as well as the partnership shall be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

Offences due to the act or default of a third party

21. Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that other person shall be guilty of the offence; and a person may be charged with and convicted of the offence whether or not proceedings are taken against the first mentioned person.

Time limit for prosecutions

22. No prosecution for an offence under these Regulations shall be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.

General defences

23.—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence to prove that the person accused ("the accused") took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by the accused or by a person under the control of the accused.

(2) Without prejudice to the generality of paragraph (1), a person accused of an offence under regulation 4(3), 7(1), 14(1), 16(4) or 18(1)(a) who did not import or prepare the material or article in respect of which the offence is alleged to have been committed shall be taken to have established the defence provided by paragraph (1) if the requirements of paragraphs (3) or (4) are satisfied.

(3) The requirements of this paragraph are satisfied if it is proved that —

(a) the commission of the offence was due to the act or default of some other person who was not under the control of the accused, or to reliance on information supplied by such a person;

(b) either —

(i) the accused carried out all such checks of the material or article in question as were reasonable in all the circumstances, or

(ii) it was reasonable in all the circumstances for the accused to rely on checks carried out by the person who supplied the accused with that material or article; and

(c) the accused did not know and had no reason to suspect at the time the offence was committed that the act or omission would amount to an offence under these Regulations.

(4) The requirements of this paragraph are satisfied if the offence is one of placing on the market and it is proved that —

(a) the commission of the offence was due to the act or default of some other person who was not under the control of the accused, or to reliance on information supplied by such a person;

(b) the placing on the market of which the offence consisted was not done under the name or mark of the accused; and

(c) the accused did not know and could not reasonably be expected to know at the time the offence was committed that the act or omission would amount to an offence under these Regulations.

(5) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the accused shall not without leave of the court be entitled to rely on that defence unless —

(a) at least seven clear days before the hearing; and

(b) where the accused has previously appeared before the court in connection with the alleged offence, within one month of the first such appearance,

the accused has served on the prosecutor a written notice giving such information identifying or assisting in the identification of that other person as was then in the possession of the accused.

Procedure where a sample is to be analysed

24.—(1) An authorised officer who has procured a sample under section 29 of the Act and who considers it should be analysed shall divide the sample into three parts.

(2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.

(3) The authorised officer shall —

(a) if necessary place each part in a suitable container and seal it;

(b) mark each part or container;

(c) as soon as is reasonably practicable, give one part to the owner and notify the owner in writing that the sample will be analysed;

(d) submit one part for analysis in accordance with section 30 of the Act; and

(e) retain one part for future submission under regulation 25.

Secondary analysis by the Government Chemist

25.—(1) Where a sample has been retained under regulation 24 and —

(a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and

(b) the prosecution intends to adduce as evidence the result of the analysis mentioned above,

paragraphs (2) to (7) apply.

(2) The authorised officer —

(a) may of the officer's own volition; or

(b) shall —

(i) if requested by the prosecutor (if a person other than the authorised officer),

(ii) if the court so orders, or

(iii) (subject to paragraph (6)) if requested by the defendant,

send the retained part of the sample to the Government Chemist for analysis.

(3) The Government Chemist shall analyse the part sent under paragraph (2) and send to the authorised officer a certificate specifying the results of the analysis.

(4) Any certificate of the results of analysis transmitted by the Government Chemist shall be signed by or on behalf of the Government Chemist, but the analysis may be carried out by any person under the direction of the person who signs the certificate.

(5) The authorised officer shall immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the defendant with a copy of the Government Chemist's certificate of analysis.

(6) Where a request is made under paragraph (2)(b)(iii) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

(7) In this regulation "defendant" includes a prospective defendant.

Application of various provisions of the Act

26.—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations —

(a) section 2 (extending meaning of "sale" etc);

(b) section 30(8) (which relates to documentary evidence).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the reference to the Act in subsection (1) shall be construed as including a reference to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 or Regulation 10/2011 as appropriate.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act shall be construed as including a reference to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 or Regulation 10/2011, as appropriate, and to these Regulations —

(a) section 3 (presumptions that food intended for human consumption) with the modifications that the references to "sold" and "sale" shall be deemed to include references to "placed on the market" and "placing on the market" respectively;

(b) section 44 (protection of officers acting in good faith).

PART 9

General and supplementary

Consequential amendment to the Food Safety (Sampling and Qualifications) Regulations 1990

27. In the Food Safety (Sampling and Qualifications) Regulations 1990(**a**), in Schedule 1 (provisions to which those Regulations do not apply) —

(a) for the title and reference of the Materials and Articles in Contact with Food (England) Regulations 2010 substitute the title and reference of these Regulations; and

(b) omit the title and reference of the Plastic Materials and Articles in Contact with Food (England) Regulations 2009(**b**).

(**a**) S.I. 1990/2463, amended by S.I. 2007/2790; there are other amending instruments but none is relevant.
(**b**) S.I. 2009/205.

Amendment to the Food Labelling Regulations 1996

28.—(1) The Food Labelling Regulations 1996(**a**) are amended in accordance with paragraph (2).

(2) In regulation 2(1) (interpretation), for the definition of "ingredient" substitute the following definition —

> ""ingredient" means —
>
> (a) any substance, including any additive or food enzyme and any constituent of a compound ingredient, which is used in the preparation of a food and which is still present in the finished product, even if in altered form; or
>
> (b) any released active substance within the meaning of Article 3(f) of Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food,
>
> and a "compound ingredient" shall be composed of two or more such substances;".

Statutory Review

29.—(1) The Food Standards Agency must from time to time —

(a) carry out a review of regulations 1 to 26;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Food Standards Agency must, so far as is reasonable, have regard to how the EU instruments are implemented or executed and enforced in other Member States.

(3) The report must in particular —

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if they do, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

(6) In this regulation "the EU instruments" means Directive 84/500/EEC, Directive 2007/42/EC, Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 and Regulation 10/2011.

Revocations

30. The following Regulations are revoked —

(a) The Ceramic Articles in Contact with Food (England) Regulations 2006(**b**);

(b) The Plastic Materials and Articles in Contact with Food (England) Regulations 2009(**c**);

(c) The Materials and Articles in Contact with Food (England) Regulations 2010(**d**);

(d) The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011(**a**)

(**a**) S.I. 1996/1499. The definition of ingredient was previously amended by S.I. 2009/3235 and S.I. 2010/2225.
(**b**) S.I. 2006/1179, amended by S.I. 2007/2790.
(**c**) S.I. 2009/205, amended by S.I. 2010/2225.
(**d**) S.I. 2010/2225.

Signed by authority of the Secretary of State for Health

Minister's name
Parliamentary Under-Secretary of State
Date Department of Health

SCHEDULE

Regulation 14(1)

Specified provisions of Regulation 10/2011

Specified provision	*Subject matter*
Article 4(e), as read with Articles 17 and 18	Prohibition on placing on the market plastic materials or articles if they do not meet specified compositional and declaration requirements
Article 5(1) and Annex I, as read with Article 6	Requirement to use only authorised substances in the manufacture of plastic layers in plastic materials and articles
Article 8, first sentence	General quality standards that must be observed for substances used in the manufacture of plastic layers in plastic materials and articles
Article 9 as read with Annex I	Particular restrictions and specifications for substances used in the manufacture of plastic layers in plastic materials and articles
Article 10 as read with Annex II	General restrictions on plastic materials and articles
Article 11(1) and (2) and Annex I, as read with Article 11(3)	Specific limits on the degree to which constituents of plastic materials and articles are permitted to migrate into foods
Article 12	Overall limits on the permitted level of migration of the constituents of plastic materials and articles into foods
Article 13(1),(3),(4) and (5) and Annex I as read with Article 13(2)	Particular restrictions and specifications for plastic multi-layered materials and articles
Article 14(1) and (5) and Annex 1, as read with Article 14(2),(3) and (4)	Particular restrictions and specifications for multi-material multi-layered materials and articles
Article 15 and Annex IV	Requirements for written declaration of compliance for plastic materials and articles, for products from the intermediate stages of their manufacture and for substances intended for the manufacture of those materials or articles

(**a**) S.I. 2011/231.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. The Regulations provide for —

(a) ***DN:*** *To be completed after consultation*

2.[A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Food Safety Group of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.]

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 10/2011

of 14 January 2011

on plastic materials and articles intended to come into contact with food

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC [1], and in particular Article 5(1)(a), (c), (d), (e), (f), (h), (i) and (j) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1935/2004 lays down the general principles for eliminating the differences between the laws of the Member States as regards food contact materials. Article 5(1) of that Regulation provides for the adoption of specific measures for groups of materials and articles and describes in detail the procedure for the authorisation of substances at EU level when a specific measure provides for a list of authorised substances.

(2) This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs [2].

(3) Directive 2002/72/EC sets out basic rules for the manufacture of plastic materials and articles. The Directive has been substantially amended 6 times. For reasons of clarity the text should be consolidated and redundant and obsolete parts removed.

(4) In the past Directive 2002/72/EC and its amendments have been transposed into national legislation without any major adaptation. For transposition into national law usually a time period of 12 months is necessary. In case of amending the lists of monomers and additives in order to authorise new substances this transposition time leads to a retardation of the authorisation and thus slows down innovation. Therefore it seems appropriate to adopt rules on plastic materials and articles in form of a Regulation directly applicable in all Member States.

[1] OJ L 338, 13.11.2004, p. 4.

[2] OJ L 220, 15.8.2002, p. 18.

(5) Directive 2002/72/EC applies to materials and articles purely made of plastics and to plastic gaskets in lids. In the past these were the main use of plastics on the market. However, in recent years, besides materials and articles purely made of plastics, plastics are also used in combination with other materials in so called multi-material multi-layers. Rules on the use of vinyl chloride monomer laid down in Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs [1] already apply to all plastics. Therefore it seems appropriate to extend the scope of this Regulation to plastic layers in multi-material multi-layers.

(6) Plastic materials and articles may be composed of different layers of plastics held together by adhesives. Plastic materials and articles may also be printed or coated with an organic or inorganic coating. Printed or coated plastic materials and articles as well as those held together by adhesives should be within the scope of the Regulation. Adhesives, coatings and printing inks are not necessarily composed of the same substances as plastics. Regulation (EC) No 1935/2004 foresees that for adhesives, coatings and printing inks specific measures can be adopted. Therefore plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules.

(7) Plastics as well as ion exchange resins, rubbers and silicones are macromolecular substances obtained by polymerisation processes. Regulation (EC) No 1935/2004 foresees that for ion exchange resins, rubbers and silicones specific measures can be adopted. As those materials are composed of different substances than plastics and have different physico-chemical properties specific rules for them need to apply and it should be made clear that they are not within the scope of this Regulation.

(8) Plastics are made of monomers and other starting substances which are chemically reacted to a macromolecular structure, the polymer, which forms the main structural component of the plastics. To the polymer additives are added to achieve defined technological effects. The polymer as such is an inert high molecular weight structure. As substances with a molecular weight above 1 000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal. Potential health risk may occur from non- or incompletely reacted monomers or other starting substances or from low molecular weight additives which are transferred into food via migration from the plastic food contact material. Therefore monomers, other starting substances and additives should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.

(9) The risk assessment of a substance to be performed by the European Food Safety Authority (hereinafter the Authority) should cover the substance itself, relevant impurities and foreseeable reaction and degradation products in the intended use. The risk assessment should cover the potential migration under worst foreseeable conditions of use and the toxicity. Based on the risk assessment the authorisation should if necessary set out specifications for the substance and restrictions of use, quantitative restrictions or migration limits to ensure the safety of the final material or article.

(10) No rules have yet been set out at EU level for the risk assessment and use of colorants in plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.

(11) Solvents used in the manufacture of plastics to create a suitable reaction environment are expected to be removed in the manufacturing process as they are usually volatile. No rules have yet been set out at EU level for the risk assessment and use of solvents in the manufacture of plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.

(12) Plastics can also be made of synthetic or natural occurring macromolecular structures which are chemically reacted with other starting substances to create a modified macromolecule. Synthetic macromolecules used are often intermediate structures which are not fully polymerised. Potential health risk may occur from the migration of non- or incompletely reacted other starting substances used to modify the macromolecule or an incompletely reacted macromolecule. Therefore the other starting substances as well as the macromolecules used in the manufacture of modified macromolecules should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.

[1] OJ L 44, 15.2.1978, p. 15.

(13) Plastics can also be made by micro-organisms that create macromolecular structures out of starting substances by fermentation processes. The macromolecule is then either released to a medium or extracted. Potential health risk may occur from the migration of non- or incompletely reacted starting substances, intermediates or by-products of the fermentation process. In this case the final product should be risk assessed and authorised before its use in the manufacture of plastic materials and articles.

(14) Directive 2002/72/EC contains different lists for monomers or other starting substances and for additives authorised for the manufacture of plastic materials and articles. For monomers, other starting substances and additives the Union list is now complete, this means that only substances authorised at EU level may be used. Therefore a separation of monomers or other starting substances and of additives in separate lists due to their authorisation status is no longer necessary. As certain substances can be used both as monomer or other starting substances and as additive for reasons of clarity they should be published in one list of authorised substances indicating the authorised function.

(15) Polymers can not only be used as main structural component of plastics but also as additives achieving defined technological effects in the plastic. If such a polymeric additive is identical to a polymer that can form the main structural component of a plastic material the risk from polymeric additive can be regarded as evaluated if the monomers have already been evaluated and authorised. In such a case it should not be necessary to authorise the polymeric additive but it could be used on the basis of the authorisation of its monomers and other starting substances. If such a polymeric additive is not identical to a polymer that can form the main structural component of a plastic material then the risk of the polymeric additive can not be regarded as evaluated by evaluation of the monomers. In such a case the polymeric additive should be risk assessed as regards its low molecular weight fraction below 1 000 Da and authorised before its use in the manufacture of plastic materials and articles.

(16) In the past no clear differentiation has been made between additives that have a function in the final polymer and polymer production aids (PPA) that only exhibit a function in the manufacturing process and are not intended to be present in the final article. Some substances acting as PPA had already been included in the incomplete list of additives in the past. These PPA should remain in the Union list of authorised substances. However, it should be made clear that the use of other PPA will remain possible, subject to national law. That situation should be reassessed at a later stage.

(17) The Union list contains substances authorised to be used in the manufacture of plastics. Substances such as acids, alcohols and phenols can also occur in form of salts. As the salts usually are transformed in the stomach to acid, alcohol or phenol the use of salts with cations that have undergone a safety evaluation should in principle be authorised together with the acid, alcohol or phenol. In certain cases, where the safety assessment indicates concerns on the use of the free acids, only the salts should be authorised by indicating in the list the name as '… acid(s), salts'.

(18) Substances used in the manufacture of plastic materials or articles may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added together with the substance in the manufacture of the plastic material (non-intentionally added substance – NIAS). As far as they are relevant for the risk assessment the main impurities of a substance should be considered and if necessary be included in the specifications of a substance. However it is not possible to list and consider all impurities in the authorisation. Therefore they may be present in the material or article but not included in the Union list.

(19) In the manufacture of polymers substances are used to initiate the polymerisation reaction such as catalysts and to control the polymerisation reaction such as chain transfer, chain extending or chain stop reagents. These aids to polymerisation are used in minute amounts and are not intended to remain in the final polymer. Therefore they should at this point of time not be subject to the authorisation procedure at EU level. Any potential health risk in the final material or article arising from their use should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.

(20) During the manufacture and use of plastic materials and articles reaction and degradation products can be formed. These reaction and degradation products are non-intentionally present in the plastic material (NIAS). As far as they are relevant for the risk assessment the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance. However it is not possible to list and consider all reaction and degradation products in the authorisation. Therefore they should not be listed as single entries in the Union list. Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.

(21) Prior to the establishment of the Union list of additives, other additives than those authorised at EU level could be used in the manufacture of plastics. For those additives which were permitted in the Member States, the time limit for the submission of data for their safety evaluation by the Authority with a view to their inclusion in the Union list expired on 31 December 2006. Additives for which a valid application was submitted within this time limit were listed in a provisional list. For certain additives on the provisional list a decision on their authorisation at EU level has not yet been taken. For those additives, it should be possible to continue to be used in accordance with national law until their evaluation is completed and a decision is taken on their inclusion in the Union list.

(22) When an additive included in the provisional list is inserted in the Union list or when it is decided not to include it in the Union list, that additive should be removed from the provisional list of additives.

(23) New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.

(24) Based on the risk assessment the authorisation should if necessary set out specific migration limits to ensure the safety of the final material or article. If an additive that is authorised for the manufacture of plastic materials and articles is at the same time authorised as food additive or flavouring substance it should be ensured that the release of the substance does not change the composition of the food in an unacceptable way. Therefore the release of such a dual use additive or flavouring should not exhibit a technological function on the food unless such a function is intended and the food contact material complies with the requirements on active food contact materials set out in Regulation (EC) No 1935/2004 and Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food ([1]). The requirements of Regulations (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ([2]) or (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ([3]) should be respected where applicable.

(25) According to Article 3(1)(b) of Regulation (EC) No 1935/2004 the release of substances from food contact materials and articles should not bring about unacceptable changes in the composition of the food. According to good manufacturing practice it is feasible to manufacture plastic materials in such a way that they are not releasing more than 10 mg of substances per 1 dm^2 of surface area of the plastic material. If the risk assessment of an individual substance is not indicating a lower level, this level should be set as a generic limit for the inertness of a plastic material, the overall migration limit. In order to achieve comparable results in the verification of compliance with the overall migration limit, testing should be performed under standardised test conditions including testing time, temperature and test medium (food simulant) representing worst foreseeable conditions of use of the plastic material or article.

(26) The overall migration limit of 10 mg per 1 dm^2 results for a cubic packaging containing 1kg of food to a migration of 60 mg per kg food. For small packaging where the surface to volume ratio is higher the resulting migration into food is higher. For infants and small children which have a higher consumption of food per kilogram bodyweight than adults and do not yet have a diversified nutrition, special provisions should be set in order to limit the intake of substances migrating from food contact materials. In order to allow also for small volume packaging the same protection as for high volume packaging, the overall migration limit for food contact materials that are dedicated for packaging foods for infants and small children should be linked to the limit in food and not to the surface area of the packaging.

(27) In recent years plastic food contact materials are being developed that do not only consist of one plastic but combine up to 15 different plastic layers to attain optimum functionality and protection of the food, while reducing packaging waste. In such a plastic multi-layer material or article, layers may be separated from the food by a functional barrier. This barrier is a layer within food contact materials or articles preventing the migration of substances from behind that barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided

([1]) OJ L 135, 30.5.2009, p. 3.
([2]) OJ L 354, 31.12.2008, p. 16.
([3]) OJ L 354, 31.12.2008, p. 34.

they fulfil certain criteria and their migration remains below a given detection limit. Taking into account foods for infants and other particularly susceptible persons, as well as the large analytical tolerance of the migration analysis, a maximum level of 0,01 mg/kg in food should be established for the migration of a non-authorised substance through a functional barrier. Substances that are mutagenic, carcinogenic or toxic to reproduction should not be used in food contact materials or articles without previous authorisation and should therefore not be covered by the functional barrier concept. New technologies that engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles, should be assessed on a case-by-case basis as regards their risk until more information is known about such new technology. Therefore, they should not be covered by the functional barrier concept.

(28) In recent years food contact materials and articles are being developed that consist of a combination of several materials to achieve optimum functionality and protection of the food while reducing packaging waste. In these multi-material multi-layer materials and articles plastic layers should comply with the same compositional requirements as plastic layers which are not combined with other materials. For plastic layers in a multi-material multi-layer which are separated from the food by a functional barrier the functional barrier concept should apply. As other materials are combined with the plastic layers and for these other materials specific measures are not yet adopted at EU level it is not yet possible to set out requirements for the final multi-material multi-layer materials and articles. Therefore specific migration limits and the overall migration limit should not be applicable except for vinyl chloride monomer for which such a restriction is already in place. In the absence of a specific measure at EU level covering the whole multi-material multi-layer material or article Member States may maintain or adopt national provisions for these materials and articles provided they comply with the rules of the Treaty.

