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FOOD STANDARDS AGENCY CONSULTATION

EUROPEAN COMMISSION REGULATION INTRODUCING CHANGES TO THE CONDITIONS AND LEVELS OF USE FOR FOOD ADDITIVES CONTAINING ALUMINIUM

CONSULTATION SUMMARY PAGE

Date consultation launched:	**Closing date for responses:**
11th January 2013	**5th April 2013**

Who will this consultation be of most interest to?

Manufacturers of E 541 Sodium Aluminium Phosphate (SALP), Ingredients manufacturers and businesses using SALP in their products. The consultation may also be of interest to health professionals, consumer groups, local authorities and others with an interest in food additives legislation.

What is the subject of this consultation?

New EU legislation has been introduced which restricts the use of aluminium-containing food additives such as aluminium silicates (commonly used in as anti-caking agents), and aluminium lakes of colours. The legislation also restricts the use of Sodium Aluminium Phosphate (SALP) as a raising agent to one product only, sponge cakes produced from contrasting coloured segments held together by jam or spreading jelly and encased by a flavoured sugar paste (i.e. Battenberg style cakes)

What is the purpose of this consultation?

To provide stakeholders with an opportunity to comment on the attached Impact Assessment; this has been prepared to assess the costs associated with the changes outlined in the new EU legislation. The consultation is being used as a means of providing stakeholders with an opportunity to comment on the likely financial impact arising from the restrictions on the use of aluminium containing additives.

Responses to this consultation should be sent to:

Name: Nasreen Shah **Division/Branch : Chemical Safety Division** **FOOD STANDARDS AGENCY** **Tel: 020 7276 8538** **Fax: 020 7276 8446**	**Name: Nasreen Shah** **Division/Branch : Chemical Safety Division** **FOOD STANDARDS AGENCY** **Tel: 020 7276 8538** **Fax: 020 7276 8446**

Is an Impact Assessment included with this consultation?	**Yes** ☒	**No** ☐

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

EUROPEAN COMMISSION REGULATION INTRODUCING CHANGES TO THE CONDITIONS AND LEVELS OF USE FOR FOOD ADDITIVES CONTAINING ALUMINIUM

DETAIL OF CONSULTATION

1. European Commission Regulation 380/2012 ("the new EU Regulation"), which came into force on 23rd May 2012, introduces restrictions on the use of aluminium-containing additives. The restrictions tighten the use of aluminium silicates (commonly used as anti-caking agents) and the use of aluminium lakes and restrict E541 Sodium Aluminium Phosphate (SALP) as a raising agent to one product only - namely sponge cakes produced from contrasting coloured segments held together by jam or spreading jelly and encased by a flavoured sugar paste (i.e. Battenberg style cakes), at a level of 0.4 g/kg in the sponge parts only.

2. The aim of the legislation is to reduce levels of aluminium containing additives following the European Food Safety Authority's (EFSA) opinion in 2008 (see paragraph 3 below). The current 1 g aluminium/kg limit for SALP in scones and spongewares will no longer be an option. No Member State other than the UK has food business operators who use SALP in their foods. An industry compromise proposal to reduce levels of SALP in scones and spongewares from 1g/kg to 0.8 g/kg and 0.5 g/kg respectively was rejected during discussions in Brussels on the legislation, as this would perpetuate unacceptable intakes of aluminium for consumers.

EU Proposal on Reduction of Aluminium Containing Additives

3. In 2008 the European Food Safety Authority (EFSA) reduced the Tolerable Weekly Intake of aluminium from all sources to 1mg aluminium/kg body weight (TWI of 1 mg Al/kg bw) from the previous level of 7 mg/kg bw. In their assessment EFSA noted that many adult consumers in the EU are exceeding this level with exposure varying from 0.2 to 1.5 mg Al/kg bw/week for mean consumers and up to 2.3 mg Al/kg bw/week in high level consumers. Data collated from the UK's own 2006 Total Diet Survey shows exposure for mean consumer toddlers (1.5 – 4.5 years old) to be 1.3 mg/kg, whilst for high level consumer toddlers it is 2.4 mg/kg bw/week.

4. Although the percentage of total aluminium in the diet which comes from aluminium-containing food additives is not known, to minimise exposure, the European Commission proposed to reduce the existing use of these additives.

5. Sodium aluminium phosphate (SALP) is currently permitted for use as a raising agent at 1g Al/kg product in scones and spongewares under EU Regulation 1333/2008[1] of the European Parliament and the Council on food additives, enforcement provisions for which are included in the Food Additives (England) Regulations 2009[2]. A proposed Commission Regulation to restrict approval for the use of SALP to Battenberg style cake only was agreed by Member States at Standing Committee in Brussels on 23rd November 2011. The UK voted in favour of the proposed Regulation which

[1] OJ Ref L354, 31.12.2008, p16-33
[2] SI 2009 No. 3238

protected consumer safety by minimising exposure to aluminium containing additives, whilst permitting the continued use of SALP in the one product which UK industry had been unable to reformulate.

6. The Regulation was published in the Official Journal (OJ) of the European Communities on 4th May 2012 as European Regulation (EU) No. 380/2012 ("the new EU Regulation")[3], amending Annex ll to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use of levels for aluminium-containing food additives. Transitional arrangements (until 1 August 2014 for foods containing aluminium lakes and 1 February 2014 for all other restrictions, including SALP) have been agreed to allow industry to adapt to the proposed changes.

7. The new EU Regulation applies throughout the EU in accordance with the main provisions outlined below:

   I. Article 1 - foods not complying with the provisions laid down in the new EU Regulation, which is applicable from 1st February 2014, which have been lawfully placed on the market before that date, may continue to be marketed until their date of minimum durability or use-by date.

   II. Article 2 – by derogation from Article 1 above, foods containing aluminium lakes and not complying with the provisions laid down in the new EU Regulation applicable from 1st August 2014, which have been lawfully placed on the market before that date, may continue to be marketed until their date of minimum durability or use-by date.

8. The new EU Regulation can be downloaded from the EUR-Lex website at the link below:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:119:0014:0038:EN:PDF

9. Due to the ambulatory provisions contained in the 2009 Regulations, an amending Statutory Instrument is not required to bring into force any change to the permitted levels of SALP.

International Safety Standards

10. The World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) Joint Committee on Food Additives (JECFA) – the international risk assessor for food additives, considered new data on aluminium at their meeting in June 2011 and increased the TWI from 1 to 2 mg Al/kg bw. Although EFSA's 2008 opinion recommended lowering the level to 1 mg Al/kg bw, the Food Standards Agency (FSA) considers the international TWI set by JECFA to be more appropriate, as it is based on the most up-to-date evidence.

11. The FSA carried out exposure assessments for the UK population for toddlers (1-5 and 4-5 years of age) and adults; for mean and high level

[3] OJ L 119, 4.5.2012, pg 14 - 38

consumers, for levels of use of 0.8 and 0.4 g Al/kg product, and assuming SALP was used as a raising agent in one third of scones and spongewares. The key conclusion is that even at a use level of 0.4 g Al/kg in one third of products, the intake levels for aluminium by toddlers exceed the TWI set by JECFA.

Salt Targets

12. Where SALP is removed as a raising agent, food manufacturers have indicated that the closest and most suitable alternative will often be Sodium Acid Pyrophosphate (SAPP, E450(i)). In eliminating aluminium, it is estimated that using SAPP could increase the amount of sodium in scones and spongecakes by an average of 324mg/100g. For an average adult consumer this could result in an increase in their sodium consumption by about 20 mg/day. In terms of costs to consumer health for elevated salt consumption, the Department of Health (DH) assessment equates to 207 extra deaths a year and would result in extra financial costs of £14.4 million to the National Health Service (NHS). These impacts need to be balanced against the unquantified reproductive and neuro-toxicity effects of exceeding the TWI for aluminium if exposure is not decreased. This impact is explored further in the IA.

UK Industry Reaction to EU Proposal

13. Due to historical differences in baking practices, use of SALP is largely confined to the UK, with no reported current use in other Member States. On the basis of technological performance and lower sodium content, some parts of the UK industry sought approval at a level of 0.8 g Al/kg in scones and a range of 0.4 – 0.7 g Al/kg in various sponges and American style muffins.

14. Since 2008 a major UK food producer has removed the use of SALP from its recipes for 70 different products. There is only one product (Battenberg style cake) for which they have been unable to find a suitable alternative to SALP. A SALP level of 0.4 g Al/kg in the sponge component of this product is required to enable continued manufacturing this type of cake, which is produced for retail and consumed in the UK.

Purpose of Consultation

15. The purpose of this consultation is to provide stakeholders with an opportunity to comment on the attached Impact Assessment which has been prepared to assess the costs associated with the changes prescribed in the new EU legislation.

16. Separate consultations will be carried out in Scotland, Wales and Northern Ireland on the Impact Assessment relating to those parts of the UK.

Proposals

Key proposal:

The restriction on the use of sodium aluminium phosphate (E 541) to be used in one product only - sponge cakes produced from contrasting coloured segments held together by jam or spreading jelly and encased by a flavoured sugar paste (i.e. Battenberg style cakes), at a level of 0.4 g aluminium/kg in the sponge parts only.

Consultation Process / Impact

17. Whilst discussions with the Commission were ongoing, the FSA carried out an informal consultation with those stakeholders that are likely to be affected by the proposals discussed in here. Three comments were received from manufacturers, the sectors most likely to be affected (including those in the SME sector).

18. Based on the comments provided by the Association of Bakery Ingredient Manufacturers (ABIM), various costs to business were identified as a result of the introduction of tighter controls on the removal of SALP. There may also be incremental public health costs, should an alternative to SALP be introduced.

19. This consultation is being conducted for a period of 12 weeks.

Questions asked in this consultation – (please refer to the Impact Assessment (IA)).

Q1: Only four businesses were identified through the questionnaire as being affected by this regulation. Stakeholders are invited to comment on whether we have captured all businesses affected by this regulation. If you believe we have omitted any firms, please provide information on any firm that may be affected.

Q2: Stakeholders are invited to comment on whether Options 2 and 3 would have the same or significantly different impact on businesses (*e.g., the cost of reducing SALP to a lower level would be lower than the cost of removing the authorisation to use the product altogether*). Please provide evidence on costs and benefits to support your answer to enable us to monetise all costs/ benefits, should this difference be significant.

Q3: Stakeholders are invited to comment on whether or not they agree with the reformulation costs presented in Table 4 to Table 7 of the IA. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Q4: Stakeholders are invited to comment on whether or not they agree with the raw materials costs presented in Table 8 of the IA and the re-labelling costs presented in Table 9a to Table 9b of the IA. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Q5: Stakeholders are invited to comment on whether or not they agree with the statement that costs to enforcement authorities as a result of the Regulation would be negligible. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Q6: Businesses are invited to comment on whether or not they agree with the cost savings presented in Table 11 of the IA. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Q7: Stakeholders are invited to comment on whether or not they agree with the statement that costs to enforcement authorities as a result of the Regulation would be negligible. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Q8: Stakeholders are invited to provide data and evidence on the likely benefits resulting from a reduced dietary exposure to aluminium. Please provide as detailed data and evidence as possible, including sources, as we aim to monetise this potential benefit to consumers.

Q9: Under policy Option 3, do you agree with our assessment of the costs to industry, and that costs resulting from a removal of the authorisation of the use of SALP (other than for Battenberg-style cakes) will be similar to the costs of reducing the limit of SALP in production? Please quantify any implications with supporting evidence in as much detail as possible.

Q10: Under policy Option 3 do you agree with our assessment of the benefits to industry, and that benefits resulting from a removal of the authorisation of the use of SALP will be similar to the benefits of reducing the limit of SALP in production? Please quantify any implications with supporting evidence in as much detail as possible.

Q11: Stakeholders are invited to provide data and supporting evidence on the likely costs resulting from a lower dietary exposure to aluminium. Data and evidence should be as detailed as possible and sources provided.

Q12: Stakeholders are invited to comment on whether they agree with the outcome of the specific impact test analysis. If you disagree, please provide as detailed evidence as possible so that we can monetise impacts

Other relevant documents

20. European Regulation (EU) No. 380/2012 ("the new EU Regulation")[4], 3rd May 2012, amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use of levels for aluminium-containing food additives.

    http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:119:0014:0038:EN:PDF

[4] OJ L 119, 4.5.2012, pg 14 - 38

21. The national Regulations on food additives mentioned in this document are available on the 'legislation.gov.uk' website at:

http://www.legislation.gov.uk/uksi/2009/3238/pdfs/uksi_20093238_en.pdf

22. Responses are requested by close of business on **5th April 2013**. 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).

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

Yours faithfully,

Nasreen Shah,
Team Leader
Regulation and Business Support Unit
Chemical Safety Division

Enclosed

Annex A: Standard Consultation Information

Annex B: Commission Regulation (EU) No. 380/2012

Annex C: Draft Impact Assessment

Annex D: 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 we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8140). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. 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 C. 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 consultation principles[5].

8. An Impact Assessment will normally be published alongside a formal consultation. Please see the Impact Assessment at Annex C.

9. 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.

[5] http://www.bis.gov.uk/policies/bre/consultation-guidance

Comments on the consultation process itself

10. 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**

11. 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.

COMMISSION REGULATION (EU) No 380/2012

of 3 May 2012

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for aluminium-containing food additives

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [1], and in particular Article 10(3) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) The European Food Safety Authority (EFSA), in its opinion of 22 May 2008 [2] recommended to lower the tolerable weekly intake (TWI) for aluminium to 1 mg/kg body weight/week. In addition, EFSA considers that the revised TWI is generally exceeded for high consumers, especially children, in a significant part of the Union.

(3) EFSA considers that the major route of exposure to aluminium compounds for the general population is through food, both as a consequence of the natural occurrence of aluminium in food and the use of aluminium compounds in food processing, including food additives. However, EFSA is not able to quantify the respective role of each source due to the design of the human dietary studies and the analytical methods used, which only determine the total aluminium content in food.

(4) Annex II to Regulation (EC) No 1333/2008 authorises the use of aluminium-containing food additives in a wide number of foodstuffs, often at very high maximum permitted levels or without any indication of the maximum concentration levels (*Quantum satis*).

(5) Annex II to Regulation (EC) No 1333/2008 and Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council [3] authorise the use of some colours that may contain aluminium in the form of lakes in a wide number of foodstuffs, in general without any indication of the maximum concentration levels of aluminium in the lakes.

(6) It is therefore appropriate to amend the current conditions of use and reduce the use levels for aluminium-containing food additives, including aluminium lakes, to ensure that the revised TWI is not exceeded.

(7) Since manufacturing practices using higher amounts of food additives have been applied since decades, a transitional period should be provided to allow the food business operators to adapt to the new requirements laid down in this Regulation for the uses of aluminium-containing food additives others than lakes.

(8) Labelling of aluminium content in aluminium lakes not intended for sale to the final consumer is currently optional. It should become mandatory within 12 months from the entry into force of this Regulation in order to allow food manufacturers using aluminium lakes to adapt to the proposed maximum limits for such lakes. Therefore a longer transitional period than 12 months should be provided to allow the food business operators to adapt to the new requirements laid down in this Regulation.

(9) Annex II as amended by Commission Regulation (EU) No 1129/2011 [4] is in principle applicable from 1 June 2013. In order to facilitate the effective implementation of Annex II, it is appropriate to insert in the Annex the periods of application that do not start on 1 June 2013 and are posterior to the entry into force of this Regulation.

(10) The aluminium containing carrier bentonite, E 558 is not used any more according to information submitted by food manufacturers. Therefore, it is not included in Part 1 of Annex III to Regulation (EC) No 1333/2008 and should also be deleted from the list of all additives in Part B of Annex II to Regulation (EC) No 1333/2008.

(11) The aluminium containing food additives calcium aluminium silicate E 556 and aluminium silicate (kaolin) E 559 should be deleted from the list of all additives in Part B of Annex II to Regulation (EC) No 1333/2008, since these substances can be replaced by other food additives.

[1] OJ L 354, 31.12.2008, p. 16.
[2] Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC) on Safety of aluminium from dietary intake, *The EFSA Journal* (2008) 754, p. 1.
[3] OJ L 83, 22.3.2012, p. 1.
[4] OJ L 295, 12.11.2011, p. 1.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

Article 2

1. Foods not complying with the provisions laid down in this Regulation applicable from 1 February 2014 that have been lawfully placed on the market before 1 February 2014, may continue to be marketed until their date of minimum durability or use-by date.

2. By derogation from paragraph 1, foods containing aluminium lakes and not complying with the provisions laid down in this Regulation applicable from 1 August 2014, that have been lawfully placed on the market before 1 August 2014, may continue to be marketed until their date of minimum durability or use-by date.

Article 3

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

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

Done at Brussels, 3 May 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(a) Part A is amended as follows:

(i) In Section 2, point 4 is replaced by the following:

"4. Aluminium lakes prepared from all colours listed in Table 1 of Part B are authorised until 31 July 2014.

From 1 August 2014 only aluminium lakes prepared from the colours listed in Table 3 of this Part A are authorised and only in those food categories where provisions on maximum limits on aluminium coming from lakes are explicitly stated in Part E ."

(ii) the following Table 3 is added:

'Table 3

Colours which may be used in the form of lakes

E-number	Name
E 100	Curcumin
E 102	Tartrazine
E 104	Quinoline Yellow
E 110	Sunset Yellow FCF/Orange Yellow S
E 120	Cochineal, Carminic acid, Carmines
E 122	Azorubine, Carmoisine
E 123	Amaranth
E 124	Ponceau 4R, Cochineal Red A
E 127	Erythrosine
E 129	Allura Red AC
E 131	Patent Blue V
E 132	Indigotine, Indigo carmine
E 133	Brilliant Blue FCF
E 141	Copper complexes of chlorophylls and chlorophyllins
E 142	Green S
E 151	Brilliant Black BN, Black PN
E 155	Brown HT
E 163	Anthocyanins
E 180	Litholrubine BK'

(b) In Part B, Table 3, (Additives other than colours and sweeteners) is amended as follows:

(i) the entries concerning E 556 Calcium aluminium silicate, E 558 Bentonite and E 559 Aluminium silicate (Kaolin) are replaced by the following:

'E 556	Calcium aluminium silicate (*)
E 558	Bentonite (**)
E 559	Aluminium silicate (Kaolin) (*)'

(ii) the following footnotes are added:

'(*) = authorised until 31 January 2014
(**) = authorised until 31 May 2013'

(c) In Part C, Table (5), point (s) "E 551 – 559: Silicon dioxide – silicates" is replaced by the following:

'(s.1.) E 551 – 559: Silicon dioxide – silicates (*)

E-number	Name
E 551	Silicon dioxide
E 552	Calcium silicate
E 553a	Magnesium silicate
E 553b	Talc
E 554	Sodium aluminium silicate
E 555	Potassium aluminium silicate
E 556	Calcium aluminium silicate
E 559	Aluminium silicate (Kaolin)

(s.2.) E 551 – 553: Silicon dioxide – silicates (**)

E-number	Name
E 551	Silicon dioxide
E 552	Calcium silicate
E 553a	Magnesium silicate
E 553b	Talc

(*) applicable until 31 January 2014.
(**) applicable from 1 February 2014.'

(d) Part E is amended as follows:

(1) In category 0 (Food additives permitted in all categories of foods),

(i) the entry concerning additives E 551-559 (only foods in dried powdered form (i.e. foods dried during the production process, and mixtures thereof), excluding foods listed in table 1 of Part A of this Annex) is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000	(1) (57)	only foods in dried powdered form (i.e. foods dried during the production process, and mixtures thereof), excluding foods listed in table 1 of Part A of this Annex	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1) (57)	only foods in dried powdered form (i.e. foods dried during the production process, and mixtures thereof), excluding foods listed in table 1 of Part A of this Annex	Period of application: from 1 February 2014.'