(29) Article 16(1) of Regulation (EC) No 1935/2004 provides that materials and articles covered by specific measures be accompanied by a written declaration of compliance stating that they comply with the rules applicable to them. To strengthen the coordination and responsibility of the suppliers at each stage of manufacture, including that of the starting substances, the responsible persons should document the compliance with the relevant rules in a declaration of compliance which is made available to their customers.

(30) Coatings, printing inks and adhesives are not yet covered by a specific EU legislation and therefore not subject to the requirement of a declaration of compliance. However, for coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in this Regulation.

(31) Article 17(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1] requires the food business operator to verify that foods are compliant with the rules applicable to them. To this end and subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration from the materials and articles to food complies with the specifications and restrictions laid down in food legislation.

(32) At each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing. Test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.

(33) When testing articles not yet in contact with food, for certain articles, such as films or lids, it is often not feasible to determine the surface area that is in contact with a defined volume of food. For these articles specific rules should be set out for verification of compliance.

(34) The setting of migration limits takes into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm^2 surface area releasing the substance. For very small and very large containers the real surface area to volume of packaged food is varying a lot from the conventional assumption. Therefore, their surface area should be normalised before comparing testing results with migration limits. These rules should be reviewed when new data on food packaging uses become available.

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

(35) The specific migration limit is a maximum permitted amount of a substance in food. This limit should ensure that the food contact material does not pose a risk to health. It should be ensured by the manufacturer that materials and articles not yet in contact with food will respect these limits when brought into contact with food under the worst foreseeable contact conditions. Therefore compliance of materials and articles not yet in contact with food should be assessed and the rules for this testing should be set out.

(36) Food is a complex matrix and therefore the analysis of migrating substances in food may pose analytical difficulties. Therefore test media should be assigned that simulate the transfer of substances from the plastic material into food. They should represent the major physico-chemical properties exhibited by food. When using food simulants standard testing time and temperature should reproduce, as far as possible, the migration which may occur from the article into the food.

(37) For determining the appropriate food simulant for certain foods the chemical composition and the physical properties of the food should be taken into account. Research results are available for certain representative foods comparing migration into food with migration into food simulants. On the basis of the results, food simulants should be assigned. In particular, for fat containing foods the result obtained with food simulant may in certain cases significantly overestimate migration into food. In these cases it should be foreseen that the result in food simulant is corrected by a reduction factor.

(38) The exposure to substances migrating from food contact materials was based on the conventional assumption that a person consumes daily 1 kg of food. However, a person ingests at most 200 g of fat on a daily basis. For lipophilic substances that only migrate into fat this should be taken into consideration. Therefore a correction of the specific migration by a correction factor applicable to lipophilic substances in accordance with the opinion of the Scientific Committee on Food (SCF) [1] and the opinion of the Authority [2] should be foreseen.

(39) Official control should establish testing strategies which allow the enforcement authorities to perform controls efficiently making best use of available resources. Therefore it should be admissible to use screening methods for checking compliance under certain conditions. Non-compliance of a material or article should be confirmed by a verification method.

(40) Basic rules on migration testing should be set out in this Regulation. As migration testing is a very complex issue, these basic rules can, however, not cover all foreseeable cases and details necessary for performing the testing. Therefore a EU guidance document should be established, dealing with more detailed aspects of the implementation of the basic migration testing rules.

(41) The updated rules on food simulants and migration testing provided by this Regulation will supersede those in Directive 78/142/EEC and the Annex to Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs [3].

(42) Substances present in the plastic but not listed in Annex I to this Regulation have not necessarily been risk assessed as they had not been subject to an authorisation procedure. Compliance with Article 3 of Regulation (EC) No 1935/2004 for these substances should be assessed by the relevant business operator in accordance with internationally recognised scientific principles taking into account exposure from food contact materials and other sources.

(43) Recently additional monomers, other starting substances and additives have received a favourable scientific evaluation by the Authority and should now be added to the Union list.

(44) As new substances are added to the Union list the Regulation should apply as soon as possible to allow for manufacturers to adapt to technical progress and allow for innovation.

(45) Certain migration testing rules should be updated in view of new scientific knowledge. Enforcement authorities and industry need to adapt their current testing regime to these updated rules. To allow for this adaptation it seems appropriate that the updated rules only apply 2 years after the adoption of the Regulation.

[1] SCF opinion of 4 December 2002 on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials.
http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf

[2] Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the introduction of a Fat (consumption) Reduction Factor for infants and children, The EFSA Journal (2004) 103, 1-8.

[3] OJ L 297, 23.10.1982, p. 26.

(46) Business operators are currently basing their declaration of compliance on supporting documentation following the requirements set out in Directive 2002/72/EC. Declaration of compliance need, in principle, only to be updated when substantial changes in the production bring about changes in the migration or when new scientific data are available. In order to limit the burden to business operators, materials which have been lawfully placed on the market based on the requirements set out in Directive 2002/72/EC should be able to be placed on the market with a declaration of compliance based on supporting documentation in accordance with Directive 2002/72/EC until 5 years after the adoption of the Regulation.

(47) Analytical methods for testing migration and residual content of vinyl chloride monomer as described in Commission Directives 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs [1] and 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs [2] are outdated. Analytical methods should comply with the criteria set out in Article 11 of Regulation (EC) No 882/2004 [3] of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Therefore Directives 80/766/EEC and 81/432/EEC should be repealed.

(48) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.

2. This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles:

(a) intended to come into contact with food; or

(b) already in contact with food; or

(c) which can reasonably be expected to come into contact with food.

Article 2

Scope

1. This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:

(a) materials and articles and parts thereof consisting exclusively of plastics;

(b) plastic multi-layer materials and articles held together by adhesives or by other means;

(c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;

(d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;

(e) plastic layers in multi-material multi-layer materials and articles.

2. This Regulation shall not apply to the following materials and articles which are placed on the EU market and are intended to be covered by other specific measures:

(a) ion exchange resins;

(b) rubber;

(c) silicones.

3. This Regulation shall be without prejudice to the EU or national provisions applicable to printing inks, adhesives or coatings.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(1) 'plastic materials and articles' means:

(a) materials and articles referred to in points (a), (b) and (c) of Article 2(1); and

(b) plastic layers referred to in Article 2(1)(d) and (e);

[1] OJ L 213, 16.8.1980, p. 42.
[2] OJ L 167, 24.6.1981, p. 6.
[3] OJ L 165, 30.4.2004, p. 1.

(2) 'plastic' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;

(3) 'polymer' means any macromolecular substance obtained by:

(a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or

(b) chemical modification of natural or synthetic macromolecules; or

(c) microbial fermentation;

(4) 'plastic multi-layer' means a material or article composed of two or more layers of plastic;

(5) 'multi-material multi-layer' means a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer;

(6) 'monomer or other starting substance' means:

(a) a substance undergoing any type of polymerisation process to manufacture polymers; or

(b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or

(c) a substance used to modify existing natural or synthetic macromolecules;

(7) 'additive' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;

(8) 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;

(9) 'non-intentionally added substance' means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product;

(10) 'aid to polymerisation' means a substance which initiates polymerisation and/or controls the formation of the macromolecular structure;

(11) 'overall migration limit' (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants;

(12) 'food simulant' means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;

(13) 'specific migration limit' (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;

(14) 'total specific migration limit' (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;

(15) 'functional barrier' means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation;

(16) 'non-fatty food' means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex V to this Regulation;

(17) 'restriction' means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;

(18) 'specification' means composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits.

Article 4

Placing on the market of plastic materials and articles

Plastic materials and articles may only be placed on the market if they:

(a) comply with the relevant requirements set out in Article 3 of Regulation (EC) No 1935/2004 under intended and foreseeable use; and

(b) comply with the labelling requirements set out in Article 15 of Regulation (EC) No 1935/2004; and

(c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and

(d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006 [1]; and

(e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

CHAPTER II

COMPOSITIONAL REQUIREMENTS

SECTION 1

Authorised substances

Article 5

Union list of authorised substances

1. Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

2. The Union list shall contain:

(a) monomers or other starting substances;

(b) additives excluding colorants;

(c) polymer production aids excluding solvents;

(d) macromolecules obtained from microbial fermentation.

3. The Union list may be amended in accordance with the procedure established by Articles 8 to 12 of Regulation (EC) No 1935/2004.

Article 6

Derogations for substances not included in the Union list

1. By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to national law.

2. By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

3. The following substances not included in the Union list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:

(a) salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;

(b) mixtures obtained by mixing authorised substances without a chemical reaction of the components;

(c) when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, except macromolecules obtained from microbial fermentation, complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;

(d) when used as monomer or other starting substance, prepolymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the Union list.

4. The following substances not included in the Union list may be present in the plastic layers of plastic materials or articles:

(a) non-intentionally added substances;

(b) aids to polymerisation.

5. By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

Article 7

Establishment and management of the provisional list

1. The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.

2. An additive shall be removed from the provisional list:

(a) when it is included in the Union list set out in Annex I; or

(b) when a decision is taken by the Commission not to include it in the Union list; or

(c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

[1] OJ L 384, 29.12.2006, p. 75.

SECTION 2

General requirements, restrictions and specifications

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

Article 9

Specific requirements on substances

1. Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:

(a) the specific migration limit set out in Article 11;

(b) the overall migration limit set out in Article 12;

(c) the restrictions and specifications set out in column 10 of Table 1 of point 1 of Annex I;

(d) the detailed specifications set out in point 4 of Annex I.

2. Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I.

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

Article 11

Specific migration limits

1. Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

2. For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply.

3. By derogation from paragraphs 1 and 2, additives which are also authorised as food additives by Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008 shall not migrate into foods in quantities having a technical effect in the final foods and shall not:

(a) exceed the restrictions provided for in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I to this Regulation for foods for which their use is authorised as food additive or flavouring substances; or

(b) exceed the restrictions set out in Annex I to this Regulation in foods for which their use is not authorised as food additive or flavouring substances.

Article 12

Overall migration limit

1. Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2).

2. By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC [1] and 2006/125/EC [2], shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

CHAPTER III

SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

Article 13

Plastic multi-layer materials and articles

1. In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2. By derogation from paragraph 1, a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may:

(a) not comply with the restrictions and specifications set out in this Regulation except for vinyl chloride monomer as provided in Annex I; and/or

(b) be manufactured with substances not listed in the Union list or in the provisional list.

[1] OJ L 401, 30.12.2006, p. 1.
[2] OJ L 339, 6.12.2006, p. 16.

3. The migration of the substances under paragraph 2(b) into food or food simulant shall not be detectable measured with statistical certainty by a method of analysis set out in Article 11 of Regulation (EC) No 882/2004 with a limit of detection of 0,01 mg/kg. That limit shall always be expressed as concentration in foods or food simulants. That limit shall apply to a group of compounds, if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.

4. The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:

(a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council [1];

(b) substances in nanoform.

5. The final plastic multi-layer material or article shall comply with the specific migration limits set out in Article 11 and the overall migration limit set out in Article 12 of this Regulation.

Article 14

Multi-material multi-layer materials and articles

1. In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2. By derogation from paragraph 1, in a multi-material multi-layer material or article a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances not listed in the Union list or the provisional list.

3. The substances not listed in the Union list or provisional list referred to in paragraph 2 shall not belong to either of the following categories:

(a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008;

(b) substances in nanoform.

[1] OJ L 353, 31.12.2008, p. 1.

4. By derogation from paragraph 1, Articles 11 and 12 of this Regulation do not apply to plastic layers in multi-material multi-layer materials and articles.

5. The plastic layers in a multi-material multi-layer material or article shall always comply with the restrictions for vinyl chloride monomer laid down in Annex I to this Regulation.

6. In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.

CHAPTER IV

DECLARATION OF COMPLIANCE AND DOCUMENTATION

Article 15

Declaration of compliance

1. At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

2. The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.

3. The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

Article 16

Supporting documents

1. Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.

2. That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

CHAPTER V

COMPLIANCE

Article 17

Expression of migration test results

1. To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2. By derogation from paragraph 1 for:

(a) containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,

(b) materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,

(c) sheets and films that are not yet in contact with food,

(d) sheets and films containing less than 500 millilitres or grams or more than 10 litres,

the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm^2 per kg of food.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.

3. By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:

(a) mg/kg using the actual content of the container for which the closure is intended or in mg/dm^2 applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2;

(b) mg/article if the intended use of the article is unknown.

4. For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:

(a) mg/dm^2 applying the total contact surface of sealing article and sealed container if the intended use of the article is known;

(b) mg/article if the intended use of the article is unknown.

Article 18

Rules for assessing compliance with migration limits

1. For materials and articles already in contact with food verification of compliance with specific migration limits shall be carried out in accordance with the rules set out in Chapter 1 of Annex V.

2. For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V.

3. For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2.

4. For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants A, B, C, D1 and D2 as set out in Annex III in accordance with the rules set out in Chapter 3, Section 3.1 of Annex V.

5. For materials and articles not yet in contact with food screening of compliance with the overall migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 3, Section 3.4 of Annex V. If a material or article fails to comply with the migration limit in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 4.

6. The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

7. Before comparing specific and overall migration test results with the migration limits the correction factors in Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

CHAPTER VI

FINAL PROVISIONS

Article 20

Amendments of EU acts

The Annex to Council Directive 85/572/EEC [1] is replaced by the following:

'The food simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with a single food or specific groups of foods are set out in point 3 of Annex III to Commission Regulation (EU) No 10/2011.'

Article 21

Repeal of EU acts

Directives 80/766/EEC, 81/432/EEC, and 2002/72/EC are hereby repealed with effect from 1 May 2011.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation tables in Annex VI.

Article 22

Transitional provisions

1. Until 31 December 2012 the supporting documents referred to in Article 16 shall be based on the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

2. As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:

(a) the rules for migration testing set out in Article 18 of this Regulation; or

(b) the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

3. As from 1 January 2016, the supporting documents referred to in Article 16 shall be based on the rules for migration testing set out in Article 18, without prejudice to paragraph 2 of this Article.

4. Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.

5. Materials and articles that have been lawfully placed on the market before 1 May 2011 may be placed on the market until 31 December 2012.

Article 23

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2011.

The provision of Article 5 as regards the use of additives, others than plasticisers, shall apply for plastic layers or plastic coatings in caps and closures referred to in Article 2(1)(d), as from 31 December 2015.

The provision of Article 5 as regards the use of additives used in glass fibre sizing for glass fibre reinforced plastics, shall apply from 31 December 2015.

The provisions of Articles 18(2), 18(4) and 20 shall apply from 31 December 2012.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 14 January 2011.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 372, 31.12.1985, p. 14.

ANNEX I

Substances

1. **Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids**

Table 1 contains the following information:

Column 1 (FCM substance No): the unique identification number of the substance

Column 2 (Ref. No): the EEC packaging material reference number

Column 3 (CAS No): the Chemical Abstracts Service (CAS) registry number

Column 4 (Substance Name): the chemical name

Column 5 (Use as additive or polymer production aid (PPA) (yes/no)): an indication if the substance is authorised to be used as additive or polymer production aid (yes) or if the substance is not authorised to be used as additive or polymer production aid (no). If the substance is only authorised as PPA it is indicated (yes) and in the specifications the use is restricted to PPA.

Column 6 (Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)): an indication if the substance is authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes) or if the substance is not authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (no). If the substance is authorised as macromolecule obtained from microbial fermentation it is indicated (yes) and in the specifications it is indicated that the substance is a macromolecule obtained from microbial fermentation.

Column 7 (FRF applicable (yes/no)): an indication if for the substance the migration results can be corrected by the Fat Consumption Reduction Factor (FRF) (yes) or if they cannot be corrected by the FRF (no).

Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column 9 (SML(T) [mg/kg] (group restriction No)): contains the identification number of the group of substances for which the group restriction in Column 1 in Table 2 of this Annex applies.

Column 10 (Restrictions and specifications): contains other restrictions than the specific migration limit specifically mentioned and it contains specifications related to the substance. In case detailed specifications are set out a reference to Table 4 is included.

Column 11 (Notes on verification of compliance): contains the Notes number which refers to the detailed rules applicable for verification of compliance for this substance included in Column 1 in Table 3 of this Annex.

If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

If in Column 8 the specific migration limit is non-detectable (ND) a detection limit of 0,01 mg substance per kg food is applicable unless specified differently for an individual substance.