(ii) the entry concerning additives E 551-559 (only foods in tablet and coated tablet form, excluding the foods listed in table 1 of Part A of this Annex) is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	*quantum satis*	(1)	only foods in tablet and coated tablet form, excluding the foods listed in table 1 of Part A of this Annex	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	*quantum satis*	(1)	only foods in tablet and coated tablet form, excluding the foods listed in table 1 of Part A of this Annex	Period of application: from 1 February 2014'

(2) In category 01.4 (Flavoured fermented milk products including heat treated products):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(74)		Period of application: from 1 August 2014'

(ii) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	150			Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	150	(74)		Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	10	(61), (74)		Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	5	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	5	(61) (74)		Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	5	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	5	(61) (74)		Period of application: from 1 August 2014'

(vi) the following footnote is added:

		'(74): Maximum limit for aluminium coming from all aluminium lakes 15 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(3) In category 01.7.2 (Ripened cheese) the entry concerning additives, E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000	(1)	only sliced or grated cheese hard and semi-hard cheese	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1)	only sliced or grated cheese hard and semi-hard cheese	Period of application: from 1 February 2014'

(4) In category 01.7.3 (Edible cheese rind):

(i) the entriy concerning Group III is replaced by the following:

'Group III	Colours with combined maximum limit	*quantum satis*			Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	*quantum satis*	(67)		Period of application: from 1 August 2014'

(ii) the entry concerning the additive E 180 is replaced by the following:

'E 180	Litholrubine BK	*quantum satis*			Period of application: until 31 July 2014
E 180	Litholrubine BK	*quantum satis*	(67)		Period of application: from 1 August 2014'

(iii) the following footnote is added:

		'(67): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines and E 180 litholrubine BK 10 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(5) In category 01.7.5 (Processed cheese):

(i) the entry concerning the additive E 120 is replaced by the following:

'E 120	Cochineal, Carminic acid, Carmines	100	(33)	only flavoured processed cheese	Period of application: until 31 July 2014
E 120	Cochineal, Carminic acid, Carmines	100	(33) (66)	only flavoured processed cheese	Period of application: from 1 August 2014'

(ii) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000	(1)		Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1)		Period of application: from 1 February 2014'

(iii) the following footnote is added:

		'(66): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 1,5 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(6) In category 01.7.6 (Cheese products (excluding products falling in category 16)) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide, calcium silicate, magnesium silicate, talc	10 000	(1)	only sliced or grated hard and semi-hard products	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1)	only sliced or grated hard and semi-hard products	Period of application: from 1 February 2014'

(7) In category 01.8 (Dairy analogues, including beverage whiteners), the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000	(1)	only sliced or grated cheese analogues and processed cheese analogue;beverage whiteners	Period of application: Until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1)	only sliced or grated cheese analogues and processed cheese analogue; beverage whiteners	Period of application: from 1 February 2014'

(8) In category 02.2.2 (Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions), the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	30 000	(1)	only tin greasing products	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	30 000	(1)	only tin greasing products	Period of application: from 1 February 2014'

(9) In category 02.3 (Vegetable oil pan spray) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	30 000	(1)	only tin greasing products	Period of application: Until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	30 000	(1)	only tin greasing products	Period of application: from 1 February 2014'

(10) In category 03.(Edible ices):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(75)		Period of application: from 1 August 2014'

(ii) the following footnote is added:

		'(75): Maximum limit for aluminium coming from all aluminium lakes 30 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(11) In category 04.2.5.2 (Jams, jellies and marmalades and sweeteneted chestnut purée as defined by Directive 2001/113/EC):

(i) the entry concerning the additive E 120 is replaced by the following:

'E 120	Cochineal, Carminic acid, Carmines	100	(31)	except chestnut puree	Period of application: until 31 July 2014
E 120	Cochineal, Carminic acid, Carmines	100	(31) (66)	except chestnut puree	Period of application: from 1 August 2014'

(ii) the following footnote is added:

		'(66): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 1,5 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(12) In category 05.2 (Other confectionery including breath refreshening microsweets):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(72)		Period of application: from 1 August 2014'

(ii) the entry concerning group III (except candied fruit and vegetables) is replaced by the following:

'Group III	Colours with combined maximum limit	300	(25)	except candied fruit and vegetables	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	300	(25) (72)	except candied fruit and vegetables	Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 used in fodstuffs falling under category 05.2 except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc. is replaced by the following:

'E 104	Quinoline Yellow	30	(61)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 January 2014 to 31 July 2014

E 104	Quinoline Yellow	30	(61) (72)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 used in fodstuffs falling under category 05.2 except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc. is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	35	(61)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	35	(61) (72)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 used in fodstuffs falling under category 05.2 except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc. is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	20	(61)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	20	(61) (72)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 August 2014'

(vi) the entry concerning group III (only candied fruit and vegetables) is replaced by the following:

'Group III	Colours with combined maximum limit	200		only candied fruit and vegetables	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	200	(72)	only candied fruit and vegetables	Period of application: from 1 August 2014'

(vii) the entry concerning the additive E 104 used only in candied fruit and vegetables is replaced by the following:

'E 104	Quinoline Yellow	30	(61)	only candied fruit and vegetables	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	30	(61) (72)	only candied fruit and vegetables	Period of application: from 1 August 2014'

(viii) the entry concerning the additive E 110 used only in candied fruit and vegetables is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	10	(61)	only candied fruit and vegetables	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	10	(61) (72)	only candied fruit and vegetables	Period of application: from 1 August 2014'

(ix) the entry concerning the additive E 124 used only in candied fruit and vegetables is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	10	(61)	only candied fruit and vegetables	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	10	(61) (72)	only candied fruit and vegetables	Period of application: from 1 August 2014'

(x) the entry concerning the additive E 104 used only in traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc. is replaced by the following:

'E 104	Quinoline Yellow	300	(61)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	300	(61) (72)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 August 2014'

(xi) the entry concerning the additive E 110 used only in traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc. is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	50	(61)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	50	(61) (72)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 August 2014'

(xii) the entry concerning the additive E 124 used only in traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc. is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	50	(61)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	50	(61) (72)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.	Period of application: from 1 August 2014'

(xiii) the entry concerning the additive E 173 Aluminium is replaced by the following:

'E 173	Aluminium	*quantum satis*		only external coating of sugar confectionery for the decoration of cakes and pastries	Period of application: until 1 February 2014'

(xiv) the entry concerning additives E 520 – 523 aluminium sulphates is replaced by the following:

'E 520 – 523	Aluminium sulphates	200	(1), (38)	only candied, crystillized or glacé fruit and vegetables	Period of application: until 31 January 2014
E 520 – 523	Aluminium sulphates	200	(1) (38)	only candied cherries	Period of application: from 1 February 2014'

(xv) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	*quantum satis*	(1)	surface treatment only	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	*quantum satis*	(1)	surface treatment only	Period of application: from 1 February 2014'

(xvi) the following footnote is added:

		'(72): Maximum limit for aluminium coming from all aluminium lakes 70 mg/kg. As a derogation to this rule, the maximum limit only for microsweets shall be 40 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(13) In category 05.3 (Chewing gum):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(73)		Period of application: from 1 August 2014'

(ii) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	300	(25)		Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	300	(25) (73)		Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	30	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	30	(61) (73)		Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	10	(61) (73)		Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	10	(61) (73)		Period of application: from 1 August 2014'

(vi) the following footnote is added:

		'(73): Maximum limit for aluminium coming from all aluminium lakes 300 mg/kg For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(14) In category 05.4 (Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4)

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(73)		Period of application: from 1 August 2014'

(ii) the entry concerning group III (only decorations, coatings and sauces, except fillings) is replaced by the following:

'Group III	Colours with combined maximum limit	500		only decorations, coatings and sauces, except fillings	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	500	(73)	only decorations, coatings and sauces, except fillings	Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 (only decorations, coatings and sauces, except fillings) is replaced by the following:

'E 104	Quinoline Yellow	50	(61)	only decorations, coatings and sauces, except fillings	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	50	(61) (73)	only decorations, coatings and sauces, except fillings	Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 (only decorations, coatings and sauces, except fillings) is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	35	(61)	only decorations, coatings and sauces, except fillings	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	35	(61) (73)	only decorations, coatings and sauces, except fillings	Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 (only decorations, coatings and sauces, except fillings) is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	55	(61)	only decorations, coatings and sauces, except fillings	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	55	(61) (73)	only decorations, coatings and sauces, except fillings	Period of application: from 1 August 2014'

(vi) the entry concerning group III (only fillings) is replaced by the following:

'Group III	Colours with combined maximum limit	300	(25)	only fillings	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	300	(25) (73)	only fillings	Period of application: from 1 August 2014'

(vii) the entry concerning the additive E 104 (only fillings) is replaced by the following:

'E 104	Quinoline Yellow	50	(61)	only fillings	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	50	(61) (73)	only fillings	Period of application: from 1 August 2014'

(viii) the entry concerning the additive E 110 (only fillings) is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	35	(61)	only fillings	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	35	(61) (73)	only fillings	Period of application: from 1 August 2014'

(ix) the entry concerning the additive E 124 (only fillings) is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	55	(61)	only fillings	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	55	(61) (73)	only fillings	Period of application: from 1 August 2014'

(x) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	*quantum satis*		surface treatment only	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	*quantum satis*		surface treatment only	Period of application: from 1 February 2014'

(xi) the following footnote is added:

		'(73): Maximum limit for aluminium coming from all aluminium lakes 300 mg/kg .For the puroposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(15) In category 07.2 (Fine bakery wares):

(i) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	200	(25)		Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	200	(25) (76)		Period of application: from 1 August 2014'

(ii) the entry concerning the additive E 541 is replaced by the following:

'E 541	Sodium aluminium phosphate acidic	1 000	(38)	only scones and sponge wares	Period of application: until 31 January 2014
E 541	Sodium aluminium phosphate acidic	400	(38)	only sponge cakes produced from contrasting coloured segments held together by jam or spreading jelly and encased by a flavoured sugar paste (the maximum limit applies only to the sponge part of the cake)	Period of application: from 1 February 2014'

(iii) the following footnote is added:

		'(76): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 5 mg/kg. No other aluminium lakes may be used. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(16) In category 08.2.1 (Non heat treated processed meat)

(i) the entry concerning the additive E 120 (only sausages) is replaced by the following:

'E 120		Cochineal, Carminic acid, Carmines	100		only sausages	Period of application: until 31 July 2014
E 120		Cochineal, Carminic acid, Carmines	100	(66)	only sausages	Period of application: from 1 August 2014'