Table 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
1	12310	0266309-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C_5-C_{15})acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C_7-C_{17}), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		
9	30610	—	acids, C_2-C_{24}, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occuring levels are included)	yes	no	no				
10	30612	—	acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
11	30960	—	acids, aliphatic, monocarboxylic (C_6-C_{22}), esters with polyglycerol	yes	no	no				
12	31328	—	acids, fatty, from animal or vegetable food fats and oils	yes	no	no				
13	33120	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{24})	yes	no	no				
14	33801	—	n-alkyl(C_{10}-C_{13}) benzenesulphonic acid	yes	no	no	30			
15	34130	—	alkyl, linear with even number of carbon atoms (C_{12}-C_{20}) dimethylamines	yes	no	yes	30			
16	34230	—	alkyl(C_8-C_{22})sulphonic acids	yes	no	no	6			
17	34281	—	alkyl(C_8-C_{22})sulphuric acids, linear, primary with an even number of carbon atoms	yes	no	no				
18	34475	—	aluminium calcium hydroxide phosphite, hydrate	yes	no	no				
19	39090	—	N,N-bis(2-hydroxyethyl)alkyl (C_8-C_{18})amine	yes	no	no		(7)		
20	39120	—	N,N-bis(2-hydroxyethyl)alkyl (C_8-C_{18})amine hydrochlorides	yes	no	no		(7)	SML(T) expressed excluding HCl	
21	42500	—	carbonic acid, salts	yes	no	no				
22	43200	—	castor oil, mono- and diglycerides	yes	no	no				
23	43515	—	chlorides of choline esters of coconut oil fatty acids	yes	no	no	0,9			(1)
24	45280	—	cotton fibers	yes	no	no				
25	45440	—	cresols, butylated, styrenated	yes	no	no	12			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
26	46700	—	5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w)	yes	no	no	5			
27	48960	—	9,10-dihydroxy stearic acid and its oligomers	yes	no	no	5			
28	50160	—	di-n-octyltin bis(n-alkyl(C_{10}-C_{16}) mercaptoacetate)	yes	no	no		(10)		
29	50360	—	di-n-octyltin bis(ethyl maleate)	yes	no	no		(10)		
30	50560	—	di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	yes	no	no		(10)		
31	50800	—	di-n-octyltin dimaleate, esterified	yes	no	no		(10)		
32	50880	—	di-n-octyltin dimaleate, polymers (n = 2-4)	yes	no	no		(10)		
33	51120	—	di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	yes	no	no		(10)		
34	54270	—	ethylhydroxymethylcellulose	yes	no	no				
35	54280	—	ethylhydroxypropylcellulose	yes	no	no				
36	54450	—	fats and oils, from animal or vegetable food sources	yes	no	no				
37	54480	—	fats and oils, hydrogenated, from animal or vegetable food sources	yes	no	no				
38	55520	—	glass fibers	yes	no	no				
39	55600	—	glass microballs	yes	no	no				
40	56360	—	glycerol, esters with acetic acid	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
41	56486	—	glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C_{14}-C_{18}) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C_{16}-C_{18})	yes	no	no				
42	56487	—	glycerol, esters with butyric acid	yes	no	no				
43	56490	—	glycerol, esters with erucic acid	yes	no	no				
44	56495	—	glycerol, esters with 12-hydroxystearic acid	yes	no	no				
45	56500	—	glycerol, esters with lauric acid	yes	no	no				
46	56510	—	glycerol, esters with linoleic acid	yes	no	no				
47	56520	—	glycerol, esters with myristic acid	yes	no	no				
48	56535	—	glycerol, esters with nonanoic acid	yes	no	no				
49	56540	—	glycerol, esters with oleic acid	yes	no	no				
50	56550	—	glycerol, esters with palmitic acid	yes	no	no				
51	56570	—	glycerol, esters with propionic acid	yes	no	no				
52	56580	—	glycerol, esters with ricinoleic acid	yes	no	no				
53	56585	—	glycerol, esters with stearic acid	yes	no	no				
54	57040	—	glycerol monooleate, ester with ascorbic acid	yes	no	no				
55	57120	—	glycerol monooleate, ester with citric acid	yes	no	no				
56	57200	—	glycerol monopalmitate, ester with ascorbic acid	yes	no	no				
57	57280	—	glycerol monopalmitate, ester with citric acid	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
58	57600	—	glycerol monostearate, ester with ascorbic acid	yes	no	no				
59	57680	—	glycerol monostearate, ester with citric acid	yes	no	no				
60	58300	—	glycine, salts	yes	no	no				
62	64500	—	lysine, salts	yes	no	no				
63	65440	—	manganese pyrophosphite	yes	no	no				
64	66695	—	methylhydroxymethylcellulose	yes	no	no				
65	67155	—	mixture of 4-(2-benzoxazolyl)-4′-(5-methyl-2-benzoxazolyl) stilbene, 4,4′-bis (2-benzoxazolyl) stilbene and 4,4′-bis(5-methyl-2-benzoxazolyl)stilbene	yes	no	no			Not more than 0,05 % (w/w) (quantity of substance used/quantity of the formulation). Mixture obtained from the manufacturing process in the typical ratio of (58-62 %):(23-27 %):(13-17 %).	
66	67600	—	mono-n-octyltin tris(alkyl (C_{10}-C_{16}) mercaptoacetate)	yes	no	no		(11)		
67	67840	—	montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	yes	no	no				
68	73160	—	phosphoric acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters	yes	no	yes	0,05			
69	74400	—	phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	yes	no	yes	30			
70	76463	—	polyacrylic acid, salts	yes	no	no		(22)		
71	76730	—	polydimethylsiloxane, γ-hydroxypropylated	yes	no	no	6			
72	76815	—	polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C_{12}-C_{22} fatty acids	yes	no	no		(32)	The fraction with molecular weight below 1 000 Da should not exceed 5 % (w/w)	
73	76866	—	polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol	yes	no	yes		(31) (32)		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
74	77440	—	polyethyleneglycol diricinoleate	yes	no	yes	42			
75	77702	—	polyethyleneglycol esters of aliph. monocarb. acids (C_6-C_{22}) and their ammonium and sodium sulphates	yes	no	no				
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	yes	no	no	0,05		Only for use in PET	
77	77733	—	polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	yes	no	no	0,05		Only for use in PET	
78	77897	—	polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C_8-C_{20}) sulphate, salts	yes	no	no	5			
79	80640	—	polyoxyalkyl (C_2-C_4) dimethylpolysiloxane	yes	no	no				
80	81760	—	powders, flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron	yes	no	no				
81	83320	—	propylhydroxyethylcellulose	yes	no	no				
82	83325	—	propylhydroxymethylcellulose	yes	no	no				
83	83330	—	propylhydroxypropylcellulose	yes	no	no				
84	85601	—	silicates, natural (with the exception of asbestos)	yes	no	no				
85	85610	—	silicates, natural, silanated (with the exception of asbestos)	yes	no	no				
86	86000	—	silicic acid, silylated	yes	no	no				
87	86285	—	silicon dioxide, silanated	yes	no	no				
88	86880	—	sodium monoalkyl dialkylphenoxybenzenedisulphonate	yes	no	no	9			
89	89440	—	stearic acid, esters with ethyleneglycol	yes	no	no		(2)		
90	92195	—	taurine, salts	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
91	92320	—	tetradecyl-polyethyleneglycol (EO = 3-8) ether of glycolic acid	yes	no	yes	15			
92	93970	—	tricyclodecanedimethanol bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not less than 2,5 cSt ($2,5 \times 10^{-6}$ m^2/s). Content of hydrocarbons with Carbon number less than 25, not more than 40 % (w/w).	
94	95859	—	waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity	yes	no	no			Average molecular weight not less than 500 Da. Viscosity at 100 °C not less than 11 cSt (11×10^{-6} m^2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).	
95	95883	—	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	yes	no	no			Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt ($8,5 \times 10^{-6}$ m^2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).	
96	95920	—	wood flour and fibers, untreated	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
97	72081/10	—	petroleum hydrocarbon resins (hydrogenated)	yes	no	no			Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. Properties: — Viscosity at 120 °C: > 3 Pa.s, — Softening point: > 95 °C as determined by ASTM Method E 28-67, — Bromine number: < 40 (ASTM D1159), — The colour of a 50 % solution in toluene < 11 on the Gardner scale, — Residual aromatic monomer ≤ 50 ppm,	
98	17260 54880	0000050-00-0	formaldehyde	yes	yes	no		(15)		
99	19460 62960	0000050-21-5	lactic acid	yes	yes	no				
100	24490 88320	0000050-70-4	sorbitol	yes	yes	no				
101	36000	0000050-81-7	ascorbic acid	yes	no	no				
102	17530	0000050-99-7	glucose	no	yes	no				
103	18100 55920	0000056-81-5	glycerol	yes	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
104	58960	0000057-09-0	hexadecyltrimethylammonium bromide	yes	no	no	6			
105	22780	0000057-10-3	palmitic acid	yes	yes	no				
	70400									
106	24550	0000057-11-4	stearic acid	yes	yes	no				
	89040									
107	25960	0000057-13-6	urea	no	yes	no				
108	24880	0000057-50-1	sucrose	no	yes	no				
109	23740	0000057-55-6	1,2-propanediol	yes	yes	no				
	81840									
110	93520	0000059-02-9 0010191-41-0	α-tocopherol	yes	no	no				
111	53600	0000060-00-4	ethylenediaminetetraacetic acid	yes	no	no				
112	64015	0000060-33-3	linoleic acid	yes	no	no				
113	16780	0000064-17-5	ethanol	yes	yes	no				
	52800									
114	55040	0000064-18-6	formic acid	yes	no	no				
115	10090	0000064-19-7	acetic acid	yes	yes	no				
	30000									
116	13090	0000065-85-0	benzoic acid	yes	yes	no				
	37600									
117	21550	0000067-56-1	methanol	no	yes	no				
118	23830	0000067-63-0	2-propanol	yes	yes	no				
	81882									
119	30295	0000067-64-1	acetone	yes	no	no				
120	49540	0000067-68-5	dimethyl sulphoxide	yes	no	no				
121	24270	0000069-72-7	salicylic acid	yes	yes	no				
	84640									
122	23800	0000071-23-8	1-propanol	no	yes	no				
123	13840	0000071-36-3	1-butanol	no	yes	no				
124	22870	0000071-41-0	1-pentanol	no	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
125	16950	0000074-85-1	ethylene	no	yes	no				
126	10210	0000074-86-2	acetylene	no	yes	no				
127	26050	0000075-01-4	vinyl chloride	no	yes	no	ND		1 mg/kg in final product	
128	10060	0000075-07-0	acetaldehyde	no	yes	no		(1)		
129	17020	0000075-21-8	ethylene oxide	no	yes	no	ND		1 mg/kg in final product	(10)
130	26110	0000075-35-4	vinylidene chloride	no	yes	no	ND			(1)
131	48460	0000075-37-6	1,1-difluoroethane	yes	no	no				
132	26140	0000075-38-7	vinylidene fluoride	no	yes	no	5			
133	14380	0000075-44-5	carbonyl chloride	no	yes	no	ND		1 mg/kg in final product	(10)
	23155									
134	43680	0000075-45-6	chlorodifluoromethane	yes	no	no	6		Content of chlorofluoromethane less than 1 mg/kg of the substance	
135	24010	0000075-56-9	propylene oxide	no	yes	no	ND		1 mg/kg in final product	
136	41680	0000076-22-2	camphor	yes	no	no				(3)
137	66580	0000077-62-3	2,2′-methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	yes	no	yes		(5)		
138	93760	0000077-90-7	tri-n-butyl acetyl citrate	yes	no	no		(32)		
139	14680	0000077-92-9	citric acid	yes	yes	no				
	44160									
140	44640	0000077-93-0	citric acid, triethyl ester	yes	no	no		(32)		
141	13380	0000077-99-6	1,1,1-trimethylolpropane	yes	yes	no	6			
	25600									
	94960									
142	26305	0000078-08-0	vinyltriethoxysilane	no	yes	no	0,05		Only to be used as a surface treatment agent	(1)
143	62450	0000078-78-4	isopentane	yes	no	no				
144	19243	0000078-79-5	2-methyl-1,3-butadiene	no	yes	no	ND		1 mg/kg in final product	
	21640									

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
145	10630	0000079-06-1	acrylamide	no	yes	no	ND			
146	23890 82000	0000079-09-4	propionic acid	yes	yes	no				
147	10690	0000079-10-7	acrylic acid	no	yes	no		(22)		
148	14650	0000079-38-9	chlorotrifluoroethylene	no	yes	no	ND			(1)
149	19990	0000079-39-0	methacrylamide	no	yes	no	ND			
150	20020	0000079-41-4	methacrylic acid	no	yes	no		(23)		
151	13480 13607	0000080-05-7	2,2-bis(4-hydroxyphenyl) propane	no	yes	no	0,6			
152	15610	0000080-07-9	4,4′-dichlorodiphenyl sulphone	no	yes	no	0,05			
153	15267	0000080-08-0	4,4′-diaminodiphenyl sulphone	no	yes	no	5			
154	13617 16090	0000080-09-1	4,4′-dihydroxydiphenyl sulphone	no	yes	no	0,05			
155	23470	0000080-56-8	α-pinene	no	yes	no				
156	21130	0000080-62-6	methacrylic acid, methyl ester	no	yes	no		(23)		
157	74880	0000084-74-2	phthalic acid, dibutyl ester	yes	no	no	0,3	(32)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0,05 % in the final product.	(7)
158	23380 76320	0000085-44-9	phthalic anhydride	yes	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
159	74560	0000085-68-7	phthalic acid, benzyl butyl ester	yes	no	no	30	(32)	Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; (c) technical support agent in concentrations up to 0,1 % in the final product.	(7)
160	84800	0000087-18-3	salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
161	92160	0000087-69-4	tartaric acid	yes	no	no				
162	65520	0000087-78-5	mannitol	yes	no	no				
163	66400	0000088-24-4	2,2′-methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	0000088-68-6	2-aminobenzamide	yes	no	no	0,05		Only for use in PET for water and beverages	
165	23200 74480	0000088-99-3	*o*-phthalic acid	yes	yes	no				
166	24057	0000089-32-7	pyromellitic anhydride	no	yes	no	0,05			
167	25240	0000091-08-7	2,6-toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
168	13075 15310	0000091-76-9	2,4-diamino-6-phenyl-1,3,5-triazine	no	yes	no	5			(1)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
169	16240	0000091-97-4	3,3′-dimethyl-4,4′-diisocyanatobiphenyl	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
170	16000	0000092-88-6	4,4′-dihydroxybiphenyl	no	yes	no	6			
171	38080	0000093-58-3	benzoic acid, methyl ester	yes	no	no				
172	37840	0000093-89-0	benzoic acid, ethyl ester	yes	no	no				
173	60240	0000094-13-3	4-hydroxybenzoic acid, propyl ester	yes	no	no				
174	14740	0000095-48-7	*o*-cresol	no	yes	no				
175	20050	0000096-05-9	methacrylic acid, allyl ester	no	yes	no	0,05			
176	11710	0000096-33-3	acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	0000096-49-1	ethylene carbonate	no	yes	no	30		SML expressed as ethyleneglycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food.	
178	92800	0000096-69-5	4,4′-thiobis(6-tert-butyl-3-methylphenol)	yes	no	yes	0,48			
179	48800	0000097-23-4	2,2′-dihydroxy-–5,5′-dichlorodiphenylmethane	yes	no	yes	12			
180	17160	0000097-53-0	eugenol	no	yes	no	ND			
181	20890	0000097-63-2	methacrylic acid, ethyl ester	no	yes	no		(23)		
182	19270	0000097-65-4	itaconic acid	no	yes	no				
183	21010	0000097-86-9	methacrylic acid, isobutyl ester	no	yes	no		(23)		
184	20110	0000097-88-1	methacrylic acid, butyl ester	no	yes	no		(23)		
185	20440	0000097-90-5	methacrylic acid, diester with ethyleneglycol	no	yes	no	0,05			
186	14020	0000098-54-4	4-tert-butylphenol	no	yes	no	0,05			
187	22210	0000098-83-9	α-methylstyrene	no	yes	no	0,05			
188	19180	0000099-63-8	isophthalic acid dichloride	no	yes	no		(27)		
189	60200	0000099-76-3	4-hydroxybenzoic acid, methyl ester	yes	no	no				
190	18880	0000099-96-7	*p*-hydroxybenzoic acid	no	yes	no				
191	24940	0000100-20-9	terephthalic acid dichloride	no	yes	no		(28)		
192	23187	—	phthalic acid	no	yes	no		(28)		
193	24610	0000100-42-5	styrene	no	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
194	13150	0000100-51-6	benzyl alcohol	no	yes	no				
195	37360	0000100-52-7	benzaldehyde	yes	no	no				(3)
196	18670 59280	0000100-97-0	hexamethylenetetramine	yes	yes	no		(15)		
197	20260	0000101-43-9	methacrylic acid, cyclohexyl ester	no	yes	no	0,05			
198	16630	0000101-68-8	diphenylmethane-4,4′-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
199	24073	0000101-90-6	resorcinol diglycidyl ether	no	yes	no	ND		Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	(8)
200	51680	0000102-08-9	N,N′-diphenylthiourea	yes	no	yes	3			
201	16540	0000102-09-0	diphenyl carbonate	no	yes	no	0,05			
202	23070	0000102-39-6	(1,3-phenylenedioxy) diacetic acid	no	yes	no	0,05			(1)
203	13323	0000102-40-9	1,3-bis(2-hydroxyethoxy) benzene	no	yes	no	0,05			
204	25180 92640	0000102-60-3	N,N,N′,N′-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	no				
205	25385	0000102-70-5	triallylamine	no	yes	no			40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. Only to be used in hydrogels intended for non-direct food contact use.	
206	11500	0000103-11-7	acrylic acid, 2-ethylhexyl ester	no	yes	no	0,05			
207	31920	0000103-23-1	adipic acid, bis(2-ethylhexyl) ester	yes	no	yes	18	(32)		(2)
208	18898	0000103-90-2	N-(4-hydroxyphenyl) acetamide	no	yes	no	0,05			
209	17050	0000104-76-7	2-ethyl-1-hexanol	no	yes	no	30			
210	13390 14880	0000105-08-8	1,4-bis(hydroxymethyl) cyclohexane	no	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
211	23920	0000105-38-4	propionic acid, vinyl ester	no	yes	no		(1)		
212	14200	0000105-60-2	caprolactam	yes	yes	no		(4)		
	41840									
213	82400	0000105-62-4	1,2-propyleneglycol dioleate	yes	no	no				
214	61840	0000106-14-9	12-hydroxystearic acid	yes	no	no				
215	14170	0000106-31-0	butyric anhydride	no	yes	no				
216	14770	0000106-44-5	*p*-cresol	no	yes	no				
217	15565	0000106-46-7	1,4-dichlorobenzene	no	yes	no	12			
218	11590	0000106-63-8	acrylic acid, isobutyl ester	no	yes	no		(22)		
219	14570	0000106-89-8	epichlorohydrin	no	yes	no	ND		1 mg/kg in final product	(10)
	16750									
220	20590	0000106-91-2	methacrylic acid, 2,3-epoxypropyl ester	no	yes	no	0,02			(10)
221	40570	0000106-97-8	butane	yes	no	no				
222	13870	0000106-98-9	1-butene	no	yes	no				
223	13630	0000106-99-0	butadiene	no	yes	no	ND		1 mg/kg in final product	
224	13900	0000107-01-7	2-butene	no	yes	no				
225	12100	0000107-13-1	acrylonitrile	no	yes	no	ND			
226	15272	0000107-15-3	ethylenediamine	no	yes	no	12			
	16960									
227	16990	0000107-21-1	ethyleneglycol	yes	yes	no		(2)		
	53650									
228	13690	0000107-88-0	1,3-butanediol	no	yes	no				
229	14140	0000107-92-6	butyric acid	no	yes	no				
230	16150	0000108-01-0	dimethylaminoethanol	no	yes	no	18			
231	10120	0000108-05-4	acetic acid, vinyl ester	no	yes	no	12			
232	10150	0000108-24-7	acetic anhydride	yes	yes	no				
	30280									
233	24850	0000108-30-5	succinic anhydride	no	yes	no				
234	19960	0000108-31-6	maleic anhydride	no	yes	no		(3)		
235	14710	0000108-39-4	*m*-cresol	no	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
236	23050	0000108-45-2	1,3-phenylenediamine	no	yes	no	ND			
237	15910	0000108-46-3	1,3-dihydroxybenzene	no	yes	no	2,4			
	24072									
238	18070	0000108-55-4	glutaric anhydride	no	yes	no				
239	19975	0000108-78-1	2,4,6-triamino-1,3,5-triazine	yes	yes	no	30			
	25420									
	93720									
240	45760	0000108-91-8	cyclohexylamine	yes	no	no				
241	22960	0000108-95-2	phenol	no	yes	no				
242	85360	0000109-43-3	sebacic acid, dibutyl ester	yes	no	no		(32)		
243	19060	0000109-53-5	isobutyl vinyl ether	no	yes	no	0,05			(10)
244	71720	0000109-66-0	pentane	yes	no	no				
245	22900	0000109-67-1	1-pentene	no	yes	no	5			
246	25150	0000109-99-9	tetrahydrofuran	no	yes	no	0,6			
247	24820	0000110-15-6	succinic acid	yes	yes	no				
	90960									
248	19540	0000110-16-7	maleic acid	yes	yes	no		(3)		
	64800									
249	17290	0000110-17-8	fumaric acid	yes	yes	no				
	55120									
250	53520	0000110-30-5	N,N′-ethylenebisstearamide	yes	no	no				
251	53360	0000110-31-6	N,N′-ethylenebisoleamide	yes	no	no				
252	87200	0000110-44-1	sorbic acid	yes	no	no				
253	15250	0000110-60-1	1,4-diaminobutane	no	yes	no				
254	13720	0000110-63-4	1,4-butanediol	yes	yes	no		(30)		
	40580									
255	25900	0000110-88-3	trioxane	no	yes	no	5			
256	18010	0000110-94-1	glutaric acid	yes	yes	no				
	55680									
257	13550	0000110-98-5	dipropyleneglycol	yes	yes	no				
	16660									
	51760									

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
258	70480	0000111-06-8	palmitic acid, butyl ester	yes	no	no				
259	58720	0000111-14-8	heptanoic acid	yes	no	no				
260	24280	0000111-20-6	sebacic acid	no	yes	no				
261	15790	0000111-40-0	diethylenetriamine	no	yes	no	5			
262	35284	0000111-41-1	N-(2-aminoethyl)ethanolamine	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	
263	13326 15760 47680	0000111-46-6	diethyleneglycol	yes	yes	no		(2)		
264	22660	0000111-66-0	1-octene	no	yes	no	15			
265	22600	0000111-87-5	1-octanol	no	yes	no				
266	25510 94320	0000112-27-6	triethyleneglycol	yes	yes	no				
267	15100	0000112-30-1	1-decanol	no	yes	no				
268	16704	0000112-41-4	1-dodecene	no	yes	no	0,05			
269	25090 92350	0000112-60-7	tetraethyleneglycol	yes	yes	no				
270	22763 69040	0000112-80-1	oleic acid	yes	yes	no				
271	52720	0000112-84-5	erucamide	yes	no	no				
272	37040	0000112-85-6	behenic acid	yes	no	no				
273	52730	0000112-86-7	erucic acid	yes	no	no				
274	22570	0000112-96-9	octadecyl isocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
275	23980	0000115-07-1	propylene	no	yes	no				
276	19000	0000115-11-7	isobutene	no	yes	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
277	18280	0000115-27-5	hexachloroendomethylenetetrahydrophthalic anhydride	no	yes	no	ND			
278	18250	0000115-28-6	hexachloroendomethylenetetrahydrophthalic acid	no	yes	no	ND			
279	22840 71600	0000115-77-5	pentaerythritol	yes	yes	no				
280	73720	0000115-96-8	phosphoric acid, trichloroethyl ester	yes	no	no	ND			
281	25120	0000116-14-3	tetrafluoroethylene	no	yes	no	0,05			
282	18430	0000116-15-4	hexafluoropropylene	no	yes	no	ND			
283	74640	0000117-81-7	phthalic acid, bis(2-ethylhexyl) ester	yes	no	no	1,5	(32)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product.	(7)
284	84880	0000119-36-8	salicylic acid, methyl ester	yes	no	no	30			
285	66480	0000119-47-1	2,2′-methylene bis(4-methyl-6-tert-butylphenol)	yes	no	yes		(13)		
286	38240	0000119-61-9	benzophenone	yes	no	yes	0,6			
287	60160	0000120-47-8	4-hydroxybenzoic acid, ethyl ester	yes	no	no				
288	24970	0000120-61-6	terephthalic acid, dimethyl ester	no	yes	no				
289	15880 24051	0000120-80-9	1,2-dihydroxybenzene	no	yes	no	6			
290	55360	0000121-79-9	gallic acid, propyl ester	yes	no	no		(20)		
291	19150	0000121-91-5	isophthalic acid	no	yes	no		(27)		
292	94560	0000122-20-3	triisopropanolamine	yes	no	no	5			
293	23175	0000122-52-1	phosphorous acid, triethyl ester	no	yes	no	ND		1 mg/kg in final product	(1)
294	93120	0000123-28-4	thiodipropionic acid, didodecyl ester	yes	no	yes		(14)		
295	15940 18867 48620	0000123-31-9	1,4-dihydroxybenzene	yes	yes	no	0,6			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
296	23860	0000123-38-6	propionaldehyde	no	yes	no				
297	23950	0000123-62-6	propionic anhydride	no	yes	no				
298	14110	0000123-72-8	butyraldehyde	no	yes	no				
299	63840	0000123-76-2	levulinic acid	yes	no	no				
300	30045	0000123-86-4	acetic acid, butyl ester	yes	no	no				
301	89120	0000123-95-5	stearic acid, butyl ester	yes	no	no				
302	12820	0000123-99-9	azelaic acid	no	yes	no				
303	12130	0000124-04-9	adipic acid	yes	yes	no				
	31730									
304	14320	0000124-07-2	caprylic acid	yes	yes	no				
	41960									
305	15274	0000124-09-4	hexamethylenediamine	no	yes	no	2,4			
	18460									
306	88960	0000124-26-5	stearamide	yes	no	no				
307	42160	0000124-38-9	carbon dioxide	yes	no	no				
308	91200	0000126-13-6	sucrose acetate isobutyrate	yes	no	no				
309	91360	0000126-14-7	sucrose octaacetate	yes	no	no				
310	16390	0000126-30-7	2,2-dimethyl-1,3-propanediol	no	yes	no	0,05			
	22437									
311	16480	0000126-58-9	dipentaerythritol	yes	yes	no				
	51200									
312	21490	0000126-98-7	methacrylonitrile	no	yes	no	ND			
313	16650	0000127-63-9	diphenyl sulphone	yes	yes	no	3			
	51570									
314	23500	0000127-91-3	β-pinene	no	yes	no				
315	46640	0000128-37-0	2,6-di-tert-butyl-p-cresol	yes	no	no	3			
316	23230	0000131-17-9	phthalic acid, diallyl ester	no	yes	no	ND			
317	48880	0000131-53-3	2,2′-dihydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
318	48640	0000131-56-6	2,4-dihydroxybenzophenone	yes	no	no		(8)		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
319	61360	0000131-57-7	2-hydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
320	37680	0000136-60-7	benzoic acid, butyl ester	yes	no	no				
321	36080	0000137-66-6	ascorbyl palmitate	yes	no	no				
322	63040	0000138-22-7	lactic acid, butyl ester	yes	no	no				
323	11470	0000140-88-5	acrylic acid, ethyl ester	no	yes	no		(22)		
324	83700	0000141-22-0	ricinoleic acid	yes	no	yes	42			
325	10780	0000141-32-2	acrylic acid, n-butyl ester	no	yes	no		(22)		
326	12763 35170	0000141-43-5	2-aminoethanol	yes	yes	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer.	
327	30140	0000141-78-6	acetic acid, ethyl ester	yes	no	no				
328	65040	0000141-82-2	malonic acid	yes	no	no				
329	59360	0000142-62-1	hexanoic acid	yes	no	no				
330	19470 63280	0000143-07-7	lauric acid	yes	yes	no				
331	22480	0000143-08-8	1-nonanol	no	yes	no				
332	69760	0000143-28-2	oleyl alcohol	yes	no	no				
333	22775 69920	0000144-62-7	oxalic acid	yes	yes	no	6			
334	17005	0000151-56-4	ethyleneimine	no	yes	no	ND			
335	68960	0000301-02-0	oleamide	yes	no	no				
336	15095 45940	0000334-48-5	n-decanoic acid	yes	yes	no				
337	15820	0000345-92-6	4,4′-difluorobenzophenone	no	yes	no	0,05			
338	71020	0000373-49-9	palmitoleic acid	yes	no	no				
339	86160	0000409-21-2	silicon carbide	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
340	47440	0000461-58-5	dicyanodiamide	yes	no	no				
341	13180	0000498-66-8	bicyclo[2.2.1]hept-2-ene	no	yes	no	0,05			
	22550									
342	14260	0000502-44-3	caprolactone	no	yes	no		(29)		
343	23770	0000504-63-2	1,3-propanediol	no	yes	no	0,05			
344	13810	0000505-65-7	1,4-butanediol formal	no	yes	no	ND			(10)
	21821									
345	35840	0000506-30-9	arachidic acid	yes	no	no				
346	10030	0000514-10-3	abietic acid	no	yes	no				
347	13050	0000528-44-9	trimellitic acid	no	yes	no		(21)		
	25540									
348	22350	0000544-63-8	myristic acid	yes	yes	no				
	67891									
349	25550	0000552-30-7	trimellitic anhydride	no	yes	no		(21)		
350	63920	0000557-59-5	lignoceric acid	yes	no	no				
351	21730	0000563-45-1	3-methyl-1-butene	no	yes	no	ND		Only to be used in polypropylene	(1)
352	16360	0000576-26-1	2,6-dimethylphenol	no	yes	no	0,05			
353	42480	0000584-09-8	carbonic acid, rubidium salt	yes	no	no	12			
354	25210	0000584-84-9	2,4-toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
355	20170	0000585-07-9	methacrylic acid, tert-butyl ester	no	yes	no		(23)		
356	18820	0000592-41-6	1-hexene	no	yes	no	3			
357	13932	0000598-32-3	3-buten-2-ol	no	yes	no	ND		Only to be used as a co-monomer for the preparation of polymeric additive	(1)
358	14841	0000599-64-4	4-cumylphenol	no	yes	no	0,05			
359	15970	0000611-99-4	4,4′-dihydroxybenzophenone	yes	yes	no		(8)		
	48720									
360	57920	0000620-67-7	glycerol triheptanoate	yes	no	no				
361	18700	0000629-11-8	1,6-hexanediol	no	yes	no	0,05			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
362	14350	0000630-08-0	carbon monoxide	no	yes	no				
363	16450	0000646-06-0	1,3-dioxolane	no	yes	no	5			
364	15404	0000652-67-5	1,4:3,6-dianhydrosorbitol	no	yes	no	5		Only to be used as a co-monomer in poly(ethylene-co-isosorbide terephthalate)	
365	11680	0000689-12-3	acrylic acid, isopropyl ester	no	yes	no		(22)		
366	22150	0000691-37-2	4-methyl-1-pentene	no	yes	no	0,05			
367	16697	0000693-23-2	n-dodecanedioic acid	no	yes	no				
368	93280	0000693-36-7	thiodipropionic acid, dioctadecyl ester	yes	no	yes		(14)		
369	12761	0000693-57-2	12-aminododecanoic acid	no	yes	no	0,05			
370	21460	0000760-93-0	methacrylic anhydride	no	yes	no		(23)		
371	11510	0000818-61-1	acrylic acid, monoester with ethyleneglycol	no	yes	no		(22)		
	11830									
372	18640	0000822-06-0	hexamethylene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
373	22390	0000840-65-3	2,6-naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05			
374	21190	0000868-77-9	methacrylic acid, monoester with ethyleneglycol	no	yes	no		(23)		
375	15130	0000872-05-9	1-decene	no	yes	no	0,05			
376	66905	0000872-50-4	N-methylpyrrolidone	yes	no	no				
377	12786	0000919-30-2	3-aminopropyltriethoxysilane	no	yes	no	0,05		Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of materials and articles.	
378	21970	0000923-02-4	N-methylolmethacrylamide	no	yes	no	0,05			
379	21940	0000924-42-5	N-methylolacrylamide	no	yes	no	ND			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
380	11980	0000925-60-0	acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	0000931-88-4	cyclooctene	no	yes	no	0,05		Only to be used in polymers contacting foods for which simulant A is laid down	
382	19490	0000947-04-6	laurolactam	no	yes	no	5			
383	72160	0000948-65-2	2-phenylindole	yes	no	yes	15			
384	40000	0000991-84-4	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			
385	11530	0000999-61-1	acrylic acid, 2-hydroxypropyl ester	no	yes	no	0,05		SML expressed as the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).	(1)
386	55280	0001034-01-1	gallic acid, octyl ester	yes	no	no		(20)		
387	26155	0001072-63-5	1-vinylimidazole	no	yes	no	0,05			(1)
388	25080	0001120-36-1	1-tetradecene	no	yes	no	0,05			
389	22360	0001141-38-4	2,6-naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	0001166-52-5	gallic acid, dodecyl ester	yes	no	no		(20)		
391	22932	0001187-93-5	perfluoromethyl perfluorovinyl ether	no	yes	no	0,05		Only to be used in anti-stick coatings	
392	72800	0001241-94-7	phosphoric acid, diphenyl 2-ethylhexyl ester	yes	no	yes	2,4			
393	37280	0001302-78-9	bentonite	yes	no	no				
394	41280	0001305-62-0	calcium hydroxide	yes	no	no				
395	41520	0001305-78-8	calcium oxide	yes	no	no				
396	64640	0001309-42-8	magnesium hydroxide	yes	no	no				
397	64720	0001309-48-4	magnesium oxide	yes	no	no				
398	35760	0001309-64-4	antimony trioxide	yes	no	no	0,04		SML expressed as antimony	(6)
399	81600	0001310-58-3	potassium hydroxide	yes	no	no				
400	86720	0001310-73-2	sodium hydroxide	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
401	24475	0001313-82-2	sodium sulphide	no	yes	no				
402	96240	0001314-13-2	zinc oxide	yes	no	no				
403	96320	0001314-98-3	zinc sulphide	yes	no	no				
404	67200	0001317-33-5	molybdenum disulphide	yes	no	no				
405	16690	0001321-74-0	divinylbenzene	no	yes	no	ND		SML expressed as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.	(1)
406	83300	0001323-39-3	1,2-propyleneglycol monostearate	yes	no	no				
407	87040	0001330-43-4	sodium tetraborate	yes	no	no		(16)		
408	82960	0001330-80-9	1,2-propyleneglycol monooleate	yes	no	no				
409	62240	0001332-37-2	iron oxide	yes	no	no				
410	62720	0001332-58-7	kaolin	yes	no	no				
411	42080	0001333-86-4	carbon black	yes	no	no			Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1 200 nm which may form agglomerates within the size distribution of 300 nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w.	
412	45200	0001335-23-5	copper iodide	yes	no	no		(6)		
413	35600	0001336-21-6	ammonium hydroxide	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
414	87600	0001338-39-2	sorbitan monolaurate	yes	no	no				
415	87840	0001338-41-6	sorbitan monostearate	yes	no	no				
416	87680	0001338-43-8	sorbitan monooleate	yes	no	no				
417	85680	0001343-98-2	silicic acid	yes	no	no				
418	34720	0001344-28-1	aluminium oxide	yes	no	no				
419	92150	0001401-55-4	tannic acids	yes	no	no			According to the JECFA specifications	
420	19210	0001459-93-4	isophthalic acid, dimethyl ester	no	yes	no	0,05			
421	13000	0001477-55-0	1,3-benzenedimethanamine	no	yes	no	0,05			
422	38515	0001533-45-5	4,4′-bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05			(2)
423	22937	0001623-05-8	perfluoropropylperfluorovinyl ether	no	yes	no	0,05			
424	15070	0001647-16-1	1,9-decadiene	no	yes	no	0,05			
425	10840	0001663-39-4	acrylic acid, tert-butyl ester	no	yes	no		(22)		
426	13510 13610	0001675-54-3	2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether	no	yes	no			In compliance with Commission Regulation (EC) No 1895/2005 [1]	
427	18896	0001679-51-2	4-(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05			
428	95200	0001709-70-2	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene	yes	no	no				
429	13210	0001761-71-3	bis(4-aminocyclohexyl)methane	no	yes	no	0,05			
430	95600	0001843-03-4	1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	yes	no	yes	5			
431	61600	0001843-05-6	2-hydroxy-4-n-octyloxybenzophenone	yes	no	yes		(8)		
432	12280	0002035-75-8	adipic anhydride	no	yes	no				
433	68320	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	yes	no	yes	6			
434	20410	0002082-81-7	methacrylic acid, diester with 1,4-butanediol	no	yes	no	0,05			
435	14230	0002123-24-2	caprolactam, sodium salt	no	yes	no		(4)		
436	19480	0002146-71-6	lauric acid, vinyl ester	no	yes	no				
437	11245	0002156-97-0	acrylic acid, dodecyl ester	no	yes	no	0,05			(2)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
438	38875	0002162-74-5	bis(2,6-diisopropylphenyl) carbodiimide	yes	no	no	0,05		For indirect food contact only, behind a PET layer	
439	21280	0002177-70-0	methacrylic acid, phenyl ester	no	yes	no		(23)		
440	21340	0002210-28-8	methacrylic acid, propyl ester	no	yes	no		(23)		
441	38160	0002315-68-6	benzoic acid, propyl ester	yes	no	no				
442	13780	0002425-79-8	1,4-butanediol bis(2,3-epoxypropyl)ether	no	yes	no	ND		Residual content = 1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	(10)
443	12788	0002432-99-7	11-aminoundecanoic acid	no	yes	no	5			
444	61440	0002440-22-4	2-(2′-hydroxy-5′-methylphenyl)benzotriazole	yes	no	no		(12)		
445	83440	0002466-09-3	pyrophosphoric acid	yes	no	no				
446	10750	0002495-35-4	acrylic acid, benzyl ester	no	yes	no		(22)		
447	20080	0002495-37-6	methacrylic acid, benzyl ester	no	yes	no		(23)		
448	11890	0002499-59-4	acrylic acid, n-octyl ester	no	yes	no		(22)		
449	49840	0002500-88-1	dioctadecyl disulphide	yes	no	yes	3			
450	24430	0002561-88-8	sebacic anhydride	no	yes	no				
451	66755	0002682-20-4	2-methyl-4-isothiazolin-3-one	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions	
452	38885	0002725-22-6	2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	yes	no	no	0,05		Only to be used in aqueous foods	
453	26320	0002768-02-7	vinyltrimethoxysilane	no	yes	no	0,05			(10)
454	12670	0002855-13-2	1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6			
455	20530	0002867-47-2	methacrylic acid, 2-(dimethylamino)-ethyl ester	no	yes	no	ND			
456	10810	0002998-08-5	acrylic acid, sec-butyl ester	no	yes	no		(22)		
457	20140	0002998-18-7	methacrylic acid, sec-butyl ester	no	yes	no		(23)		
458	36960	0003061-75-4	behenamide	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
459	46870	0003135-18-0	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no	no				
460	14950	0003173-53-3	cyclohexyl isocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
461	22420	0003173-72-6	1,5-naphthalene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
462	26170	0003195-78-6	N-vinyl-N-methylacetamide	no	yes	no	0,02			(1)
463	25840	0003290-92-4	1,1,1-trimethylolpropane trimethacrylate	no	yes	no	0,05			
464	61280	0003293-97-8	2-hydroxy-4-n-hexyloxybenzophenone	yes	no	yes		(8)		
465	68040	0003333-62-8	7-[2H-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no				
466	50640	0003648-18-8	di-n-octyltin dilaurate	yes	no	no		(10)		
467	14800	0003724-65-0	crotonic acid	yes	yes	no	0,05			(1)
	45600									
468	71960	0003825-26-1	perfluorooctanoic acid, ammonium salt	yes	no	no			Only to be used in repeated use articles, sintered at high temperatures	
469	60480	0003864-99-1	2-(2′-hydroxy-3,5′-di-tert-butylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
470	60400	0003896-11-5	2-(2′-hydroxy-3′-tert-butyl-5′-methylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
471	24888	0003965-55-7	5-sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	0004066-02-8	2,2′-methylenebis(4-methyl-6-cyclohexylphenol)	yes	no	yes		(5)		
473	12265	0004074-90-2	adipic acid, divinyl ester	no	yes	no	ND		5 mg/kg in final product. Only to be used as co-monomer.	(1)
474	43600	0004080-31-3	1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3			
475	19110	0004098-71-9	1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
476	16570	0004128-73-8	diphenylether-4,4′-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
477	46720	0004130-42-1	2,6-di-tert-butyl-4-ethylphenol	yes	no	yes	4,8			(1)
478	60180	0004191-73-5	4-hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	0004196-95-6	azelaic anhydride	no	yes	no				
480	46790	0004221-80-1	3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	yes	no	no				
481	13060	0004422-95-1	1,3,5-benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML expressed as 1,3,5-benzenetricarboxylic acid	(1)
482	21100	0004655-34-9	methacrylic acid, isopropyl ester	no	yes	no		(23)		
483	68860	0004724-48-5	n-octylphosphonic acid	yes	no	no	0,05			
484	13395	0004767-03-7	2,2-bis(hydroxymethyl) propionic acid	no	yes	no	0,05			(1)
485	13560 15700	0005124-30-1	dicyclohexylmethane-4,4′-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
486	54005	0005136-44-7	ethylene-N-palmitamide-N′-stearamide	yes	no	no				
487	45640	0005232-99-5	2-cyano-3,3-diphenylacrylic acid, ethyl ester	yes	no	no	0,05			
488	53440	0005518-18-3	N,N′-ethylenebispalmitamide	yes	no	no				
489	41040	0005743-36-2	calcium butyrate	yes	no	no				
490	16600	0005873-54-1	diphenylmethane-2,4′-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
491	82720	0006182-11-2	1,2-propyleneglycol distearate	yes	no	no				
492	45650	0006197-30-4	2-cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	yes	no	no	0,05			
493	39200	0006200-40-4	bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy) methylammonium chloride	yes	no	no	1,8			
494	62140	0006303-21-5	hypophosphorous acid	yes	no	no				
495	35160	0006642-31-5	6-amino-1,3-dimethyluracil	yes	no	no	5			
496	71680	0006683-19-8	pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
497	95020	0006846-50-0	2,2,4-trimethyl-1,3-pentanediol diisobutyrate	yes	no	no	5		Only to be used in single-use gloves	
498	16210	0006864-37-5	3,3′-dimethyl-4,4′-diaminodicyclohexylmethane	no	yes	no	0,05		Only to be used in polyamides	(5)
499	19965	0006915-15-7	malic acid	yes	yes	no			In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis	
	65020									
500	38560	0007128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	yes	no	yes	0,6			
501	34480	—	aluminium fibers, flakes and powders	yes	no	no				
502	22778	0007456-68-0	4,4′-oxybis(benzenesulphonyl azide)	no	yes	no	0,05			(1)
503	46080	0007585-39-9	β-dextrin	yes	no	no				
504	86240	0007631-86-9	silicon dioxide	yes	no	no			For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 μm which may form agglomerates within the size distribution of 0,3 μm to the mm size.	
505	86480	0007631-90-5	sodium bisulphite	yes	no	no		(19)		
506	86920	0007632-00-0	sodium nitrite	yes	no	no	0,6			
507	59990	0007647-01-0	hydrochloric acid	yes	no	no				
508	86560	0007647-15-6	sodium bromide	yes	no	no				
509	23170	0007664-38-2	phosphoric acid	yes	yes	no				
	72640									
510	12789	0007664-41-7	ammonia	yes	yes	no				
	35320									
511	91920	0007664-93-9	sulphuric acid	yes	no	no				
512	81680	0007681-11-0	potassium iodide	yes	no	no		(6)		
513	86800	0007681-82-5	sodium iodide	yes	no	no		(6)		
514	91840	0007704-34-9	sulphur	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
515	26360 95855	0007732-18-5	water	yes	yes	no			In compliance with Directive 98/83/EC (2)	
516	86960	0007757-83-7	sodium sulphite	yes	no	no		(19)		
517	81520	0007758-02-3	potassium bromide	yes	no	no				
518	35845	0007771-44-0	arachidonic acid	yes	no	no				
519	87120	0007772-98-7	sodium thiosulphate	yes	no	no		(19)		
520	65120	0007773-01-5	manganese chloride	yes	no	no				
521	58320	0007782-42-5	graphite	yes	no	no				
522	14530	0007782-50-5	chlorine	no	yes	no				
523	45195	0007787-70-4	copper bromide	yes	no	no				
524	24520	0008001-22-7	soybean oil	no	yes	no				
525	62640	0008001-39-6	japan wax	yes	no	no				
526	43440	0008001-75-0	ceresin	yes	no	no				
527	14411 42880	0008001-79-4	castor oil	yes	yes	no				
528	63760	0008002-43-5	lecithin	yes	no	no				
529	67850	0008002-53-7	montan wax	yes	no	no				
530	41760	0008006-44-8	candelilla wax	yes	no	no				
531	36880	0008012-89-3	beeswax	yes	no	no				
532	88640	0008013-07-8	soybean oil, epoxidised	yes	no	no	60 30(*)	(32)	(*) In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC, the SML is lowered to 30 mg/kg. Oxirane < 8 %, iodine number < 6.	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
533	42720	0008015-86-9	carnauba wax	yes	no	no				
534	80720	0008017-16-1	polyphosphoric acids	yes	no	no				
535	24100	0008050-09-7	rosin	yes	yes	no				
	24130									
	24190									
	83840									
536	84320	0008050-15-5	rosin, hydrogenated, ester with methanol	yes	no	no				
537	84080	0008050-26-8	rosin, ester with pentaerythritol	yes	no	no				
538	84000	0008050-31-5	rosin, ester with glycerol	yes	no	no				
539	24160	0008052-10-6	rosin tall oil	no	yes	no				
540	63940	0008062-15-5	lignosulphonic acid	yes	no	no	0,24		Only to be used as dispersant for plastics dispersions	
541	58480	0009000-01-5	gum arabic	yes	no	no				
542	42640	0009000-11-7	carboxymethylcellulose	yes	no	no				
543	45920	0009000-16-2	dammar	yes	no	no				
544	58400	0009000-30-0	guar gum	yes	no	no				
545	93680	0009000-65-1	tragacanth gum	yes	no	no				
546	71440	0009000-69-5	pectin	yes	no	no				
547	55440	0009000-70-8	gelatin	yes	no	no				
548	42800	0009000-71-9	casein	yes	no	no				
549	80000	0009002-88-4	polyethylene wax	yes	no	no				
550	81060	0009003-07-0	polypropylene wax	yes	no	no				
551	79920	0009003-11-6 0106392-12-5	poly(ethylene propylene) glycol	yes	no	no				
552	81500	0009003-39-8	polyvinylpyrrolidone	yes	no	no			The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC (3)	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
553	14500 43280	0009004-34-6	cellulose	yes	yes	no				
554	43300	0009004-36-8	cellulose acetate butyrate	yes	no	no				
555	53280	0009004-57-3	ethylcellulose	yes	no	no				
556	54260	0009004-58-4	ethylhydroxyethylcellulose	yes	no	no				
557	66640	0009004-59-5	methylethylcellulose	yes	no	no				
558	60560	0009004-62-0	hydroxyethylcellulose	yes	no	no				
559	61680	0009004-64-2	hydroxypropylcellulose	yes	no	no				
560	66700	0009004-65-3	methylhydroxypropylcellulose	yes	no	no				
561	66240	0009004-67-5	methylcellulose	yes	no	no				
562	22450	0009004-70-0	nitrocellulose	no	yes	no				
563	78320	0009004-97-1	polyethyleneglycol monoricinoleate	yes	no	yes	42			
564	24540 88800	0009005-25-8	starch, edible	yes	yes	no				
565	61120	0009005-27-0	hydroxyethyl starch	yes	no	no				
566	33350	0009005-32-7	alginic acid	yes	no	no				
567	82080	0009005-37-2	1,2-propyleneglycol alginate	yes	no	no				
568	79040	0009005-64-5	polyethyleneglycol sorbitan monolaurate	yes	no	no				
569	79120	0009005-65-6	polyethyleneglycol sorbitan monooleate	yes	no	no				
570	79200	0009005-66-7	polyethyleneglycol sorbitan monopalmitate	yes	no	no				
571	79280	0009005-67-8	polyethyleneglycol sorbitan monostearate	yes	no	no				
572	79360	0009005-70-3	polyethyleneglycol sorbitan trioleate	yes	no	no				
573	79440	0009005-71-4	polyethyleneglycol sorbitan tristearate	yes	no	no				
574	24250 84560	0009006-04-6	rubber, natural	yes	yes	no				
575	76721	0063148-62-9	polydimethylsiloxane (Mw > 6 800 Da)	yes	no	no			Viscosity at 25 °C not less than 100 cSt (100×10^{-6} m^2/s)	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
576	60880	0009032-42-2	hydroxyethylmethylcellulose	yes	no	no				
577	62280	0009044-17-1	isobutylene-butene copolymer	yes	no	no				
578	79600	0009046-01-9	polyethyleneglycol tridecyl ether phosphate	yes	no	no	5		For materials and articles intended for contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono-and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether.	
579	61800	0009049-76-7	hydroxypropyl starch	yes	no	no				
580	46070	0010016-20-3	α-dextrin	yes	no	no				
581	36800	0010022-31-8	barium nitrate	yes	no	no				
582	50240	0010039-33-5	di-n-octyltin bis(2-ethylhexyl maleate)	yes	no	no		(10)		
583	40400	0010043-11-5	boron nitride	yes	no	no		(16)		
584	13620	0010043-35-3	boric acid	yes	yes	no		(16)		
	40320									
585	41120	0010043-52-4	calcium chloride	yes	no	no				
586	65280	0010043-84-2	manganese hypophosphite	yes	no	no				
587	68400	0010094-45-8	octadecylerucamide	yes	no	yes	5			
588	64320	0010377-51-2	lithium iodide	yes	no	no		(6)		
589	52645	0010436-08-5	cis-11-eicosenamide	yes	no	no				
590	21370	0010595-80-9	methacrylic acid, 2-sulphoethyl ester	no	yes	no	ND			(1)
591	36160	0010605-09-1	ascorbyl stearate	yes	no	no				
592	34690	0011097-59-9	aluminium magnesium carbonate hydroxide	yes	no	no				
593	44960	0011104-61-3	cobalt oxide	yes	no	no				
594	65360	0011129-60-5	manganese oxide	yes	no	no				
595	19510	0011132-73-3	lignocellulose	no	yes	no				
596	95935	0011138-66-2	xanthan gum	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
597	67120	0012001-26-2	mica	yes	no	no				
598	41600	0012004-14-7 0037293-22-4	calcium sulphoaluminate	yes	no	no				
599	36840	0012007-55-5	barium tetraborate	yes	no	no		(16)		
600	60030	0012072-90-1	hydromagnesite	yes	no	no				
601	35440	0012124-97-9	ammonium bromide	yes	no	no				
602	70240	0012198-93-5	ozokerite	yes	no	no				
603	83460	0012269-78-2	pyrophyllite	yes	no	no				
604	60080	0012304-65-3	hydrotalcite	yes	no	no				
605	11005	0012542-30-2	acrylic acid, dicyclopentenyl ester	no	yes	no	0,05			(1)
606	65200	0012626-88-9	manganese hydroxide	yes	no	no				
607	62245	0012751-22-3	iron phosphide	yes	no	no			Only to be used in PET polymers and copolymers	
608	40800	0013003-12-8	4,4′-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	yes	no	yes	6			
609	83455	0013445-56-2	pyrophosphorous acid	yes	no	no				
610	93440	0013463-67-7	titanium dioxide	yes	no	no				
611	35120	0013560-49-1	3-aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	yes	no	no				
612	16694	0013811-50-2	N,N′-divinyl-2-imidazolidinone	no	yes	no	0,05			(10)
613	95905	0013983-17-0	wollastonite	yes	no	no				
614	45560	0014464-46-1	cristobalite	yes	no	no				
615	92080	0014807-96-6	talc	yes	no	no				
616	83470	0014808-60-7	quartz	yes	no	no				
617	10660	0015214-89-8	2-acrylamido-2-methylpropanesulphonic acid	no	yes	no	0,05			
618	51040	0015535-79-2	di-n-octyltin mercaptoacetate	yes	no	no		(10)		
619	50320	0015571-58-1	di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)		
620	50720	0015571-60-5	di-n-octyltin dimaleate	yes	no	no		(10)		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
621	17110	0016219-75-3	5-ethylidenebicyclo[2,2,1] hept-2-ene	no	yes	no	0,05			(9)
622	69840	0016260-09-6	oleylpalmitamide	yes	no	yes	5			
623	52640	0016389-88-1	dolomite	yes	no	no				
624	18897	0016712-64-4	6-hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	0017194-00-2	barium hydroxide	yes	no	no				
626	57800	0018641-57-1	glycerol tribehenate	yes	no	no				
627	59760	0019569-21-2	huntite	yes	no	no				
628	96190	0020427-58-1	zinc hydroxide	yes	no	no				
629	34560	0021645-51-2	aluminium hydroxide	yes	no	no				
630	82240	0022788-19-8	1,2-propyleneglycol dilaurate	yes	no	no				
631	59120	0023128-74-7	1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionamide)	yes	no	yes	45			
632	52880	0023676-09-7	4-ethoxybenzoic acid, ethyl ester	yes	no	no	3,6			
633	53200	0023949-66-8	2-ethoxy-2′-ethyloxanilide	yes	no	yes	30			
634	25910	0024800-44-0	tripropyleneglycol	no	yes	no				
635	40720	0025013-16-5	tert-butyl-4-hydroxyanisole	yes	no	no	30			
636	31500	0025134-51-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester	
637	71635	0025151-96-6	pentaerythritol dioleate	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down	
638	23590	0025322-68-3	polyethyleneglycol	yes	yes	no				
	76960									
639	23651	0025322-69-4	polypropyleneglycol	yes	yes	no				
	80800									
640	54930	0025359-91-5	formaldehyde-1-naphthol, copolymer	yes	no	no	0,05			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
641	22331	0025513-64-8	mixture of (35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w)1,6-diamino-2,4,4-trimethylhexane	no	yes	no	0,05			(10)
642	64990	0025736-61-2	maleic anhydride-styrene, copolymer, sodium salt	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 0,05 % (w/w)	
643	87760	0026266-57-9	sorbitan monopalmitate	yes	no	no				
644	88080	0026266-58-0	sorbitan trioleate	yes	no	no				
645	67760	0026401-86-5	mono-n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no		(11)		
646	50480	0026401-97-8	di-n-octyltin bis(isooctyl mercaptoacetate)	yes	no	no		(10)		
647	56720	0026402-23-3	glycerol monohexanoate	yes	no	no				
648	56880	0026402-26-6	glycerol monooctanoate	yes	no	no				
649	47210	0026427-07-6	dibutylthiostannoic acid polymer	yes	no	no			Molecular unit = $(C_8H_{18}S_3Sn_2)n$ (n = 1,5-2)	
650	49600	0026636-01-1	dimethyltin bis(isooctyl mercaptoacetate)	yes	no	no		(9)		
651	88240	0026658-19-5	sorbitan tristearate	yes	no	no				
652	38820	0026741-53-7	bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	yes	no	yes	0,6			
653	25270	0026747-90-0	2,4-toluene diisocyanate dimer	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
654	88600	0026836-47-5	sorbitol monostearate	yes	no	no				
655	25450	0026896-48-0	tricyclodecanedimethanol	no	yes	no	0,05			
656	24760	0026914-43-2	styrenesuphonic acid	no	yes	no	0,05			
657	67680	0027107-89-7	mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	yes	no	no		(11)		
658	52000	0027176-87-0	dodecylbenzenesulphonic acid	yes	no	no	30			
659	82800	0027194-74-7	1,2-propyleneglycol monolaurate	yes	no	no				
660	47540	0027458-90-8	di-tert-dodecyl disulphide	yes	no	yes	0,05			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
661	95360	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	5			
662	25927	0027955-94-8	1,1,1-tris(4-hydroxyphenol) ethane	no	yes	no	0,005		Only to be used in polycarbonates	(1)
663	64150	0028290-79-1	linolenic acid	yes	no	no				
664	95000	0028931-67-1	trimethylolpropane trimethacrylate-methyl methacrylate copolymer	yes	no	no				
665	83120	0029013-28-3	1,2-propyleneglycol monopalmitate	yes	no	no				
666	87280	0029116-98-1	sorbitan dioleate	yes	no	no				
667	55190	0029204-02-2	gadoleic acid	yes	no	no				
668	80240	0029894-35-7	polyglycerol ricinoleate	yes	no	no				
669	56610	0030233-64-8	glycerol monobehenate	yes	no	no				
670	56800	0030899-62-8	glycerol monolaurate diacetate	yes	no	no		(32)		
671	74240	0031570-04-4	phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	yes	no	no				
672	76845	0031831-53-5	polyester of 1,4-butanediol with caprolactone	yes	no	no		(29) (30)	The fraction with molecular weight below 1 000 Da should not exceed 0,5 % (w/w)	
673	53670	0032509-66-3	ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	yes	no	yes	6			
674	46480	0032647-67-9	dibenzylidene sorbitol	yes	no	no				
675	38800	0032687-78-8	N,N′-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15			
676	50400	0033568-99-9	di-n-octyltin bis(isooctyl maleate)	yes	no	no		(10)		
677	82560	0033587-20-1	1,2-propyleneglycol dipalmitate	yes	no	no				
678	59200	0035074-77-2	1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	yes	no	yes	6			
679	39060	0035958-30-6	1,1-bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	yes	no	yes	5			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
680	94400	0036443-68-2	triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	yes	no	no	9			
681	18310	0036653-82-4	1-hexadecanol	no	yes	no				
682	53270	0037205-99-5	ethylcarboxymethylcellulose	yes	no	no				
683	66200	0037206-01-2	methylcarboxymethylcellulose	yes	no	no				
684	68125	0037244-96-5	nepheline syenite	yes	no	no				
685	85950	0037296-97-2	silicic acid, magnesium-sodium-fluoride salt	yes	no	no	0,15		SML expressed as fluoride. Only to be used in layers of multi-layer materials not coming into direct contact with food.	
686	61390	0037353-59-6	hydroxymethylcellulose	yes	no	no				
687	13530	0038103-06-9	2,2-bis(4-hydroxyphenyl) propane bis(phthalic anhydride)	no	yes	no	0,05			
	13614									
688	92560	0038613-77-3	tetrakis(2,4-di-tert-butyl-phenyl)-4,4′-biphenylylene diphosphonite	yes	no	yes	18			
689	95280	0040601-76-1	1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	yes	no	yes	6			
690	92880	0041484-35-9	thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)	yes	no	yes	2,4			
691	13600	0047465-97-4	3,3-bis(3-methyl-4-hydroxyphenyl)2-indolinone	no	yes	no	1,8			
692	52320	0052047-59-3	2-(4-dodecylphenyl)indole	yes	no	yes	0,06			
693	88160	0054140-20-4	sorbitan tripalmitate	yes	no	no				
694	21400	0054276-35-6	methacrylic acid, sulphopropyl ester	no	yes	no	0,05			(1)
695	67520	0054849-38-6	monomethyltin tris(isooctyl mercaptoacetate)	yes	no	no		(9)		
696	92205	0057569-40-1	terephthalic acid, diester with 2,2′-methylenebis(4-methyl-6-tert-butylphenol)	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
697	67515	0057583-34-3	monomethyltin tris(ethylhexyl mercaptoacetate)	yes	no	no		(9)		
698	49595	0057583-35-4	dimethyltin bis(ethylhexyl mercaptoacetate)	yes	no	no		(9)		
699	90720	0058446-52-9	stearoylbenzoylmethane	yes	no	no				
700	31520	0061167-58-6	acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	yes	no	yes	6			
701	40160	0061269-61-2	N,N′-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	yes	no	no	2,4			
702	87920	0061752-68-9	sorbitan tetrastearate	yes	no	no				
703	17170	0061788-47-4	fatty acids, coco	no	yes	no				
704	77600	0061788-85-0	polyethyleneglycol ester of hydrogenated castor oil	yes	no	no				
705	10599/90A 10599/91	0061788-89-4	acids, fatty, unsaturated (C_{18}), dimers, non hydrogenated, distilled and non-distilled	no	yes	no		(18)		(1)
706	17230	0061790-12-3	fatty acids, tall oil	no	yes	no				
707	46375	0061790-53-2	diatomaceous earth	yes	no	no				
708	77520	0061791-12-6	polyethyleneglycol ester of castor oil	yes	no	no	42			
709	87520	0062568-11-0	sorbitan monobehenate	yes	no	no				
710	38700	0063397-60-4	bis(2-carbobutoxyethyl)tin-bis (isooctyl mercaptoacetate)	yes	no	yes	18			
711	42000	0063438-80-2	(2-carbobutoxyethyl)tin-tris (isooctyl mercaptoacetate)	yes	no	yes	30			
712	42960	0064147-40-6	castor oil, dehydrated	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
713	43480	0064365-11-3	charcoal, activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC [4] with exception of ash content which can be up to 10 % (w/w).	
714	84400	0064365-17-9	rosin, hydrogenated, ester with pentaerythritol	yes	no	no				
715	46880	0065140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	yes	no	no	6			
716	60800	0065447-77-0	1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	yes	no	no	30			
717	84210	0065997-06-0	rosin, hydrogenated	yes	no	no				
718	84240	0065997-13-9	rosin, hydrogenated, ester with glycerol	yes	no	no				
719	65920	0066822-60-4	N-methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt -octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	yes	no	no				
720	67360	0067649-65-4	mono-n-dodecyltin tris(isooctyl mercaptoacetate)	yes	no	no		(25)		
721	46800	0067845-93-6	3,5-di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	yes	no	no				
722	17200	0068308-53-2	fatty acids, soya	no	yes	no				
723	88880	0068412-29-3	starch, hydrolysed	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
724	24903	0068425-17-2	syrups, hydrolysed starch, hydrogenated	no	yes	no			In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC [5]	
725	77895	0068439-49-6	polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	yes	no	no	0,05		The composition of this mixture is as follows: — polyethyleneglycol (EO = 2-6)monoalkyl (C_{16}-C_{18}) ether (approximately 28 %), — fatty alcohols (C_{16}-C_{18}) (approximately 48 %), — ethyleneglycol monoalkyl (C_{16}-C_{18}) ether (approximately 24 %),	
726	83599	0068442-12-6	reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	yes	no	yes		(9)		
727	43360	0068442-85-3	cellulose, regenerated	yes	no	no				
728	75100	0068515-48-0 0028553-12-0	phthalic acid, diesters with primary, saturated C_8-C_{10} branched alcohols, more than 60 % C_9	yes	no	no		(26) (32)	Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; (c) technical support agent in concentrations up to 0,1 % in the final product.	(7)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
729	75105	0068515-49-1 0026761-40-0	phthalic acid, diesters with primary, saturated C_9-C_{11} alcohols more than 90 % C_{10}	yes	no	no		(26) (32)	Only to be used as: (a) plasticiser in repeated use materials and articles; (b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; (c) technical support agent in concentrations up to 0,1 % in the final product.	(7)
730	66930	0068554-70-1	methylsilsesquioxane	yes	no	no			Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane	
731	18220	0068564-88-5	N-heptylaminoundecanoic acid	no	yes	no	0,05			(2)
732	45450	0068610-51-5	*p*-cresol-dicyclopentadiene-isobutylene, copolymer	yes	no	yes	5			
733	10599/92A 10599/93	0068783-41-5	acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled and non-distilled	no	yes	no		(18)		(1)
734	46380	0068855-54-9	diatomaceous earth, soda ash flux-calcined	yes	no	no				
735	40120	0068951-50-8	bis(polyethyleneglycol)hydroxymethylphosphonate	yes	no	no	0,6			
736	50960	0069226-44-4	di-n-octyltin ethyleneglycol bis-(mercaptoacetate)	yes	no	no		(10)		