(ii) the entry concerning the additive E 120 (only *pasturmas*) is replaced by the following:

'E 120		Cochineal, Carminic acid, Carmines	*quantum satis*		only *pasturmas*	Period of application: until 31 July 2014
E 120		Cochineal, Carminic acid, Carmines	*quantum satis*	(66)	only *pasturmas*	Period of application: from 1 August 2014'

(iii) the following footnote is added:

		'(66): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 1,5 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(17) In category 08.2.2 (Heat treated processed meat):

(i) the entry concerning the additive E 120 is replaced by the following:

'E 120	Cochineal, Carminic acid, Carmines	100		only sausages, patés and terrines	Period of application: until 31 July 2014
E 120	Cochineal, Carminic acid, Carmines	100	(66)	only sausages, patés and terrines	Period of application: from 1 August 2014'

(ii) the following footnote is added:

		'(66): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 1,5 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(18) In category 08.2.3 (Casings and coatings and decorations for meat)

(i) the entry concerning group III (only decorations and coatings except edible external coating of *pasturmas*) is replaced by the following:

'Group III	Colours with combined maximum limit	500		only decorations and coatings except edible external coating of *pasturmas*	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	500	(78)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 August 2014'

(ii) the entry concerning the additive E 104 (only decorations and coatings except edible external coating of *pasturmas*) is replaced by the following:

'E 104	Quinoline Yellow	50	(61)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	50	(61) (78)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 110 (only decorations and coatings except edible external coating of *pasturmas*) is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	35	(61)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	35	(61) (78)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 124 (only decorations and coatings except edible external coating of *pasturmas*) is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	55	(61)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	55	(61) (78)	only decorations and coatings except edible external coating of *pasturmas*	Period of application: from 1 August 2014'

(v) the entry concerning group III (only edible casings) is replaced by the following:

'Group III	Colours with combined maximum limit	*quantum satis*		only edible casings	Period of application: Until 31 July 2014
Group III	Colours with combined maximum limit	*quantum satis*	(78)	only edible casings	Period of application: From 1 August 2014'

(vi) the entry concerning the additive E 104 (only edible casings) is replaced by the following:

'E 104	Quinoline Yellow	10	(62)	only edible casings	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	10	(62) (78)	only edible casings	Period of application: from 1 August 2014'

(vii) the entry concerning the additive E 120 is replaced by the following:

'E 120	Cochineal, Carminic acid, Carmines	*quantum satis*		only edible external coating of *pasturmas*	Period of application: until 31 July 2014
E 120	Cochineal, Carminic acid, Carmines	*quantum satis*	(78)	only edible external coating of *pasturmas*	Period of application: from 1 August 2014'

(viii) the following footnote is added:

		'(78): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 10 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(19) In category 09.3 (Fish roe):

(i) the entry concerning the additive E123 is replaced by the following:

'E 123	Amaranth	30		except Sturgeons' eggs (Caviar)	Period of application: until 31 July 2014
E 123	Amaranth	30	(68)	except Sturgeons' eggs (Caviar)	Period of application: from 1 August 2014'

(ii) the following footnote is added:

		'(68): Maximum limit for aluminium coming from aluminium lakes of E 123 amaranth 10 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(20) In category 10.1 (Unprocessed eggs):

(i) the entry is replaced by the following:

'The Food colours listed in Annex II, part B 1 may be used for the decorative colouring of egg shells or for the stamping of egg shells as provided in Regulation (EC) No 589/2008.	Period of application: until 31 July 2014
The Food colours listed in Annex II, part B 1 may be used for the decorative colouring of egg shells or for the stamping of egg shells as provided in Regulation (EC) No 589/2008. (77)	Period of application: from 1 August 2014'

(ii) the following footnote is added:

		'(77): Maximum limit for aluminium coming from all aluminium lakes "*quantum satis*". For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(21) In category 10.2 (Processed eggs and egg products):

(i) the first line is replaced by the following:

'The Food colours listed in part B 1 of this Annex may be used for the decorative colouring of egg shells	Period of application: until 31 July 2014
The Food colours listed in part B 1 of this Annex may be used for the decorative colouring of egg shells (77)	Period of application: from 1 August 2014'

(ii) the entry concerning additives E 520 – 523 is replaced by the following:

'E 520 – 523	Aluminium sulphates	30	(1) (38)	only egg white	Period of application: until 31 January 2014
E 520	Aluminium sulphate	25	(38)	Liquid egg white for egg foams only	Period of application: from 1 February 2014'

(iii) the following footnote is added:

		'(77): Maximum limit for aluminium coming from all aluminium lakes "*quantum satis*". For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(22) In category 11.1 (Sugars and syrups as defined by Directive 2001/111/EC):

(i) the entry concerning additives E 551 – 559 (only foods in tablet and coated tablet form) is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	*quantum satis*	(1)	only foods in tablet and coated tablet form	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	*quantum satis*	(1)	only foods in tablet and coated tablet form	Period of application: from 1 February 2014'

(ii) the entry concerning additives E 551 – 559 (only dried powdered foods) is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000	(1)	only dried powdered foods	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1)	only dried powdered foods	Period of application: from 1 February 2014'

(23) In category 11.4.2 (Table Top Sweeteners in powder form), the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000	(1)		Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000	(1)		Period of application: from 1 February 2014'

(24) In category 11.4.3 (Table Top Sweeteners in tablets), the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	*quantum satis*			Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	*quantum satis*			Period of application: from 1 February 2014'

(25) In category 12.1.1 (Salt):

(i) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000			Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000			Period of application: from 1 February 2014
E 554	Sodium aluminium silicate	20 mg/kg carry over in cheese	(38)	Only for salt intended for surface treatment of ripened cheese, food category 01.7.2	Period of application: from 1 February 2014'

(ii) the following footnote is inserted:

		'(38): Expressed as aluminium'

(26) In category 12.1.2 (Salt substitutes) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	20 000			Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	20 000			Period of application: from 1 February 2014'

(27) In category 12.2.2 (Seasonings and condiments):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*		only seasonings, for example curry powder, tandoori	Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(70)	only seasonings, for example curry powder, tandoori	Period of application: from 1 August 2014'

(ii) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	500		only seasonings, for example curry powder, tandoori	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	500	(70)	only seasonings, for example curry powder, tandoori	Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	10	(62)	only seasonings, for example curry powder, tandoori	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	10	(62) (70)	only seasonings, for example curry powder, tandoori	Period of application: from 1 August 2014'

(iv) the entry concerning additives E 551 – 559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	30 000	(1)	only seasoning	Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	30 000	(1)	only seasoning	Period of application: from 1 February 2014'

(v) the following footnote is added:

		'(70): Maximum limit for aluminium coming from all aluminium lakes 120 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(28) In category 12.6 (Sauces):

(i) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	500		including pickles, relishes, chutney and picalilli; excluding tomato-based sauces	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	500	(65)	including pickles, relishes, chutney and picalilli; excluding tomato-based sauces	Period of application: from 1 August 2014'

(ii) the following footnote is added:

		'(65): Maximum limit for aluminium coming from aluminium lakes of E 120 cochineal, carminic acid, carmines 10 mg/kg. No other aluminium lakes may be used. For the puroposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(29) In category 14.1.4 (Flavoured drinks):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*		excluding chocolate milk and malt products	Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(74)	excluding chocolate milk and malt products	Period of application: from 1 August 2014'

(ii) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	100	(25)	excluding chocolate milk and malt products	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	100	(25) (74)	excluding chocolate milk and malt products	Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	10	(61)	excluding chocolate milk and malt products	Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	10	(61) (74)	excluding chocolate milk and malt products	Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	20	(61)	excluding chocolate milk and malt products	Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	20	(61) (74)	excluding chocolate milk and malt products	Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	10	(61)	excluding chocolate milk and malt products	Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	10	(61) (74)	excluding chocolate milk and malt products	Period of application: from 1 August 2014'

(vi) the following footnote is added:

		'(74): Maximum limit for aluminium coming from all aluminium lakes 15 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(30) In category 15.1 (Potato-, cereal-, flour- or starch-based snacks)

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(71)		Period of application: from 1 August 2014'

(ii) the entry concerning group III (excluding extruded or expanded savoury snack products) is replaced by the following:

'Group III	Colours with combined maximum limit	100		excluding extruded or expanded savoury snack products	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	100	(71)	excluding extruded or expanded savoury snack products	Period of application: from 1 August 2014'

(iii) the entry concerning group III (only extruded or expanded savoury snack products) is replaced by the following:

'Group III	Colours with combined maximum limit	200		only extruded or expanded savoury snack products	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	200	(71)	only extruded or expanded savoury snack products	Period of application: from 1 August 2014'

(iv) the following footnote is added:

		'(71): Maximum limit for aluminium coming from all aluminium lakes 30 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(31) In category 16. (Desserts excluding products covered in category 1, 3 and 4)

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(74)		Period of application: from 1 August 2014'

(ii) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	150			Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	150	(74)		Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	10	(61) (74)		Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	5	(61)		Period of application: from 1 January 2014 to 31 July 2014

E 110	Sunset Yellow FCF/Orange Yellow S	5	(61) (74)		Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	10	(61) (74)		Period of application: from 1 August 2014'

(vi) the following footnote is added:

		'(74): Maximum limit for aluminium coming from all aluminium lakes 15 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(32) In category 17.1 (Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(69)		Period of application: from 1 August 2014'

(ii) the entry concerning group III is replaced by the following:

'Group III	Colours with combined maximum limit	300			Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	300	(69)		Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	35	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	35	(61) (69)		Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	10	(61) (69)		Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	35	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	35	(61) (69)		Period of application: from 1 August 2014'

(vi) the entry concerning additives E 551-559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000			Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000			Period of application: from 1 February 2014'

(vii) the following footnote is added:

		'(69): Maximum limit for aluminium coming from all aluminium lakes 150 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

(33) In category 17.2 (Food supplements supplied in a liquid form):

(i) the entry concerning additives E 551-559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000			Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000			Period of application: from 1 February 2014'

(34) In category 17.3 (Food supplements supplied in a syrup-type or chewable form):

(i) the entry concerning group II is replaced by the following:

'Group II	Colours at *quantum satis*	*quantum satis*			Period of application: until 31 July 2014
Group II	Colours at *quantum satis*	*quantum satis*	(69)		Period of application: from 1 August 2014'