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
737	77370	0070142-34-6	polyethyleneglycol-30 dipolyhydroxystearate	yes	no	no				
738	60320	0070321-86-7	2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl] benzotriazole	yes	no	yes	1,5			
739	70000	0070331-94-1	2,2′-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				
740	81200	0071878-19-8	poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino] hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]	yes	no	yes	3			
741	24070	0073138-82-6	resin acids and rosin acids	yes	yes	no				
	83610									
742	92700	0078301-43-6	2,2,4,4-tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	yes	no	yes	5			
743	38950	0079072-96-1	bis(4-ethylbenzylidene)sorbitol	yes	no	no				
744	18888	0080181-31-3	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no			The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I	
745	68145	0080410-33-9	2,2′,2′-nitrilo(triethyl tris(3,3′,5,5′-tetra-tert-butyl-1,1′-bi-phenyl-2,2′-diyl)phosphite)	yes	no	yes	5		SML expressed as sum of phosphite and phosphate	
746	38810	0080693-00-1	bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	yes	no	yes	5		SML expressed as sum of phosphite and phosphate	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
747	47600	0084030-61-5	di-n-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes		(25)		
748	12765	0084434-12-8	N-(2-aminoethyl)-β-alanine, sodium salt	no	yes	no	0,05			
749	66360	0085209-91-2	2,2′-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5			
750	66350	0085209-93-4	2,2′-methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5			
751	81515	0087189-25-1	poly(zinc glycerolate)	yes	no	no				
752	39890	0087826-41 – 30069158-41 – 40054686-97 – 40081541-12-0	bis(methylbenzylidene)sorbitol	yes	no	no				
753	62800	0092704-41-1	kaolin, calcined	yes	no	no				
754	56020	0099880-64-5	glycerol dibehenate	yes	no	no				
755	21765	0106246-33-7	4,4′-methylenebis(3-chloro-2,6-diethylaniline)	no	yes	no	0,05			(1)
756	40020	0110553-27-0	2,4-bis(octylthiomethyl)-6-methylphenol	yes	no	yes		(24)		
757	95725	0110638-71-6	vermiculite, reaction product with citric acid, lithium salt	yes	no	no				
758	38940	0110675-26-8	2,4-bis(dodecylthiomethyl)-6-methylphenol	yes	no	yes		(24)		
759	54300	0118337-09-0	2,2′-ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
760	83595	0119345-01-6	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	yes	no	no	18		Composition: — 4,4′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl) phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)), — 4,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl) phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)), — 3,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl) phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)), — 4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl) phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)), — tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)), — 4,4′-biphenylene-0,0-bis(2,4-di-tert-butylphenyl) phosphonate-0,0-bis(2,4-di-tert-butylphenyl) phosphonite (CAS No 0112949-97-0) (< 5 % w/w (*)) (*) Quantity of substance used/quantity of formulation Other specifications: — Phosphor content of min. 5,4 % to max. 5,9 %, — Acid value of max. 10 mg KOH per gram, — Melt range of 85–110 °C,	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
761	92930	0120218-34-0	thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)	yes	no	no	6			
762	31530	0123968-25-2	acrylic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenyl ester	yes	no	yes	5			
763	39925	0129228-21-3	3,3-bis(methoxymethyl)-2,5-dimethylhexane	yes	no	yes	0,05			
764	13317	0132459-54-2	N,N′-bis[4-(ethoxycarbonyl) phenyl]-1,4,5,8-naphthalenetetracarboxydiimide	no	yes	no	0,05		Purity > 98,1 % (w/w). Only to be used as co-monomer (max 4 %) for polyesters (PET, PBT).	
765	49485	0134701-20-5	2,4-dimethyl-6-(1-methylpentadecyl)phenol	yes	no	yes	1			
766	38879	0135861-56-2	bis(3,4-dimethylbenzylidene) sorbitol	yes	no	no				
767	38510	0136504-96-6	1,2-bis(3-aminopropyl) ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	yes	no	no	5			
768	34850	0143925-92-2	amines, bis(hydrogenated tallow alkyl) oxidised	yes	no	no			Not to be used for articles in contact with fatty foods for which simulant D is laid down. Only to be used in: (a) polyolefins at 0,1 % (w/w) concentration and in (b) PET at 0,25 % (w/w) concentration.	(1)
769	74010	0145650-60-8	phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	yes	no	yes	5		SML expressed as sum of phosphite and phosphate	
770	51700	0147315-50-2	2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05			
771	34650	0151841-65-5	aluminium hydroxybis [2,2′-methylenebis (4,6-di-tert-butylphenyl) phosphate]	yes	no	no	5			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
772	47500	0153250-52-3	N,N′-dicyclohexyl-2,6-naphthalene dicarboxamide	yes	no	no	5			
773	38840	0154862-43-8	bis(2,4-dicumylphenyl) pentaerythritol-diphosphite	yes	no	yes	5		SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl) pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)	
774	95270	0161717-32-4	2,4,6-tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite	yes	no	yes	2		SML expressed as sum of phosphite, phosphate and the hydrolysis product = TTBP	
775	45705	0166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	yes	no	no		(32)		
776	76723	0167883-16-1	polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4′-diisocyanate	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 1,5 % (w/w)	
777	31542	0174254-23-0	acrylic acid, methyl ester, telomer with 1-dodecanethiol, C_{16}-C_{18} alkyl esters	yes	no	no			0,5 % in final product	(1)
778	71670	0178671-58-4	pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	yes	no	yes	0,05			
779	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	yes	no	yes	0,05			(1)
780	81220	0192268-64-7	poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl) imino]]-α-[N,N,N′,N′-tetrabutyl-N″-(2,2,6,6-tetramethyl-4-piperidinyl)-N″-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N′,N′-tetrabutyl-1,3,5-triazine-2,4-diamine]	yes	no	no	5			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
781	95265	0227099-60-7	1,3,5-tris(4-benzoylphenyl) benzene	yes	no	no	0,05			
782	76725	0661476-41-1	polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	yes	no	no			The fraction with molecular weight below 1 000 Da should not exceed 1 % (w/w)	
783	55910	0736150-63-3	glycerides, castor-oil mono-, hydrogenated, acetates	yes	no	no		(32)		
784	95420	0745070-61-5	1,3,5-tris (2,2-dimethylpropanamido) benzene	yes	no	no	0,05			
785	24910	0000100-21-0	terephthalic acid	no	yes	no		(28)		
786	14627	0000117-21-5	3-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3-chlorophthalic acid	
787	14628	0000118-45-6	4-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 4-chlorophthalic acid	
788	21498	0002530-85-0	[3-(methacryloxy)propyl] trimethoxysilane	no	yes	no	0,05		Only to be used as a surface treatment agent of inorganic fillers	(1) (11)
789	60027	—	hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440–12 000)	yes	no	no			Average molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt ($3,8 \times 10^{-6}$ m^2/s).	(2)
790	80480	0090751-07-8 0082451-48-7	poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)] hexa-methylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]	yes	no	no	5		Average molecular weight not less than 2 400 Da. Residual content of morpholine ≤ 30 mg/kg, of N,N′-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine < 15 000 mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine ≤ 20 mg/kg.	(16)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
791	92470	0106990-43-6	N,N′,N″,N‴-tetrakis(4,6-bis (N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl) amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine	yes	no	no	0,05			
792	92475	0203255-81-6	3,3′,5,5′-tetrakis(tert-butyl)-2,2′-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propyl]oxyphosphonous acid	yes	no	yes	5		SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products	
793	94000	0000102-71-6	triethanolamine	yes	no	no	0,05		SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine	
794	18117	0000079-14-1	glycolic acid	no	yes	no			For indirect food contact only, behind a PET layer	
795	40155	0124172-53-8	N,N′-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N′-diformylhexamethylenediamine	yes	no	no	0,05			(2) (12)
796	72141	0018600-59-4	2,2′-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]	yes	no	yes	0,05		SML including the sum of its hydrolysis products	
797	76807	0007328-26-5	polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)		
798	92200	0006422-86-2	terephthalic acid, bis(2-ethylhexyl)ester	yes	no	no	60	(32)		
799	77708	—	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C_8-C_{22}) alcohols	yes	no	no	1,8		In compliance with the purity criteria for ethylene oxide as laid down in Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20.9.2008, p. 1)	
800	94425	0000867-13-0	triethyl phosphonoacetate	yes	no	no			Only for use in PET	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
801	30607	—	acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt	yes	no	no				
802	33105	0146340-15-0	alcohols, C_{12}-C_{14} secondary, β-(2-hydroxyethoxy), ethoxylated	yes	no	no	5			(12)
803	33535	0152261-33-1	α-alkenes(C_{20}-C_{24}) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine	yes	no	no			Not to be used for articles in contact with fatty foods for which simulant D is laid down. Not to be used in contact with alcoholic foods.	(13)
804	80510	1010121-89-7	poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid	yes	no	no			Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)	
805	93450	—	titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]	yes	no	no			The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w	
806	14876	0001076-97-7	1,4-cyclohexanedicarboxylic acid	no	yes	no	5		Only to be used for manufacture of polyesters	
807	93485	—	titanium nitride, nanoparticles	yes	no	no			No migration of titanium nitride nanoparticles. Only to be used in PET bottles up to 20 mg/kg. In the PET, the agglomerates have a diameter of 100 – 500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.	
808	38550	0882073-43-0	bis(4-propylbenzylidene) propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
809	49080	0852282-89-4	N-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl) phenoxy]-1H-benzo[de] isoquinolin-1,3(2H)-dione	yes	no	yes	0,05		Only for use in PET	(6) (14) (15)
810	68119		neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid	yes	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which simulant D is laid down.	
811	80077	0068441-17-8	polyethylene waxes, oxidised	yes	no	no	60			
812	80350	0124578-12-7	poly(12-hydroxystearic acid)-polyethyleneimine copolymer	yes	no	no			Only to be used in polyethylene terephthalate (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA) up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.	
813	91530	—	sulphosuccinic acid alkyl (C_4-C_{20}) or cyclohexyl diesters, salts	yes	no	no	5			
814	91815	—	sulphosuccinic acid monoalkyl (C_{10}-C_{16}) polyethyleneglycol esters, salts	yes	no	no	2			
815	94985	—	trimethylolpropane, mixed tri-esters and diesters with benzoic acid and 2-ethylhexanoic acid	yes	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which simulant D is laid down	
816	45704	—	cis-1,2-cyclohexanedicarboxylic acid, salts	yes	no	no	5			
817	38507	—	cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts	yes	no	no	5		Not to be used with polyethylene in contact with acidic foods. Purity ≥ 96 %.	
818	21530	—	methallylsulphonic acid, salts	no	yes	no	5			

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
819	68110	—	neodecanoic acid, salts	yes	no	no	0,05		Not to be used in polymers contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D is laid down. SML expressed as neodecanoic acid.	
820	76420	—	pimelic acid, salts	yes	no	no				
821	90810	—	stearoyl-2-lactylic acid, salts	yes	no	no				
822	71938	—	perchloric acid, salts	yes	no	no	0,05			(4)
823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5			
854	71943	0329238-24-6	perfluoro acetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy groups	yes	no	no			Only to be used in concentrations up to 0,5 % w/w in the polymerisation of fluoropolymers that are processed at temperatures at or above 340 °C and are intended for use in repeated use articles	
860	71980	0051798-33-5	perfluoro[2-(poly(n-propoxy))propanoic acid]	yes	no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles	
861	71990	0013252-13-6	perfluoro[2-(n-propoxy)propanoic acid]	yes	no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles	
862	15180	0018085-02-4	3,4-diacetoxy-1-butene	no	yes	no	0,05		SML including the hydrolysis product 3,4-dihydroxy-1-butene. Only for use as a co-monomer for ethyl vinyl alcohol copolymers.	

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
864	46330	0000056-06-4	2,4-diamino-6-hydroxypyrimidine	yes	no	no	5		Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and non-alcoholic aqueous food	
865	40619	0025322-99-0	(butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 1 %	
866	40620	—	(butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 7 %	
867	40815	0040471-03-2	(butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %	
868	53245	0009010-88-2	(ethyl acrylate, methyl methacrylate) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %	
869	66763	0027136-15-8	(butyl acrylate, methyl methacrylate, styrene) copolymer	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 3 %	
870	95500	0160535-46-6	N,N′,N″-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide	yes	no	no	5			
875	80345	0058128-22-6	poly(12-hydroxystearic acid) stearate	yes	no	yes	5			
878	31335	—	acids, fatty (C_8-C_{22}) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C_3-C_{22})	yes	no	no				
879	31336	—	acids, fatty (C_8-C_{22}) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C_1-C_{22})	yes	no	no				

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
880	31348	0085116-93-4	acids, fatty (C_8-C_{22}), esters with pentaerythritol	yes	no	no				
881	25187	0003010-96-6	2,2,4,4-tetramethylcyclobutane-1,3-diol	no	yes	no	5		Only for repeated use articles for long term storage at room temperature or below and hotfill	
882	25872	0002416-94-6	2,3,6-trimethylphenol	no	yes	no	0,05			
883	22074	0004457-71-0	3-methyl-1,5-pentanediol	no	yes	no	0,05		Only to be used in materials in contact with food at a surface to mass ratio up to 0,5 dm^2/kg	
884	34240	0091082-17-6	alkyl(C_{10}-C_{21})sulphonic acid, esters with phenol	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is laid down.	
885	45676	0263244-54-8	cyclic oligomers of (butylene terephthalate)	yes	no	no			Only to be used in poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and rigid poly(vinyl chloride) (PVC) plastics in concentrations up to 1 % w/w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature.	

(1) OJ L 302, 19.11.2005, p. 28.
(2) OJ L 330, 5.12.1998, p. 32.
(3) OJ L 253, 20.9.2008, p. 1.
(4) OJ L 226, 22.9.1995, p. 1.
(5) OJ L 158, 18.6.2008, p. 17.

2. **Group restriction of substances**

Table 2 on Group restrictions contains the following information:

Column 1 (Group restriction No): contains the identification number of the group of substances for which the group restriction applies. It is the number referred to in Column 9 in Table 1 of this Annex.

Column 2 (FCM substance No): contains the unique identification numbers of the substances for which the group restriction applies. It is the number referred to in Column 1 in Table 1 of this Annex.

Column 3 (SML (T) [mg/kg]): contains the total specific migration limit for the sum of substances applicable to this group. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column 4 (Group restriction specification): contains an indication of the substance whose molecular weight forms the basis for expression of the result.

Table 2

(1)	(2)	(3)	(4)
Group Restriction No	FCM substance No	SML (T) [mg/kg]	Group restriction specification
1	128 211	6	expressed as acetaldehyde
2	89 227 263	30	expressed as ethyleneglycol
3	234 248	30	expressed as maleic acid
4	212 435	15	expressed as caprolactam
5	137 472	3	expressed as the sum of the substances
6	412 512 513 588	1	expressed as iodine
7	19 20	1,2	expressed as tertiary amine
8	317 318 319 359 431 464	6	expressed as the sum of the substances
9	650 695 697 698 726	0,18	expressed as tin

(1)	(2)	(3)	(4)
10	28 29 30 31 32 33 466 582 618 619 620 646 676 736	0,006	expressed as tin
11	66 645 657	1,2	expressed as tin
12	444 469 470	30	expressed as the sum of the substances
13	163 285	1,5	expressed as the sum of the substances
14	294 368	5	expressed as the sum of the substances
15	98 196	15	expressed as formaldehyde
16	407 583 584 599	6	expressed as boron Without prejudice to the provisions of Directive 98/83/EC
17	4 167 169 198 274 354 372 460 461 475 476 485 490 653	ND	expressed as isocyanate moiety
18	705 733	0,05	expressed as the sum of the substances
19	505 516 519	10	expressed as SO_2
20	290 386 390	30	expressed as the sum of the substances
21	347 349	5	expressed as trimellitic acid

(1)	(2)	(3)	(4)
22	70 147 176 218 323 325 365 371 380 425 446 448 456 636	6	expressed as acrylic acid
23	150 156 181 183 184 355 370 374 439 440 447 457 482	6	expressed as methacrylic acid
24	756 758	5	expressed as the sum of the substances
25	720 747	0,05	sum of mono-n-dodecyltin tris(isooctylmercaptoacetate), di-n-dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
26	728 729	9	expressed as the sum of the substances
27	188 291	5	expressed as isophthalic acid
28	191 192 785	7,5	expressed as terephthalic acid
29	342 672	0,05	expressed as the sum of 6-hydroxyhexanoic acid and caprolactone
30	254 672	5	expressed as 1,4-butanediol
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138 140 157 159 207 242 283 532 670 728 729 775 783 797 798 810 815	60	expressed as the sum of the substances

3. **Notes on verification of compliance**

Table 3 on notes on verification of compliance contains the following information:

Column 1 (Note No): contains the identification number of the Note. It is the number referred to in Column 11 in Table 1 of this Annex.

Column 2 (Notes on verification of compliance): contains rules that shall be respected when testing for compliance of the substance with specific migration limits or other restrictions or it contains remarks on situations where there is a risk of non-compliance.

Table 3

(1)	(2)
Note No	Notes on verification of compliance
(1)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(3)	There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Article 3(1) c of the Framework Regulation (EC) No 1935/2004.
(4)	Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.
(5)	Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D2 (unstable).
(6)	Migration limit might be exceeded at very high temperature.
(7)	If testing in food is performed, Annex V 1.4 shall be taken into account.
(8)	Verification of compliance by residual content per food contact surface area (QMA); QMA = 0,005 mg/6 dm^2.
(9)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of analytical method for migration testing. The ratio surface to quantity of food shall be lower than 2dm^2/kg.
(10)	Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.
(11)	Only a method of analysis for the determination of the residual monomer in the treated filler is available.
(12)	There is a risk that the SML could be exceeded from polyolefins.
(13)	Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.
(14)	There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.
(15)	There is a risk that the SML could be exceeded in contact with foods with high alcoholic content.
(16)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods
(17)	Only a method for determination of the residual content of the substance in the polymer is available

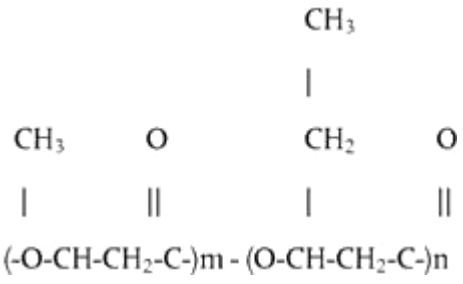
4. **Detailed specification on substances**

Table 4 on detailed specifications on substances contains the following information

Column 1 (FCM substance No): contains the unique identification number of the substances referred to in Column 1 in Table 1 of Annex I to which the specification applies.