(ii) the entry concerning III (only solid food supplements) is replaced by the following:

'Group III	Colours with combined maximum limit	300		only solid food supplements	Period of application: until 31 July 2014
Group III	Colours with combined maximum limit	300	(69)	only solid food supplements	Period of application: from 1 August 2014'

(iii) the entry concerning the additive E 104 is replaced by the following:

'E 104	Quinoline Yellow	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 104	Quinoline Yellow	10	(61) (69)		Period of application: from 1 August 2014'

(iv) the entry concerning the additive E 110 is replaced by the following:

'E 110	Sunset Yellow FCF/Orange Yellow S	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 110	Sunset Yellow FCF/Orange Yellow S	10	(61) (69)		Period of application: from 1 August 2014'

(v) the entry concerning the additive E 124 is replaced by the following:

'E 124	Ponceau 4R, Cochineal Red A	10	(61)		Period of application: from 1 January 2014 to 31 July 2014
E 124	Ponceau 4R, Cochineal Red A	10	(61) (69)		Period of application: from 1 August 2014'

(vi) the entry concerning additives E 551-559 is replaced by the following:

'E 551 – 559	Silicon dioxide – silicates	10 000			Period of application: until 31 January 2014
E 551 – 553	Silicon dioxide – silicates	10 000			Period of application: from 1 February 2014'

(vii) the following footnote is added:

		'(69): Maximum limit for aluminium coming from all aluminium lakes 150 mg/kg. For the purposes of Article 22 (1) (g) of Regulation (EC) No 1333/2008 that limit shall apply from 1 February 2013.'

Title: European Commission Regulation Introducing Changes to the Conditions and Levels of use for Food Additives Containing Aluminium **IA No: FOOD0047** **Lead department or agency:** FOOD STANDARDS AGENCY **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** January 2013 **Stage:** Consultation **Source of intervention:** EU **Type of measure:** Secondary Legislation **Contact for enquiries:** Nasreen Shah, Tel: 020 7276 8538 Nasreen.shah@foodstandards.gsi.gov.uk

Summary: Intervention and Options

RPC: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£m -143.7	£m 16.7	£m 15.9	No	In/Out/zero net cost

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

High levels of aluminium in certain food products may pose a threat to consumer health. Consumers are not able to identify how much aluminium has been used in foods they purchase, nor should they be expected to calculate how much of a food additive they can safely consume. Government intervention is necessary to ensure that exposure to aluminium is kept at safe levels. In 2008, the European Food Safety Authority (EFSA) reduced the Tolerable Weekly Intake (TWI) of aluminium from all sources of dietary intake from 7 mg to 1mg aluminium/kg body weight. However, the average dietary exposure to aluminium varies from 0.2 to 1.5 mg and up to 2.3 mg Al/kg bw/week in high level consumers. The 1mg level is therefore likely to be exceeded by a significant part of the population.

What are the policy objectives and the intended effects?

To reduce consumer exposure to aluminium from food additives and to ensure that consumers are adequately protected, whilst also, where possible, agreeing a safe level for SALP used in those bakery products for which there is no alternative, and to ensure that there is an appropriate transitional period for any proposed changes to the levels permitted for SALP. The European Regulation reduces the permitted levels of use for aluminium containing additives laid down in EU food additives legislation, and in particular, restricts the use of one additive, E 541 Sodium Aluminium Phosphate (SALP), which is currently permitted at a maximum level of 1g/kg in scones and spongewares.

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

Three options have been considered:
Option 1 – Do Nothing – Maintain the use of SALP at 1g Al/kg in all scones and spongewares. There is a risk with this option that high level users are exposed to unacceptable levels of aluminium. **Option 2** – Reduce the current limit of SALP from 1g to 0.4g Al/kg in all scones and spongewares. As per Option 1 there is a risk with option 2 that high level users are exposed to unacceptable levels of aluminium.
Both options 1 and 2 would be in breach of EU food additives legislation. **Option 3** – Maintain the use of SALP only for manufacturers of Battenberg-style cakes, at a reduced level of 0.4g Al/kg in the sponge part. **This is the preferred option**. Consumer exposure to aluminium would be lower than under option 2, but there are potential costs from increased consumer exposure to sodium. It has not been possible to monetise the potential compensating reduced costs for treating the possible effects from aluminium exposure exceeding the TWI. (See 'Summary and justification for preferred option' on page 18)

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 05/2017

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

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

Signed by the responsible Chief Executive:  ***Date:*** 09/01/13

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing – Maintain the use of SALP at 1g Al/kg in all scones and spongewares

FULL ECONOMIC ASSESSMENT

Price Base Year 2009	PV Base Year 2011	Time Period Years	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 costs associated with this option as this is the baseline against which the other options are appraised

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

There are no costs associated with this option as this is the baseline against which the other options are appraised

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 benefits associated with this option as this is the baseline against which the other options are appraised

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

There are no benefits associated with this option as this is the baseline against which the other options are appraised

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

Risk that high level consumers are exposed to unacceptably high levels of aluminium

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: Reduce the current limit of SALP from 1g to 0.4g Al/kg in all scones and spongewares

FULL ECONOMIC ASSESSMENT

Price Base Year 2009	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: -£143.7**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	£0.61		£17	£143.8

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

Industry

One off costs: familiarisation £842 (PV) (EAC[1] £98); reformulation time costs £54,806 (PV) (EAC £6,367); reformulation development costs £539,500 (PV) (EAC £62,667); re-labelling £11,000 (PV) (EAC £1,278).

Ongoing costs: raw material sourcing £258,231 (PV); costs to NHS from increased dietary intake of sodium £142,887,596 (PV).

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

Consumers

Ongoing non-monetised costs: increased levels of dietary sodium intake.

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		£0.003	£0.03

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

Industry:

Ongoing benefits: reduced cost of sourcing raw materials £25,823 (PV);

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

Consumers: **Ongoing benefits:** Reduced levels of dietary intake of aluminium from additives in certain bakery products.

NHS: **Ongoing benefit**: reduction in NHS costs for the treatment of ill health due to aluminium exposure exceeding the TWI.

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

Familiarisation costs - based on responses to the industry survey questionnaire; we envisage that it will take the equivalent of one senior manager and one product developer/technician per business approximately 4 and 4.5 hours respectively to familiarise themselves with the Regulation. In addition, we assume that it will take product developers an additional 4.5 hours each to disseminate the information to other staff in the organisation.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £16.7	**Benefits:** £0.003	**Net:** £16.7	No	IN/OUT/Zero net cost

[1] EAC = Equivalent Annual Cost

Summary: Analysis & Evidence **Policy Option 3**

Description: Maintain the use of SALP only for manufacturers of Battenberg-style cakes, at a reduced level of 0.4g Al/kg in the sponge cake

FULL ECONOMIC ASSESSMENT

Price Base Year 2009	**PV Base Year** 2011	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate: £**-143.7

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	£0.61		£17	**£143.8**

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

Industry and NHS

One off costs: familiarisation £842 (PV) (EAC[2] £98); reformulation time costs £54,806 (PV) (EAC £6,367); reformulation development costs £539,500 (PV) (EAC £62,667); re-labelling £11,000 (PV) (EAC £1,278).

Ongoing costs: raw material sourcing £258,231 (PV); costs to NHS from increased dietary intake of sodium £142,887,596 (PV).

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

Consumers

Ongoing non-monetised costs: increased levels of dietary sodium intake.

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		£0.003	£0.03

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

Industry:

Ongoing benefits: reduced cost of sourcing raw materials £25,823 (PV);

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

Consumers: **Ongoing benefits**: Reduced levels of dietary intake of aluminium from bakery products.
NHS: **Ongoing benefit**: reduction in NHS costs for the treatment of ill health due to aluminium exposure exceeding the TWI.

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

Familiarisation costs - based on responses to the industry survey questionnaire; we envisage that it will take the equivalent of one senior manager and one product developer/technician per business approximately 4 and 4.5 hours respectively to familiarise themselves with the Regulation. In addition, we assume that it will take product developers an additional 4.5 hours each to disseminate the information to other staff in the organisation.

We assume manufacturers of bakery products containing SALP would choose to invest in a reformulation technique similar to that of Options 2. As a result we estimate that the incremental costs and benefits to UK industry would equate to that of Option 2.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: £16.7	**Benefits: £**0.003	**Net: £16.7**	No	IN/OUT/Zero net cost

[2] EAC = Equivalent Annual Cost

Evidence Base (for summary sheets)

Problem under Consideration

1. To reduce the levels of aluminium consumption of aluminium in the diet to a safe level. An EFSA assessment in 2008 suggested that many adult consumers in the EU are exceeding safe levels. The European Commission has been in discussion with Member States on possible risk management measures, which involve restrictions on the use of aluminium-containing food additives. The agreed measures are contained within European Commission Regulation 380/2012, which came into force on 23rd May 2012. These:

   I. tighten restrictions on the use of aluminium silicates, commonly used as anti-caking agents;

   II. tighten restrictions on the use of aluminium lakes of colours;

   III. restrict Sodium Aluminium phosphate (SALP) as a raising agent to use in only one product type, Battenberg-style cakes, at a maximum limit of 0.4 g/kg in sponge parts only.

2. The European Commission has sought to take the above measures to reduce levels of aluminium containing additives following the EFSA opinion in 2008[3] and plan to reduce the entries permitting the use of E541 Sodium Aluminium Phosphate (SALP) laid down in the food additives legislation. The current 1 g/kg limit for scones and spongewares would no longer be viable. No other Member States use SALP in their foods. An industry compromise proposal to reduce levels of SALP in scones and spongewares from 1g/kg to 0.8 g/kg and 0.5 g/kg respectively was rejected, as this would still lead to unacceptable intakes of aluminium for consumers.

3. Alternative raising agents to SALP may increase the sodium content of some scones and spongewares as alternative methods of manufacturing use more sodium. The effects of increased sodium on health need to be considered in relation to the unquantified neurotoxicity effects of exceeding the TWI for aluminium if overall exposure is not decreased.

EU Proposals on Reduction of Aluminium Containing Additives

4. In 2008 the European Food Safety Authority (EFSA) reduced the Tolerable Weekly Intake (TWI) of aluminium from all sources to 1 mg aluminium/kg body weight (TWI of 1 mg Al/kg bw) from the previous level of 7 mg/kg bw. Their assessment suggested that many adult consumers in the EU are exceeding this level with exposure varying from 0.2 to 1.5 mg Al/kg bw/week for average consumers and up to 2.3 mg Al/kg bw/week in high level consumers. Data collated from the UK's own 2006 Total Diet Survey[4] show exposure for average consumer toddlers (1.5 – 4.5 years old) to be 1.3 mg/kg bw/week, whilst for high level consumer toddlers it is 2.4 mg/kg bw/week.

5. Although the percentage of total aluminium in the diet which comes from aluminium containing food additives is not known, to minimise exposure, the European Commission has proposed a reduction in the use of these additives. Other sources of exposure to aluminium include the mineral content of food, food contact materials, drinking water and aluminium compounds in pharmaceuticals and consumer products.

6. Sodium aluminium phosphate (SALP) is currently permitted for use as a raising agent at 1g Al/kg product in scones and spongewares under EU Regulation 1333/2008[5] of the European Parliament and the Council on food additives, enforcement provisions for which are included in the Food Additives (England) Regulations 2009[6]. Due to the ambulatory provisions in the 2009 Regulations, an amending Statutory Instrument will not be required to enforce any change to the permitted levels for SALP. The Commission Regulation will permit this additive to be used in one product only - sponge cakes produced from contrasting coloured segments

[3] EFSA (2008), Safety in aluminium from dietary intake. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC), The EFSA Journal (2008) 754, 1-34

[4] *Consultation with the Department of Health May 2012*

[5] OJ Ref L354, 31.12.2008 p16-33

[6] SI 2009 No. 3238

held together by jam or spreading jelly and encased by a flavoured sugar paste (i.e. Battenberg-style cakes), with transitional arrangements (until 1 February 2014) to allow industry to adapt to the proposed changes.

7. European Regulation (EU) No. 380/2012 ("the new EU Regulation")[7], 3rd May 2012, amending Annex ll to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for aluminium-containing food additives, was published in the Official Journal (OJ) of the European Communities on 4th May 2012. The new EU Regulation came into force on 23rd May 2012 and will apply throughout the EU in accordance with the main provisions outlined below:

   I. – foods not complying with the provisions laid down in the new EU Regulation, which is applicable from 1st February 2014, which have been lawfully placed on the market before that date, may continue to be marketed until their date of minimum durability or use-by date.

   II. – by derogation from the paragraph above, foods containing aluminium lakes and not complying with the provisions laid down in the new EU Regulation applicable from 1st August 2014, which have been lawfully placed on the market before that date, may continue to be marketed until their date of minimum durability or use-by date.

8. The new EU Regulation can be downloaded from the EUR-Lex website at the link below:

   http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:119:0014:0038:EN:PDF

Rationale for intervention and Policy objective

9. Government intervention is necessary to ensure exposure to aluminium from its use in food additives is minimised by reducing permitted limits in foods to a level consistent with the European Food Safety Authority's (EFSA) opinion, thereby, ensuring that consumers are protected. The Government's objective is to agree a safe level for SALP to be used in those bakery products for which there is no alternative and to ensure that there is an adequate transitional period for any proposed changes to the levels currently permitted for SALP.

UK Industry Reaction to the EU Proposal

10. Due to historical differences in baking processes, use of SALP is confined to the UK, with no reported current use in other Member States. On the basis of technological performance and lower sodium content (which helps industry to keep within Government targets on sodium reduction), some parts of UK industry want approval of SALP at a level of 0.8 g Al/kg in scones and a range of 0.4 – 0.7 g Al/kg in various sponges and American style muffins.

11. Since the 2008 EFSA opinion, one major UK food producer has replaced the use of SALP with alternative ingredients in the majority of its products. There is only one product – Battenberg - for which they have been unable to find a suitable alternative to SALP. They need a SALP level of 0.4 g Al/kg in their sponge component to enable them to continue manufacturing that particular product, which is produced for retail and consumed in the UK.

12. A small number of other UK businesses are likely to accrue costs associated with finding alternatives to the use of SALP.

International Safety Standards

13. The World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) Joint Expert Committee on Food Additives (JECFA) – the international risk assessor for food additives — considered new data on aluminium at their meeting in June 2011 and increased their TWI from 1 to 2 mg Al/kg bw. Despite the fact that EFSA in their 2008 opinion recommended lowering the level to 1 mg Al/kg bw, the Food Standards Agency ("the FSA")

[7] OJ L 119, 4.5.2012, pg 14 - 38

considers the international TWI set by JECFA to be more appropriate, as it is based on the most up-to-date evidence.

14. Based on the JECFA TWI, The FSA carried out exposure assessments for the UK population for toddlers (1.5 – 4.5 years of age) and adults, for average and high level consumers, for levels of use of 0.8 and 0.4 g Al/kg product, and assuming that SALP was used as a raising agent in one third of scones and spongewares. The key conclusion is that, even at a use level of 0.4 g Al/kg in one third of products, the intake levels of aluminium for toddlers from this source led to exceeding the TWI set by JECFA.

Salt Targets

15. Where SALP is removed as a raising agent, food manufacturers have indicated that the closest and most suitable alternative will often be sodium acid pyrophosphate (SAPP, E 450(i)). In eliminating aluminium, it is estimated that using SAPP could increase the amount of sodium in scones and spongecakes by an average of 324mg/100g. For an average adult consumer this could increase their sodium consumption by about 20 mg/day. (Annex B) In terms of costs to consumer health for elevated salt consumption, the Department of Health (DH) estimates that a 20mg per day increase in sodium (which corresponds to a 0.05g increase in salt) equates to 207 extra deaths a year and would result in extra financial costs of £14.4 million to the NHS. (Annex C) These impacts need to be balanced against the unquantified, and non-monetised costs of reproductive and neuro-toxicity effects from exceeding the TWI for aluminium if exposure is not decreased.

Industry Survey

16. To contribute to an assessment of the impact of the proposal, and to gain a better understanding of the structure of the bakery ingredients supply chain, businesses from the bakery industry including the Association of bakery Ingredient Manufacturers (ABIM) were asked to complete a survey questionnaire in April 2011. The purpose of the survey was to enable the collection of data across businesses to analyse the impact of the new EU Regulation. Overall, the survey received responses from four businesses most likely to be affected by restrictions on SALP use. For reference, the survey questionnaire may be found in Annex A of this Impact Assessment.

Consultation Question 1

Only four businesses were identified through the questionnaire as being affected by this regulation. Stakeholders are invited to comment on whether we have captured all businesses affected by this regulation. If you believe we have omitted any firms, please provide information on any firm that may be affected.

Options Considered

Policy Option 1 – Do Nothing - Maintain the use of SALP at 1g Al/kg in all scones and spongewares

17. Under this option, there will be no change to the current limit of SALP of 1g Al/kg in the production of scones and spongewares. There are no costs to businesses associated with this option as this is the baseline against which all other options are appraised. A possible risk with this option is that it may result in unacceptable consumer exposure to aluminium for high level users. This option would be in breach of EU food additives legislation.

Policy Option 2 – Reduce the current limit of SALP from 1g to 0.4 g Al/kg in all scones and spongewares

18. Under this option, the current limit of the use of SALP in production will be reduced from 1g to 0.4g Al/kg in all scones and spongewares. This can lead to consumer health benefits through

a reduction in aluminium exposure to consumers but there is still a risk of consumption being greater than the TWI. Another potential risk with this option is that the use of aluminium based additives is likely to be replaced by the use of additives higher in sodium in the production of sponge and spongewares; imposing a potential cost to consumer health from elevated levels of salt consumption. This option would also be in breach of EU food additives legislation.

Policy Option 3 – Maintain the use of SALP only for manufacturers of Battenberg-style cakes, at a reduced level of 0.4g Al/kg in the sponge part

19. This is the preferred option. Under Option 3, the use of SALP is restricted to one type of product only, sponge cakes produced from contrasting coloured segments held together by jam or spreading jelly and encased by a flavoured sugar paste, i.e. Battenberg-style cakes; Manufacturers of scones and other spongewares will no longer be permitted to use SALP and are subject to transitional arrangements and are given a period of 24 months to replace SALP with alternatives in production.

Sectors and Groups Affected

Industry

20. The main businesses that will be affected by the new EU Regulation are manufacturers of bakery ingredients, such as producers of cake and scones mixes, baking powders and additives – which are likely to use SALP in their production. In order to identify the number of businesses that are likely to be affected by the proposal we contacted the Association of Bakery Ingredient Manufacturers (ABIM)[8], which is the industry representative of UK manufacturers. In addition, we sent out an industry survey questionnaire ABIM members. As a result of these we have identified four UK businesses that currently use SALP in their production.

21. Of these businesses, one major producer has indicated that it has already replaced SALP with alternative ingredients in the majority of their products, and that the costs of doing so already have been accrued. This producer also produces Battenberg-style cakes (and is the only producer of Battenberg-style cakes amongst the businesses that responded to the questionnaire), with a current use of SALP in their production at a level of 0.4g/kg sponge (which therefore meets requirements under both Option 2 and 3). This is the sole product they've been unable to reformulate.

22. The other three businesses have indicated that the proposal will be associated with costs for the replacement of SALP with alternative ingredients in their production. As a result only three businesses are affected by the proposal.

23. We assume manufacturers of bakery products containing SALP would choose to invest in a reformulation technique that could be equally applied both under Options 2 and 3. As a result we envisage that the incremental costs and benefits to the UK industry will be similar under both options.

Consultation Question 2
Stakeholders are invited to comment on whether Options 2 and 3 would have the same or significantly different impact on businesses (*e.g., the cost of reducing SALP to a lower level would be lower than the cost of removing the authorisation to use the product altogether*). Please provide evidence on costs and benefits to support your answer to enable us to monetise all costs/ benefits, should this difference be significant.

24. According to ABIM, the four companies mentioned above are the only UK manufacturers using SALP in their production and they are all located in England. We have not identified any companies which will be affected in Scotland, Wales or Northern Ireland.