Column 2 (Detailed specification on the substance): contains the specification on the substance.

Table 4

(1)	(2)	
FCM substance No	Detailed specification on the substance	
744	Definition	The copolymers are produced by the controlled fermentation of Alcaligenes eutrophus using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wildtype organism Alcaligenes eutrophus strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications
	Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)
	CAS number	0080181-31-3
	Structural formula	 where n/(m + n) greater than 0 and less or equal to 0,25
	Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromatography)
	Assay	Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydoxy-pentanoate) analysed after hydrolysis as a mixture of 3-D-hydro-xybutanoic and 3-D-hydroxypentanoic acids
	Description	White to off-white powder after isolation
	Characteristics Identification tests: Solubility	 Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
	Restriction	QMA for crotonic acid is 0,05 mg/6 dm^2
	Purity	Prior to granulation the raw material copolymer powder must contain:
	— nitrogen,	Not more than 2 500 mg/kg of plastic
	— zinc,	Not more than 100 mg/kg of plastic
	— copper,	Not more than 5 mg/kg of plastic
	— lead,	Not more than 2 mg/kg of plastic
	— arsenic,	Not more than 1 mg/kg of plastic
	— chromium,	Not more than 1 mg/kg of plastic

ANNEX II

Restrictions on materials and articles

1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

   Barium = 1 mg/kg food or food simulant.

   Cobalt = 0,05 mg/kg food or food simulant.

   Copper = 5 mg/kg food or food simulant.

   Iron = 48 mg/kg food or food simulant.

   Lithium = 0,6 mg/kg food or food simulant.

   Manganese = 0,6 mg/kg food or food simulant.

   Zinc = 25 mg/kg food or food simulant.

2. Plastic materials and articles shall not release primary aromatic amines, excluding those appearing in Table 1 of Annex I, in a detectable quantity into food or food simulant. The detection limit is 0,01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.

ANNEX III

Food simulants

1. **Food simulants**

For demonstration of compliance for plastic materials and articles not yet in contact with food the food simulants listed in Table 1 below are assigned.

Table 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Vegetable oil (*)	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

(*) This may be any vegetable oil with a fatty acid distribution of

No of carbon atoms in fatty acid chain: No of unsaturation	6-12	14	16	18:0	18:1	18:2	18:3
Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography	< 1	< 1	1,5-20	< 7	15-85	5-70	< 1,5

2. **General assignment of food simulants to foods**

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 shall be used for foods which contain free fats at the surface.

Food simulant E is assigned for testing specific migration into dry foods.

3. **Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food**

For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according Table 2 below.

For testing overall migration from materials and articles intended to come into contact with different food categories or a combination of food categories the food simulant assignment in point 4 is applicable.

Table 2 contains the following information:

Column 1 (Reference number): contains the reference number of the food category.

Column 2 (Description of food): contains a description of the foods covered by the food category

Column 3 (Food simulants): contains sub-columns for each of the food simulants

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 the cross is followed by an oblique stroke and a figure, the migration test result shall be divided by this figure before comparing the result with the migration limit. The figure is the correction factor referred to in point 4.2 of Annex V to this Regulation.

For food category 01.04 food simulant D2 shall be replaced by 95 % ethanol.

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4.5.

For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2 can be omitted if it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic food contact material.

Table 2

food category specific assignment of food simulants

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
01	**Beverages**						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						
	A. Clear drinks:		X(*)	X			
	Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract						
	B. cloudy drinks:		X(*)		X		
	juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate						
01.02	Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.			X			
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors				X		
01.04	Miscellaneous: undenaturated ethyl alcohol		X(*)			Substitute 95 % ethanol	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**						
02.01	Starches						X
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)						X
02.03	Cereal flour and meal						X
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta						X

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
02.05	Pastry, biscuits, cakes, bread, and other bakers' wares, dry:						
	A. With fatty substances on the surface					X/3	
	B. Other						X
02.06	Pastry, cakes, bread, dough and other bakers' wares, fresh:						
	A. With fatty substances on the surface					X/3	
	B. Other						X
03	**Chocolate, sugar and products thereof Confectionery products**						
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes					X/3	
03.02	Confectionery products:						
	A. In solid form:						
	I. With fatty substances on the surface					X/3	
	II. Other						X
	B. In paste form:						
	I. With fatty substances on the surface					X/2	
	II. Moist			X			
03.03	Sugar and sugar products						
	A. In solid form: crystal or powder						X
	B. Molasses, sugar syrups, honey and the like	X					
04	**Fruit, vegetables and products thereof**						
04.01	Whole fruit, fresh or chilled, unpeeled						
04.02	Processed fruit:						
	A. Dried or dehydrated fruits, whole, sliced, flour or powder						X
	B. Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products)		X(*)	X			
	C. Fruit preserved in a liquid medium:						
	I. In an oily medium					X	
	II. In an alcoholic medium				X		
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):						
	A. Shelled, dried, flaked or powdered						X
	B. Shelled and roasted						X
	C. In paste or cream form	X				X	

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
04.04	Whole vegetables, fresh or chilled, unpeeled						
04.05	Processed vegetables:						
	A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder						X
	B. Fresh vegetables, peeled or cut	X					
	C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine)		X(*)	X			
	D. Preserved vegetables:						
	I. In an oily medium	X				X	
	II. In an alcoholic medium				X		
05	**Fats and oils**						
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)					X	
05.02	Margarine, butter and other fats and oils made from water emulsions in oil					X/2	
06	**Animal products and eggs**						
06.01	Fish:						
	A. Fresh, chilled, processed, salted or smoked including fish eggs	X				X/3(**)	
	B. Preserved fish:						
	I. In an oily medium	X				X	
	II. In an aqueous medium		X(*)	X			
06.02	Crustaceans and molluscs (including oysters, mussels, snails)						
	A. Fresh within the shell						
	B. Shell removed, processed, preserved or cooked with the shell						
	I. In an oily medium	X				X	
	II. In an aqueous medium		X(*)	X			
06.03	Meat of all zoological species (including poultry and game):						
	A. Fresh, chilled, salted, smoked	X				X/4(**)	
	B. Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams	X				X/4(**)	
	C. Marinated meat products in an oily medium	X				X	
06.04	Preserved meat:						
	A. In an fatty or oily medium	X				X/3	
	B. In an aqueous medium		X(*)		X		
06.05	Whole eggs, egg yolk, egg white						
	A. Powdered or dried or frozen						X
	B. Liquid and cooked				X		

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
07	**Milk products**						
07.01	Milk						
	A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed				X		
	B. Milk powder including infant formula (based on whole milk powder)						X
07.02	Fermented milk such as yoghurt, buttermilk and similar products		X(*)		X		
07.03	Cream and sour cream		X(*)		X		
07.04	Cheeses:						
	A. Whole, with not edible rind						X
	B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese					X/3(**)	
	C. Processed cheese (soft cheese, cottage cheese and similar)		X(*)		X		
	D. Preserved cheese:						
	I. In an oily medium	X				X	
	II. In an aqueous medium (feta, mozarella, and similar)		X(*)		X		
08	**Miscellaneous products**						
08.01	Vinegar		X				
08.02	Fried or roasted foods:						
	A. Fried potatoes, fritters and the like	X				X/5	
	B. Of animal origin	X				X/4	
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents						
	A. Powdered or dried:						
	I. With fatty character					X/5	
	II. Other						X
	B. any other form than powdered or dried:						
	I. With fatty character	X	X(*)			X/3	
	II. Other		X(*)	X			
08.04	Sauces:						
	A. With aqueous character		X(*)	X			
	B. With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces	X	X(*)			X	
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A. With fatty substances on the surface	X				X/5	
	B. Other						X
08.07	Ice-creams			X			
08.08	Dried foods:						
	A. With fatty substances on the surface					X/5	
	B. Other						X
08.09	Frozen or deep-frozen foods						X
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.		X(*)		X		
08.11	Cocoa:						
	A. Cocoa powder, including fat-reduced and highly fat reduced						X
	B. Cocoa paste					X/3	
08.12	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered						X
08.13	Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom and others						X
08.14	Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other						X
08.15	Spices and seasoning in oily medium such as pesto, curry paste					X	

4. **Food simulant assignment for testing overall migration**

To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all types of food except for acidic foods testing in distilled water or water of equivalent quality or food simulant A and food simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and alcoholic foods and milk products testing in food simulant D1 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous, acidic and alcoholic foods and milk products testing in food simulant D1 and food simulant B shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C and food simulant B shall be performed.

ANNEX IV

Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

(1) the identity and address of the business operator issuing the declaration of compliance;

(2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;

(3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;

(4) the date of the declaration;

(5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004;

(6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;

(7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;

(8) specifications on the use of the material or article, such as:

(i) type or types of food with which it is intended to be put in contact;

(ii) time and temperature of treatment and storage in contact with the food;

(iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;

(9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

ANNEX V

COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

CHAPTER 1

Testing for specific migration of materials and articles already in contact with food

1.1. **Sample preparation**

The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety.

1.2. **Conditions of testing**

The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

1.3. **Analysis of migrated substances**

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

1.4. **Special cases**

When contamination occurs from sources other than food contact materials this has to be taken into account when testing for compliance of the food contact materials, in particular for phthalates (FCM substance 157, 159, 283, 728, 729) referred to in Annex I.

CHAPTER 2

Testing for specific migration of materials and articles not yet in contact with food

2.1. **Verification method**

Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests according to the rules set out in paragraphs 2.1.1 to 2.1.7.

2.1.1. *Sample preparation*

The material or article shall be treated as described by accompanying instructions or by provisions given in the declaration of compliance.

Migration is determined on the material or article or, if this is impractical, on a specimen taken from the material or article, or a specimen representative of this material or article. For each food simulant or food type, a new test specimen is used. Only those parts of the sample which are intended to come into contact with foods in actual use shall be placed in contact with the food simulant or the food.

2.1.2. *Choice of food simulant*

Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.

Materials and articles intended only for specific types of foods shall be tested with the food simulants indicated for the food types in Annex III.

2.1.3. *Conditions of contact when using food simulants*

The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

Table 1

Contact time

Contact time in worst foreseeable use	Test time
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

Table 2

Contact temperature

Conditions of contact in worst foreseeable use	Test conditions
Contact temperature	Test temperature
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C (*)
121 °C < T ≤ 130 °C	130 °C (*)
130 °C < T ≤ 150 °C	150 °C (*)
150 °C < T < 175 °C	175 °C (*)
T > 175 °C	Adjust the temperature to the real temperature at the interface with the food (*)

(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

2.1.4. *Specific conditions for contact times above 30 days at room temperature and below*

For contact times above 30 days at room temperature and below the specimen shall be tested in an accelerated test at elevated temperature for a maximum of 10 days at 60 °C. Testing time and temperature conditions shall be based on the following formula.

t2 = t1 * Exp ((-Ea/R) * (1/T1-1/T2))

Ea is the worst case activation energy 80kJ/mol

R is a factor 8,31 J/Kelvin/mol

Exp -9627 * (1/T1-1/T2)

t1 is the contact time

t2 is the testing time

T1 is the contact temperature in Kelvin. For room temperature storage this is set at 298 K (25 °C). For refrigerated and frozen conditions it is set at 278 K (5 °C).

T2 is the testing temperature in Kelvin.

Testing for 10 days at 20 °C shall cover all storage times at frozen condition.

Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Testing for 10 days at 50 °C shall cover all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes and storage times of up to 6 months at room temperature.

Testing for 10 days at 60 °C shall cover long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

The maximum testing temperature is governed by the phase transition temperature of the polymer. At the test temperature the test specimen should not undergo any physical changes.

For storage at room temperature testing time can be reduced to 10 days at 40 °C if there is scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

2.1.5. *Specific conditions for combinations of contact times and temperature*

If a material or article is intended for different applications covering different combinations of contact time and temperature the testing should be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

2.1.6. *Repeated use articles*

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

The material or article shall respect the specific migration limit already in the first test for substances for which in Annex I Table 1 column 8 or Table 2 column 3 the specific migration limit is set as non-detectable and for non-listed substances used behind a plastic functional barrier covered by the rules of point (b) of Articles 13(2) which should not migrate in detectable amounts.

2.1.7. *Analysis of migrating substances*

At the end of the prescribed contact time, the specific migration is analysed in the food or food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

2.1.8. *Verification of compliance by residual content per food contact surface area (QMA)*

For substances which are unstable in food simulant or food or for which no adequate analytical method is available it is indicated in Annex I that verification of compliance shall be undertaken by verification of residual content per 6 dm^2 of contact surface. For materials and articles between 500 ml and 10 l the real contact surface is applied. For materials and articles below 500 ml and above 10 l as well as for articles for which it is impractical to calculate the real contact surface the contact surface is assumed to be 6 dm^2 per kg food.

2.2. **Screening approaches**

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described in section 2.1.

2.2.1. *Replacing specific migration by overall migration*

To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.

2.2.2. *Residual content*

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration.

2.2.3. *Migration modelling*

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration.

2.2.4. *Food simulant substitutes*

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants overestimate migration compared to the regulated food simulants.

CHAPTER 3

Testing for overall migration

Overall migration testing shall be performed under the standardised testing conditions set out in this chapter.

3.1. **Standardised testing conditions**

The overall migration test for materials and articles intended for the food contact conditions described in column 3 of Table 3 shall be performed for the time specified and at the temperature specified in column 2. For test OM5 the test can be performed either for 2 hours at 100 °C (food simulant D2) or at reflux (food simulant A, B, C, D1) or for 1 hour at 121 °C. The food simulant shall be chosen in accordance with Annex III.

If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

Table 3

Standardised testing conditions

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C]	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
OM3	2 h at 70 °C	Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM4	1 h at 100 °C	High temperature applications for all food simulants at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM 7 covers also food contact conditions described for OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM1 and OM3.

3.2. **Substitute test for OM7 with food simulant D2**

In case it is technically NOT feasible to perform OM7 with food simulant D2 the test can be replaced by test OM 8 or OM9. Both test conditions described under the respective test shall be performed with a new test sample.

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
OM 8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only	OM1, OM3, OM4, OM5, and OM6
OM 9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6

3.3. **Repeated use articles**

Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the food simulant on each occasion.

Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the overall migration limit is not exceeded on the first test, no further test is necessary.

3.4. **Screening approaches**

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described in sections 3.1. and 3.2.

3.4.1. *Residual content*

To screen for overall migration the migration potential can be calculated based on the residual content of migratable substances determined in a complete extraction of the material or article.

3.4.2. *Food simulant substitutes*

To screen for overall migration food simulants can be replaced if based on scientific evidence the substitute food simulants overestimate migration compared to the regulated food simulants.

CHAPTER 4

Correction factors applied when comparing migration test results with migration limits

4.1. **Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF)**

For lipophilic substances for which in Annex I it is indicated in column 7 that the FRF is applicable the specific migration can be corrected by the FRF. The FRF is determined according to the formula FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100.

The FRF shall be applied according to the following rules.

The migration test results shall be divided by the FRF before comparing with the migration limits.

The correction by the FRF is not applicable in the following cases:

(a) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC;

(b) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

4.2. **Correction of migration into food simulant D2**

For the food categories where in sub-column D2 of column 3 of Table 2 of Annex III the cross is followed by a figure the migration test result into food simulant D2 shall be divided by this figure.

The migration test results shall be divided by the correction factor before comparing with the migration limits.

The correction is not applicable to the specific migration for substances in the Union list in Annex I for which the specific migration limit in column 8 is 'not detectable' and for non-listed substances used behind a plastic functional barrier covered by the rules of Article 13(2)(b) which should not migrate in detectable amounts.

4.3. **Combination of correction factors 4.1 and 4.2.**

The correction factors described in 4.1 and 4.2 can be combined for migration of substances for which the FRF is applicable when testing is performed in food simulant D2 by multiplying both factors. The applied maximum factor shall not exceed 5.

ANNEX VI

Correlation tables

Directive 2002/72/EC	This Regulation
Article 1(1)	Article 1
Article 1(2), (3) and (4)	Article 2
Article 1a	Article 3
Article 3(1), Article 4(1) and Article 5	Article 5
Article 4(2), Article 4a(1) and (4), Article 4d, Annex II (2) and (3) and Annex III (2) and (3)	Article 6
Article 4a(3) and (6)	Article 7
Annex II (4) and Annex III (4)	Article 8
Article 3(1) and Article 4(1)	Article 9
Article 6	Article 10
Article 5a(1) and Annex I (8)	Article 11
Article 2	Article 12
Article 7a	Article 13
Article 9(1) and (2)	Article 15
Article 9(3)	Article 16
Article 7 and Annex I (5a)	Article 17
Article 8	Article 18
Annex II (3) and Annex III (3)	Article 19
Annex I, Annex II, Annex IV, Annex IVa, Annex V Part B, and Annex VI	Annex I
Annex II (2), Annex III (2) and Annex V, Part A	Annex II
Article 8(5) and Annex VIa	Annex IV
Annex I	Annex V

Directive 93/8/EEC	This Regulation
Article 1	Article 11
Article 1	Article 12
Article 1	Article 18
Annex	Annex III
Annex	Annex V

Directive 97/48/EC	This Regulation
Annex	Annex III
Annex	Annex V

Title. THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2012	Impact Assessment (IA)
	Date: 10/01/2012
IA No: FOOD0027	**Stage:** Consultation
Lead department or agency:	**Source of intervention:** EU
FOOD STANDARDS AGENCY	**Type of measure:** Secondary legislation
Other departments or agencies:	**Contact for enquiries:** Nasreen Shah, Tel: 020 7276 8553 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**
£0.07m	£0.055m	-£0.006	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.

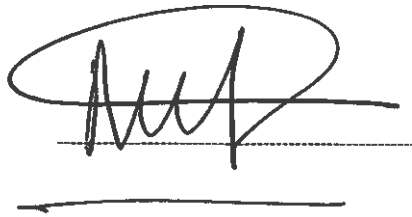
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

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 – make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation only.
3. Option 3 – make appropriate domestic Regulations 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 (other than the 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** No	**< 20** No	**Small** No	**Medium** No	**Large** No
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 Chief Executive:  Date: 9/1/12

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 £114,440 (an EAC of £13,295) 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	**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

The number of businesses affected by this proposal is 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:** 0.07

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 £114,440 (an EAC of £13,295) 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		0.023	**0.20**

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 £19,686 per year with a NPV over 10 years of £169,447. Public Sector benefits will equal £3645 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

The number of businesses affected by this proposal is 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: 0.02**	**Net:-0.006**	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 negative 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 to regulate 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.

4. 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 Regulation aims to protect consumer health in an area of food control where inadequate controls could have serious long-term implications, or are seriously suspected of carrying unacceptable risk 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.

5. 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.

6. The legislative response is designed to overcome market failures that may lead to an inefficient market response to food safety. In this case, government intervention is necessary to ensure preventative measures are taken to prevent negative impacts on public health being realised.

7. In response to the Westminster Government's Red Tape Challenge, the FSA is developing in England a simplified system of food safety legislation, including the consolidation of a number of Statutory Instruments. The consolidation proposed under Option 3, is part of this simplification.

8. 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.

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

Policy objective/Intended Effect

9. 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 Food Standards Agency's response to the Government's Red Tape Challenge 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 being 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 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.

10. The England national Regulations being revoked are:

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

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

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

   d) 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

11. 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 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.

12. 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

[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

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

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.