[8] ABIM, http://www.abim.org.uk/

25. Table 1 below shows all businesses affected by the Regulation, broken down by firm size and country.

Table 1: Businesses Affected, by Firm Size and Country

	Micro	Small	Medium	Large	Total
England	0	0	2	1	3
Wales	0	0	0	0	0
Scotland	0	0	0	0	0
Northern Ireland	0	0	0	0	0
UK	**0**	**0**	**2**	**1**	**3**

Consumers

26. The new EU Regulation will have two main impacts on consumers: a reduction in the permitted level of SALP in bakery products could yield potential health benefits in terms of a reduction in consumer exposure to aluminium. Conversely, industry has indicated that the closest suitable substitute to SALP is usually sodium acid pyrophosphate. An increase in consumer exposure to sodium can have negative impacts on consumer health, as outlined above (paragraph 15).

NHS

27. The decrease in permitted levels of aluminium additives in certain bakery products is likely to result in producers of bakery products replacing them in production with additives that are higher in sodium. A high dietary intake of salt is associated with heart disease; an increase in sodium levels could therefore potentially be associated with increased costs to the NHS for treating heart disease.

Option Appraisal

Policy Option 1 – Do Nothing - Maintain the use of SALP at 1g Al/kg in all scones and spongewares.

Costs

28. There are no incremental costs associated with this option. This is the baseline against which all other options are appraised.

Benefits

29. There are no incremental benefits associated with this option. This is the baseline against which all other options are appraised.

Policy Option 2 – Reduce the limit of SALP from 1g to 0.4g Al/kg in all scones and spongewares.

Costs

Industry

One-Off Familiarisation Costs

30. There will be a one-off cost to industry for reading and familiarising themselves with the new EU Regulation. Familiarisation costs are measured in terms of time costs and are therefore quantified by multiplying the time it takes for an official to read and familiarise him/herself with the Regulation by their wage rate.

31. We have used an industry survey questionnaire (see paragraph 16 above for details) to collect data on the time costs associated with an introduction of the new EU Regulation. All three companies affected by the new EU Regulation have responded to the questionnaire. Due to commercial confidentiality, and to preserve the anonymity of individual respondents (businesses), we present only aggregate and central (average) estimates of one-off familiarisation costs to industry.

32. In their responses to the industry survey questionnaire, industry have indicated that it will take (on average) the equivalent of one senior manager and one product developer/technician per business approximately 4 and 4.5 hours respectively to familiarise themselves with the new EU Regulation. In addition, we assume that it will take product developers an additional 4.5 hours each to disseminate the information to other staff in the organisation. This equates to a total familiarisation time of approximately 4 hours for a senior manager and 9 hours for a product developer.

33. The median hourly wage rate for a production manager and product developer is £26.10[9]; and £21.14[10] respectively. Multiplying these wage rates by the respective 4 and 9 hours required per type of official results in a total familiarisation cost per business of approximately £281[11]. Multiplying the total familiarisation cost per business by the total number of businesses affected (three) equates to a total familiarisation cost to UK industry of approximately £842[12], as shown in Table 2 below.

Table 2: Total Familiarisation Costs to Industry, by Firm Size and Country

	Micro	Small	Medium	Large	Total
England	£0	£0	£562	£281	£842
Wales	£0	£0	£0	£0	£0
Scotland	£0	£0	£0	£0	£0
Northern Ireland	£0	£0	£0	£0	£0
UK	£0	£0	£562	£281	£842

Note: Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in a rounding error.

34. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor.[13] The total one-off familiarisation cost to UK industry in this proposal is £842 which yields an equivalent annual cost of £98 over a ten year period. Table 3 shows the EAC for UK.

Table 3: Familiarisation Costs as Equivalent Annual Cost to Industry by Country

	EAC
England	£98
Wales	£0
Scotland	£0
Northern Ireland	£0
UK	**£98**

Reformulation Costs

[9] Wage rate obtained from the Annual Survey of Household Earnings, 2011, All Employees, median hourly wage rate of "Managers and Senior Officials: Production Managers". This includes an overhead of 30% (£20.08*1.3=£26.10)

[10] Wage rate obtained from the Annual Survey of Household Earnings, 2011, All Employees, median hourly wage rate of "Professional Occupations: Production and Process Engineers". This includes an overhead of 30% (£16.26*1.3=£21.14)

[11] (£26.104 (hourly wage of production manager)*3.88 (reading time))+(£21.138 (hourly wage of product developer)*8.5(reading + dissemination time)) = Total familiarisation cost per business of approx. £280.83

[12] £280.83*3=£842.49

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

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

35. Introducing the new EU Regulation will require the replacement of SALP with alternative ingredients in the production of most scone and spongeware products; with an associated one-off reformulation cost to those businesses directly affected by the proposal. It is envisaged that reformulation would consist of two key cost components: staff time and product development.

One-Off Reformulation costs: Time Costs

36. Results from the industry survey questionnaire were used to estimate the time cost associated with reformulation. However, the type of business official that will be responsible for reformulation, as well as the hours that will be required, varied among respondents. As with familiarisation costs, reformulation time costs are quantified by multiplying the number of officials required to undertake reformulation by the average wage rate of that official. Due to commercial confidentiality and in the interest of preserving the anonymity of individual respondents (businesses) we only present averages.

37. Questionnaire responses indicate that, for each business, on average, it will take the equivalent of one manager approximately 160 hours and the equivalent of one product developer/technician approximately 667 hours for reformulation.

38. Multiplying the respective hourly wage rate of a manager (£26.10[14]) and a product developer (£21.14[15]) by the number of hours required per respective business official, yields a reformulation time cost of approximately £18,269 per business.[16] Multiplying the reformulation time cost per firm with the total number of firms results in a total reformulation time cost to UK industry of approximately £54,806, as shown in Table 4 below.

Table 4: Total Reformulation Time Costs to Industry, by Firm Size and Country

	Micro	Small	Medium	Large	Total
England	£0	£0	£36,537	£18,269	£54,806
Wales	£0	£0	£0	£0	£0
Scotland	£0	£0	£0	£0	£0
Northern Ireland	£0	£0	£0	£0	£0
UK	**£0**	**£0**	**£36,537**	**£18,269**	**£54,806**

Note: Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in a rounding error.

39. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs need converting into Equivalent Annual Costs (EACs) (see paragraph 31). The total one-off time cost of reformulation to UK industry in this proposal is £54,806 which yields an equivalent annual cost of £6,367 over a ten year period. Table 5 shows the EAC for the UK.

Table 5: Reformulation Time Costs as Equivalent Annual Costs to Industry by Country

	EAC
England	£6,367
Wales	£0
Scotland	£0
Northern Ireland	£0
UK	**£6,367**

One-Off Reformulation costs: Development Costs

40. Reformulation costs will also be associated with finding alternative ingredients and modifying existing recipes. Based on questionnaire responses, it is estimated that industry as a whole

[14] Wage rate obtained from the Annual Survey of Household Earnings, 2011, All Employees, median hourly wage rate of "Managers and Senior Officials: Production Managers". This includes an overhead of 30% (20.08*1.3=26.10)

[15] Wage rate obtained from the Annual Survey of Household Earnings, 2011, All Employees, median hourly wage rate of "Professional Occupations: Production and Process Engineers". This includes an overhead of 30% (16.26*1.3=21.14)

[16] (£26.104 (hourly wage of production manager)*160 hours (reformulation time))+(£21.138 (hourly wage of product developer)*666.7 hours (reformulation time)) = Total reformulation time cost per business of approx. £18,269

will need to reformulate approximately 246 (77 in medium firms, 169 in large firms) products. Due to confidentiality, we are unable to present detailed numbers, but use the results of the questionnaire to calculate an average cost of reformulation per product of £2,193. Multiplying the cost of reformulation per product by the total number of products affected, results in a total reformulation cost to industry of approximately £539,500. The results are shown in Table 6 below broken down by firm size.

Table 6: Reformulation Development Costs to Industry by Firm Size (UK)

	Micro	Small	Medium	Large	Total
Number of products requiring reformulation	0	0	77	169	246
Total reformulation costs	**0**	**0**	**£168,868**	**£370,632**	**£539,500**

Note: all firms affected are located in England, which therefore represents the cost to the whole of UK

41. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs need converting into Equivalent Annual Costs (EACs) (see paragraph 31). The total one-off development cost of reformulation to UK industry in this proposal is £539,500 which yields an equivalent annual cost of £62,667 over a ten year period. Table 7 shows the EAC to the UK.

Table 7: Reformulation Development Costs as Equivalent Annual Costs to Industry

	EAC
England	£62,677
Wales	£0
Scotland	£0
Northern Ireland	£0
UK	**£62,677**

Consultation Question 3
Stakeholders are invited to comment on whether or not they agree with the reformulation costs presented above (Table 4 to Table 7). If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Ongoing Cost of Raw Material

42. The new EU Regulation will also be associated with an ongoing cost of replacing SALP with alternative ingredients in the production process. Questionnaire responses suggest a varying effect of the Regulation on the sourcing of raw materials. Whilst some firms stated that they will accrue a cost as a result of the proposal, others stated that the Regulation will be associated with cost savings. This section deals with potential costs on the sourcing of raw materials (for cost savings, see the benefit section).

43. Questionnaire responses suggest that only two firms (one medium and one large) will accrue increased costs for the sourcing of raw materials as a result of the new EU Regulation, at an annual average cost per firm of £15,000[17]; resulting in a total cost to UK industry of approximately £30,000 per year, as shown in Table 8.

Table 8: Ongoing Cost of Raw Materials to Industry, by Firm Size

	Micro	Small	Medium	Large	Total
England	0	0	£15,000	£15,000	£30,000
Wales	£0	£0	£0	£0	£0
Scotland	£0	£0	£0	£0	£0
Northern Ireland	£0	£0	£0	£0	£0
UK	**£0**	**£0**	**£15,000**	**£15,000**	**£30,000**

[17] A total of two businesses will incur additional ongoing costs associated with raw materials. However, due to commercial confidentiality and in the interest of preserving the anonymity of individual respondents (businesses); an average was used to estimate and quantify the cost impact on UK industry.