13. 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

14. In April 2011 the Westminster 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 Food Standards Agency's (FSA's) legislation was published on the RTC under the Hospitality Theme and remained on the site until 2 June 2011. In response to the RTC, the FSA will be developing a simplified system of food safety legislation, including the consolidation of a number of domestic Statutory Instruments. 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.

15. 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");

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 plastics,

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

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

[11] Ref: OJ L87, 2.4.2011, p1

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

[13] SI 2010 No. 2225

[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.

Consultation question 1

a). 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?

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

16. 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)

17. 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.

18. 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 and the time limit has now expired.

Consultation Question 2

Stakeholders are asked to comment on the omission of regulations 11 and regulation 12 of the current 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.

Provisions on Vinyl Chloride Monomer (VCM)

19. 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 ll of the new EU Regulation. This is based on the assumption that Directive 78/142/EEC may now be redundant (though not repealed). 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.

20. The proposed consolidated Regulations will not re-enact the provisions on VCM, which were contained in regulation 8 and 9 of the FCM Regulations, for the reasons given above.

> ***Consultation Question 3***
>
> *Stakeholders are asked to comment on the omission of the content of regulations 8 and 9 of the current FCM 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, please provide evidence to support your views.*

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

21. 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[15], 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[16],

22. Regulation 9 and 10 of the proposed consolidated Regulations reproduces the operative provisions of the Ceramic Articles in Contact with Food (England) Regulations 2006[17], 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, which is not relevant as 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

23. 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[18] 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.

24. 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[19]. The EC Regulation permitted the use of BADGE[20] 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[21] and NOGE[22].

25. 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

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15 Ref: OJ L277, 20.10.1984

16 SI 1988 No. 1647

17 SI No. 2006 No. 1179 as amended by SI 2007 No. 2790

18 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.

19 Ref OJ L302, 19.11.2005, pg 28-32

20 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether

21 Bis(2,3-epoxypropyl) ethers

22 Novolac glycidyl ethers

consolidated Regulations with some textual changes. As the provisions of the EC Regulation have not changed, it is not anticipated that there will be a new or additional burden on business or enforcement authorities.

26. The 2009 Regulations were amended recently to take account of the provisions of Commission Directive 2011/8/EC[23] (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[24] 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 prohibits the placing on the market in, import into, England 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.

Consultation Question 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 four principal national measures on food contact materials and articles into a single Statutory Instrument.

We would also welcome comments on the proposed consolidated 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 other benefits accruing to the consolidation of the national Regulations in a single set of Regulations.

Options Considered

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

27. 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 the 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

28. 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 hence may, lead to the UK being liable to infraction proceedings.

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

29. 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.

30. 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

31. This is the preferred option.

[23] Ref OJ L26, 29.1.2011, pg 11

[24] SI 2011 No. 231

32. 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 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.

33. 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.

34. 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** of food contact plastic products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment (see annex A1 for further details). Note that plastics manufacturing includes those businesses which process plastics into food contact material forms.
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** of food contact plastic products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment and, in addition, manufacturers 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** of food and beverages, including retailers of food via markets and stalls; **IMPORTERS** of food contact materials

Consultation question 5

Table 1 above 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.

Sectors Affected

Industry

35. Only options 2 and 3 set out in this Impact Assessment will affect UK manufacturers 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).

36. Any likely costs to Industry associated with the proposed consolidated Regulations relate only to the businesses that manufacture plastic materials and articles intended to come into contact with food (including articles such as food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment) not the whole packaging industry. The options will apply equally to all businesses in this sector regardless of size.

37. Option three will additionally have an impact on any UK manufacturers, importers and retailers of any food contact material products (not just plastics) as the simplification of the existing four Regulations extends beyond the plastics food contact materials industry.

38. 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 the actual subsection that is 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

39. For Option 2, affected parties will be limited to the food contact materials plastics manufacturing sector. 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.

Importers

40. 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 as a subsection of its own. We are therefore, unable to present results for this subsection separately. However, this subsector is included in the classification of the other sectors identified (manufacturers and retailers).

Retailers

41. 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. Option 2 will have no impact on retailers

Summary of businesses affected

42. 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	Food contact plastic products including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment	Manufacturers	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 retailers of food via markets and stalls
		Importers	Importers of food contact materials

43. 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

44. 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 3: Option 2: Sectors Affected by the Regulation, by Country

Industry	England	Wales	Scotland	NI	UK
Plastic Manufacture	2,192	112	108	84	2,496
Total	2,192	112	108	84	2,496

Source: Table constructed by FSA based on IDBR 2010, Table B3.14

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

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

Industry	England	Wales	Scotland	NI	UK
Plastic Manufacture	2,192	112	108	84	2,496
Other Manufacture	1,756	92	120	44	2,012
Retailers	35,328	2,088	3,912	1,492	42,820
Total	**39,276**	**2,292**	**4,140**	**1,620**	**47,328**

Source: Table constructed by FSA based on IDBR 2010, Table B3.14

Consultation question 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?

Enforcement Authorities

45. Enforcement Authorities (EAs) and public official control laboratories (OCLs) will also be affected by this policy as they will be required to read and familiarise 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

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

Source: FSA internal data

Consultation question 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.

Option Appraisal

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

46. 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 assessed.

47. By not intervening in this market 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.

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

COSTS

Costs to Enforcement Authorities

One-Off Costs

48. 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.

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

50. Either an Environmental Health Officer (EHO) or a Trading Standards Officer (TSO) in each LA, PHA or OCL will be required to familiarise themselves with the new enforcement provisions. In order to account for the differences across enforcement authorities[25], 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[26]) and as the upper bound the median hourly wage rate of a TSO (£21.01[27]). This gives us a central estimate of £20.74. For all sensitivity analysis see Annex

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

[26] 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).

[27] 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).

A2. 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[28].

51. We assume that one enforcement officer per EA and one science professional per OCL is required for familiarisation. We further assume that it will take one hour per officer to familiarise themselves, and further one hour to disseminate this information within their organisation. 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). For OCLs the familiarisation cost is £48.20. 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

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	5	4	1	329
Familiarisation Cost LAs	14,680	912	1,327	1,078	17,998
Familiarisation Cost PHA	1,617	41	0	0	1,659
Familiarisation Cost OCL	916	193	337	96	1,687
Total (Central)	**17,214**	**1,147**	**1,664**	**1,175**	**21,344**

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.

Consultation question 8

It is our assumption that it will take EAs and OCLs one hour to familiarise themselves and one hour to disseminate the new 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.

Equivalent Annual Costs (EAC)

52. 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.[29]

53. 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: Equivalent Annual Costs (£) to Enforcement Authorities by UK country

Country	EAC
England	2,000
Wales	139
Scotland	177
Northern Ireland	131

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

[29] 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:

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

UK Total	2,446

Notes: Totals may not sum due to rounding

Costs to Industry

One-Off Costs

54. Under Option 2, there will be a one-off cost to industry for reading and familiarising with the new consolidated Regulations. The only businesses affected are manufacturers of plastic articles and materials that are intended to come into contact with food. We have assumed that it is the plant production manager that will be responsible for familiarisation. These transition costs are quantified by estimating the time it will take for the manager to familiarise himself (herself) with the Regulations, multiplying by the wage rate of the manager and the number of officials that will be required to familiarise themselves.

55. The median hourly wage rate of a production manager is £26.10[30]. We assume that one production manager per plant will face familiarisation costs. We further assume that it will take a production manager one hour for familiarisation and another hour to disseminate the information within the organisation.

56. To calculate total familiarisation costs to the UK Industry by firm size and industry we have used the Interdepartmental Business Register (IDBR)[31]; note that the sectors are summarised in Table A1 in the Annex. 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

	England	Wales	Scotland	NI	UK
Micro	75,926	3,879	3,741	2,910	86,456
Small	28,427	1,452	1,401	1,089	32,369
Medium	8,986	459	443	344	10,233
Large	1,100	56	54	42	1,253
Total	114,440	5,847	5,638	4,385	**130,311**

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.

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

Equivalent Annual Costs (EAC)

57. 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 Industry, by UK Country

Country	EAC

[30] 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).
[31] http://www.ons.gov.uk/ons/about-ons/who-we-are/services/unpublished-data/business-data/idbr/index.html

England	13,295
Wales	679
Scotland	655
Northern Ireland	509
UK Total	15,139

Note: Totals may not sum due to rounding

BENEFITS

Benefits to Enforcement Authorities

58. There may be potential benefits to enforcement authorities as a result of 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, 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. As such, no quantification is provided here.

Consultation question 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.

Benefits to Industry

59. 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

60. 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. We would welcome Industry views on how the changes to testing will have an impact on business costs.

Consultation question 11

It is our assumption that there is a sampling and testing benefit to businesses as a result of changes to the new EU legislation. 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.

61. 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.

Consultation question 12

a) 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.

Public Health Benefits

62. 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.

Summary of Costs and Benefits to England under Option 2

63. Table 10 below shows a summary of total costs and benefits to England under Option 2. These costs have been categorised according to whether they are one-off costs or ongoing costs. To note; there are also health benefits from these options which are described above (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	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
One-Off Costs: Familiarisation												
Industry (plastics manufacture)	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	132,951	£114,440
Enforcement Authorities and OCLs	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	19,998	£17,214
Total	15,295	15,295	15,295	15,295	15,295	15,295	15,295	15,295	15,295	15,295	152,949	131,654

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

64. Option 3 will require manufacturers of plastic food contact materials (and EAs) to become familiar and comply with the new EU Regulation (as with option 2) but will also provide benefits to new market entrants of all affected contact materials sectors through consolidation and simplification of the existing food contact materials legislation. Costs and benefits of this option are set out below.

Costs to Public Sector (LAs, PHAs and OCLs)

65. There will be a one-off cost to EAs and OCLs for reading and familiarising themselves with the new EU Regulation. The familiarisation costs under Option 3 will be the same as under Option 2; these

are reported in Table 6. EAs and OCLs will also have to be made aware of the changes to the new consolidated legislation. However, additional familiarisation will not be required as the simplification and consolidation will not make any material difference to the enforcement of the proposed consolidated Regulations as they currently stand and EAs will be informed of this by the FSA through standard alerts/updates.

Consultation question 13

a) 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 material 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.*

Costs to Industry

One-Off Costs

66. 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. The one-off familiarisation costs to plastics manufacturers will be the same under Option 3 as under Option 2. Familiarisation costs under Option 3 are reported in Table 8 and the corresponding EACs in Table 9. As these tables show, the total familiarisation cost for England is approximately £114K, whilst the corresponding number for the UK is approximately £130K. The EACs are approximately £13K for England and £15K for the UK.

Consultation question 14

a). 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.

67. Costs to business of this option do not extend beyond plastics manufacturers. This is because businesses currently in the food contact materials sector (outside of plastics) will not have to do anything additional, or change anything they currently do as a result of the consolidation/simplification. New entrants into these markets will however be able to realise benefits from simplification – these are estimated below.

BENEFITS

Benefits to EAs

68. Under Option 3, there will be benefits accruing to simplification. The consolidation of existing 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.

69. We assume that the simplification will lead to a reduction in the time it takes for new entrants into an EA/OCL to understand the legislation. We assume this will lead to a time reduction from two hours to one.

70. At present we have been unable to assess the number of EAs that will be able to benefit from the simplification and so we have used an approximation based on the number of newly registered EHOs per annum (average of data from 2007 to 2010)[32]. We would welcome comments on whether EAs feel this is a reasonable assessment.

71. To estimate benefits we multiply the wage rate (central estimate) for a TSO/EHO (£20.74) by one hour and the number of staff employed in EAs that are affected. This yields a total annual benefit for England of £3,645.

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

	England	Wales	Scotland	NI
Annual Benefit	3,645	213	297	241

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

72. In addition, data from the HPA indicates that OCLs employ less than 1 new PA per year. Based on this evidence we have omitted potential benefits to OCLs as they are likely to be negligible.

73. 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.[33] The ongoing benefits are set out in table 12 below.

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

Ongoing Benefit: Simplification	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Benefit	NPV
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

74. Under Option 3, there will be benefits accruing from simplification. The consolidation of existing 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[34]). New entrant businesses affected by this proposal are those that may be categorised as: manufacturers and retailers of articles and materials that are intended to come into contact with food, including manufacturers of plastics, ceramics, aluminium, lead, zinc and tin. This is extended to retailers 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.

75. We assume that the simplification will lead to a reduction in the time it takes for new entrants to understand 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

[32] Data provided by CIEH

[33] 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'.

[34] 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

hourly wage rate of a production manager is £26.10[35]. Additionally, we assume that the legislation will impact on 1 production manager per firm.

76. To get an estimate of the new entrants of the relevant manufacturers and retailers we have used the ONS Business Demography dataset[36]. The data in this dataset is only available at the UK level. To account for this we have used the proportion of IDBR businesses in each sector and UK country, to produce numbers on lower levels of aggregation. The latest data is from 2009, which does not constitute a typical year, due to the recession. We have therefore 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.

77. Note that in order to maintain consistency across estimation of costs and benefits we have assumed a central estimate of 80% of the identified sectors will be affected by this proposal (for a full discussion see the 'Sectors Affected' section).

Table 13: Enterprise Birth in UK Food Contact Materials Manufacturing and Retail

	England	Wales	Scotland	NI	UK
Plastics Manufacture	639	33	32	25	728
Other Manufacture	4,567	239	312	114	5,233
Food Retail	1,536	91	170	65	1,861
Total	6,491	379	684	268	7,822

Note: Totals may not sum due to rounding

78. Table 14 shows the total simplification benefits by firm size and UK country to manufacturers of food contact materials, and retailers of food and beverages:

Table 14: Ongoing Simplification Benefits (£) to UK Manufacturers by Firm Size and UK Country

	England	Wales	Scotland	NI	UK
Micro	152,276	8,886	16,051	6,281	183,494
Small	14,765	862	1,556	609	17,792
Medium	1,991	116	210	82	2,399
Large	415	24	44	17	500
Total	169,447	9,888	17,861	6,989	**204,185**

Note: Totals may not sum due to rounding

79. 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.[37]

80. 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)

Ongoing Benefit: Simplification	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Benefit	NPV

[35] 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).

[36] http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-199624

[37] 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'.

Industry	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	196,855	169,447

Consultation question 15

It is our assumption that there is a simplification benefit for businesses associated with the proposed consolidate 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.

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.

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

Option 3												
One-Off Costs: Familiarisation	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
Industry	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	132,951	114,440
Enforcement Authorities	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000	19,998	£17,214
Total	15,295	15,295	15,295	15,295	15,295	15,295	15,295	15,295	15,295	15,295	152,949	131,654
Ongoing Benefit: Simplification	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
Industry	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	196,855	169,447
Enforcement Authorities	3,645	3,645	3,645	3,645	3,645	3,645	3,645	3,645	3,645	3,645	36,446	31,372
Total	23,330	23,330	23,330	23,330	23,330	23,330	23,330	23,330	23,330	23,330	233,302	200,819
Total Net Cost	-8,035	-8,035	-8,035	-8,035	-8,035	-8,035	-8,035	-8,035	-8,035	-8,035	-80,353	-69,165
Total Net Cost to Business	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-63,905	-55,007

Consultation

Within Government

81. 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.

82. 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.

83. 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.

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

Enforcement

85. 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

86. 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

87. 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

88. 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 reflect the impact on these businesses and we do not consider the impact on small businesses to be significant.

Small Business Impact Test

89. We do not consider the impact on small businesses to be significant. This view has been supported by industry and the Office of Fair Trading following earlier consultations on directly applicable European Regulations and during the 2006 and 2008 consultations on the on the plastic materials and articles in contact with food legislation. Small and Medium sized businesses are always encouraged to respond to issues which they may feel have an impact on their ability to compete in the wider market.

Consultation question 16

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

Sustainability

90. 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

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

Annexes

92. 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 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	

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

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	924	1,345	1,092	18,235
Central	14,680	912	1,327	1,078	17,998
High	14,487	900	1,310	1,064	17,761
Familiarisation Cost PHA					
Low	1,639	42	0	0	1,681
Central	1,617	41	0	0	1,659
High	1,596	41	0	0	1,637
Familiarisation Cost OCL					
Central	916	193	337	96	1,687
Total (Low)	**17,428**	**1,159**	**1,682**	**1,189**	**21,603**
Total (Central)	**17,214**	**1,147**	**1,664**	**1,175**	**21,344**
Total (High)	**16,999**	**1,134**	**1,647**	**1,160**	**21,085**

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)

Scenario 1 - Maximum number of businesses affected (100%)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total Cost	NPV
Total cost to business	16,619	16,619	16,619	16,619	16,619	16,619	16,619	16,619	16,619	16,619	166,189	143,050
Benefit to business	24,607	24,607	24,607	24,607	24,607	24,607	24,607	24,607	24,607	24,607	246,069	211,809
Net costs to business	-7,988	-7,988	-7,988	-7,988	-7,988	-7,988	-7,988	-7,988	-7,988	-7,988	-79,881	-68,759
Scenario 2 - Central Estimate (80%)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 9	Year 9
Total cost to business	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	13,295	132,951	114,440
Benefit to business	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	19,686	196,855	169,447
Net costs to business	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-6,390	-63,905	-55,007
Scenario 3 - Minimum number of businesses affected (50%)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 9	Year 9
Total cost to business	8,309	8,309	8,309	8,309	8,309	8,309	8,309	8,309	8,309	8,309	83,094	71,525
Benefit to business	12,303	12,303	12,303	12,303	12,303	12,303	12,303	12,303	12,303	12,303	123,035	105,904
Net costs to business	-3,994	-3,994	-3,994	-3,994	-3,994	-3,994	-3,994	-3,994	-3,994	-3,994	-39,940	-34,379

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[38] 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.

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

Annex E

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

Company
AMDEA
Alba Plastics
Association of Consumer Research
Association of Port Health Authorities
Bird and Bird
Boots UK Limited
Boots PDQ Centre
British Adhesives and Sealants Association
British Ceramics Confederation
British Coatings Federation
British Plastics Federation
British Retail Consortium
British Soft Drinks Association
British Specialist Nutrition Association
British Standards Institute
CATRA
Cadbury Schweppes
Campden & Chorleywood Food Research Association
Catering Equipment Suppliers Association
Centre for Analytical Research in the Environment
Chemical Industries Association
Chilled Food Association
CHEM Trust
Colormatrix Europe
Confederation of Paper Industries
Costco
Crown Corporate Technologies
Dairy Industry Federation
Danapak Flexibles Limited
Department for the Environment, Food and Rural Affairs
Business, Innovation and Skills
Dexter Packaging Products
Eclipse Scientific Group
Enterprise Directorate
Federation of Small Businesses
The Food and Environment Research Association
Food And Drink Federation
Food Solutions
Food Policy Update
H J Heinz
Halton Borough Council
Home Retail Group
INEOS Vinyls

Annex E

Industry Council for Packaging and the Environment
Innovia Films
JWP Ltd
Kenwood Limited
Kirkstone Plastics Limited
Kitchencraft
Laboratory of the Government Chemist
Local Government Regulation
LINPAC Packaging Limited
London Port Health Authority
Lovell White Durrant
Marks & Spencer Plc
Meridian Speciality Packaging
Metal Packaging Manufacturers Association
Nippon Gohsei
Office of Fair Trading
Packaging and Films Association
Pillsbury Europe
Philips Avent
PIRA International
Plastics Europe
Price Waterhouse Coopers
Provision Trade Federation
Pulse Speciality Products
RAPRA Technology Limited
RDA Packaging Consultants
Rexam Plastic Packaging
Sinclair International Limited
Suffolk and Coastal District Council
Technical Indexes
The Co-operative Retail Group (CWS) Ltd
The Industrial Packaging Association
Toxicology Advice & Consulting Limited
Trading Standards Institute
UNIVAR Limited
Weetabix Limited
WHICH
Wilsanco Plastics Limited
Wyeth Consumer Healthcare ER&D