One-Off Re-labelling Costs

44. The new EU Regulation will also result in a one-off re-labelling cost to industry. Replacing SALP in the production with alternative ingredients mean that all relevant labels will need to be revised and reprinted. Questionnaire responses showed that only two firms are likely to incur additional re-labelling costs as a result of the proposal, at an average cost per business of £5,500[18]. The total cost to industry of re-labelling is £11,000, as shown in Table 9a below:

Table 9a: One-Off Cost of Re-labelling to Industry, by Firm Size

	Micro	Small	Medium	Large	Total
England	£0	£0	£5,500	£5,500	£11,000
Wales	£0	£0	£0	£0	£0
Scotland	£0	£0	£0	£0	£0
Northern Ireland	£0	£0	£0	£0	£0
UK	**£0**	**£0**	**£5,500**	**£5,500**	**£11,000**

45. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs need converting into Equivalent Annual Costs (EACs) (see paragraph 30). The total one-off development cost of re-labelling to UK industry in this proposal is £11,000 which yields an equivalent annual cost of £1,278 over a ten year period. Table 7 shows the EAC for England.

Table 9b: Re-labelling Development Costs as Equivalent Annual Costs to Industry

	EAC
England	£1,278
Wales	£0
Scotland	£0
Northern Ireland	£0
UK	**£1,278**

Consultation Question 4
Stakeholders are invited to comment on whether or not they agree with the raw materials costs presented above (Table 8) and the re-labelling costs presented above (Table 9a to Table 9b). If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Enforcement

46. Under policy Option 2 we envisage no incremental costs for enforcement authorities; as the impact on Local Authorities and the Competent Authority (FSA) would be negligible.

Consultation Question 5
Stakeholders are invited to comment on whether or not they agree with the statement that costs to enforcement authorities as a result of the Regulation would be negligible. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

[18] See footnote (13) above.

Consumers

Cost of Increased Dietary Intake of Sodium

47. The new EU Regulation is associated with a potential cost to consumers in terms of an increased dietary intake of sodium. Industry has indicated that the most suitable substitute for SALP is likely to be sodium acid pyrophosphate. Increased dietary exposure to sodium carries with it a risk to consumer health. There is evidence that indicates that too much sodium can raise blood pressure and thereby increase the risk of heart disease and stroke. We have however been unable to monetise this direct cost to consumers.

NHS

Cost of Increased Dietary Intake of Sodium

48. Producers of bakery products have indicated that a reduction in the permitted levels of aluminium additives for use in certain bakery products is likely to lead to an increased use of additives higher in sodium. FSA has estimated that replacing aluminium in bakery products with SAPP could increase the amount of sodium in scones and sponge cakes by an average of 324mg/100g, which corresponds to an increase in sodium consumption for an average adult consumer of 20mg sodium (corresponding to 0.05g salt) per day (for calculation, see Annex B).[19]

49. It has been established that a high dietary intake of salt is associated with cardiovascular disease.[20] The FSA has no data on the relationship between a change in sodium (salt) intake and incidence of cardiovascular disease (CVD). Department of Health (DH) has, however, estimated that a 20mg per day increase in sodium (which corresponds to a 0.05g increase in salt) would result in an increase in costs to the NHS of £14.4m per annum (2006 prices)[21]. (See Annex C)

50. There is no more recent data available on the cost of treatment of cardiovascular disease (CVD), nor is there any more recent data available on the relationship between changes in salt levels, instances of CVD and costs to the NHS.

51. The DH estimate was based on a 1g reduction in salt levels resulting in a 2% reduction in CVD and a 2% drop in the costs to NHS to treat CVD (this cost was 14.4bn in 2006, giving a reduction in costs of £288m)[22,23]. The estimate of £14.4m has then been calculated based on this, assuming proportionality between changes in salt consumption, CVD and health care costs; so that a 0.05g increase in salt would result in an increase in CVD of 0.10% and a rise in health care costs of 0.10% (see Annex C for reconciliation of this calculation).

52. Due to the uncertainties and assumptions in this estimate we have undertaken a sensitivity analysis. For the lower bound estimate we assume that a 1g reduction in salt levels would result in a 1% reduction in health care costs, and for the higher bound estimate we assume that a 1g reduction in salt levels would result in a 3% reduction in health care costs. This gives us a lower bound estimate of £7.2m increase in health care costs, and a higher bound estimate of £21.6m increase in health care costs of the policy. We treat the DH estimate of £14.4m as the central estimate (see Annex D for details of this calculation).

53. Inflating these values to 2012 prices gives a lower bound estimate of £8.3m, a central estimate of £16.6m, and a higher bound estimate of £24.9m.

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[19] FSA Risk Assessment

[20] See for example Nice (2009), Expert testimony on salt and cardiovascular disease, http://www.gserve.nice.org.uk/nicemedia/pdf/CVDEP3Salt.pdf

[21] Communication with Department of Health (See also Annex C)

[22] Communication with Department of Health

[23] NICE (2010), Prevention of cardiovascular disease. Costing Report. Implementing NICE Guidance. http://www.nice.org.uk/nicemedia/live/13024/49325/49325.pdf, accessed on 10/09/2012

54. Once these costs are discounted at a rate of 3.5% over 10 years we obtain a present value total cost of £142,887,596 (central estimate), £71,443,798 (lower bound estimate) and £214,331,394 (higher bound estimate), see Table 10 below.

Table 10: Ongoing Costs to the NHS from an Increase in Sodium Levels

Option 2	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total	Average p.a./EAC	Present Value
Lower bound	8,300,000	8,300,000	8,300,000	8,300,000	8,300,000	8,300,000	8,300,000	8,300,000	8,300,000	8,300,000	83,000,000	15,090,909	71,443,798
Central estimate	16,600,000	16,600,000	16,600,000	16,600,000	16,600,000	16,600,000	16,600,000	16,600,000	16,600,000	16,600,000	166,000,000	16,600,000	142,887,596
Higher bound	24,900,000	24,900,000	24,900,000	24,900,000	24,900,000	24,900,000	24,900,000	24,900,000	24,900,000	24,900,000	249,000,000	45,272,727	214,331,394

Benefits

Industry

Cost Savings from the sourcing of Raw Material (Ongoing Benefit)

55. As a result of the new EU Regulation, SALP will need to be replaced with alternative ingredients in the production process. Questionnaire responses suggest a varying effect of the new EU Regulation on the sourcing of raw materials. Whilst some firms stated that they will accrue a cost as a result of the proposal, others stated that the new EU Regulation will be associated with cost savings. This section deals with potential cost savings from the sourcing of raw materials (for costs, see the costs section).

56. Questionnaire responses suggest that one firm (medium sized) will accrue cost savings for the sourcing of raw materials as a result of the new EU Regulation, at an annual average benefit of around £3,000, as shown in Table 10.

Table 11: Ongoing Cost Savings from the Sourcing of Raw Materials to Industry, by Firm Size

	Micro	Small	Medium	Large	Total
England	£0	£0	£3,000	£0	£3,000
Wales	£0	£0	£0	£0	£0
Scotland	£0	£0	£0	£0	£0
Northern Ireland	£0	£0	£0	£0	£0
UK	**£0**	**£0**	**£3,000**	**£0**	**£3,000**

Consultation Question 6
Businesses are invited to comment on whether or not they agree with the cost savings presented in Table 11 above. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Enforcement

57. Under policy Option 2 we envisage no incremental benefits for enforcement authorities; as the impact on Local Authorities and the Competent Authority (FSA) would be negligible.

Consultation Question 7
Stakeholders are invited to comment on whether or not they agree with the statement that costs to enforcement authorities as a result of the Regulation would be negligible. If you disagree, please provide as detailed evidence as possible so that we can use the numbers to monetise these costs.

Consumers

Reduced Exposure to Aluminium

58. The new EU Regulation is associated with a benefit to consumers in terms of reduced exposure to Aluminium. The current legal limit of 1g Al/kg is likely to lead to a significant part of UK consumers exceeding the TWI. Although there is evidence that high levels of aluminium can have negative impacts on consumer health, for example, EFSA expressed concerns that the neurotoxicity effects of exceeding the TWI for aluminium if overall exposure is not decreased; we have been unable to find any studies that have monetised these costs.

NHS

Reduced Costs for the Treatment of Illness due to High Levels of Aluminium Exposure

59. The new EU Regulation could also benefit the NHS if a decrease in aluminium exposure reduces the costs of treatment of illness due to aluminium exposure exceeding the TWI. We have however been unable to monetise this benefit.

Consultation Question 8
Stakeholders are invited to provide data and evidence on the likely benefits resulting from a reduced dietary exposure to aluminium. Please provide as detailed data and evidence as possible, including sources, as we aim to monetise this potential benefit to consumers.

Table 12: Summary of Costs and Benefits for Policy Option 2 (Central Estimates)

Option 2	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total	Average p.a./EAC	Present Value
COSTS													
ONE-OFF COSTS													
Industry													
Familiarisation	£842	£0	£0	£0	£0	£0	£0	£0	£0	£0	£842	£98	£842
Reformulation (time)	£54,806	£0	£0	£0	£0	£0	£0	£0	£0	£0	£54,806	£6,367	£54,806
Reformulation (development)	£539,500	£0	£0	£0	£0	£0	£0	£0	£0	£0	£539,500	£62,677	£539,500
Re-labelling	£11,000	£0	£0	£0	£0	£0	£0	£0	£0	£0	£11,000	£1,278	£11,000
Total	**£606,148**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£606,148**	**£70,419**	**£606,148**
ONGOING COSTS													
Industry Raw Material	£30,000	£30,000	£30,000	£30,000	£30,000	£30,000	£30,000	£30,000	£30,000	£30,000	£300,000	£30,000	£258,231
NHS CVD treatment	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£16,600,000	£166,000,000	£16,600,000	£142,887,596
Total	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£166,300,000**	**£16,630,000**	**£143,145,827**
TOTAL COST	**£17,236,148**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£16,630,000**	**£166,906,148**	**£16,700,419**	**£143,751,975**
BENEFITS													
ONGOING BENEFITS													
Industry Raw Materials	£3,000	£3,000	£3,000	£3,000	£3,000	£3,000	£3,000	£3,000	£3,000	£3,000	£30,000	£3,000	£25,823
Total	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£3,000**	**£30,000**	**£3,000**	**£25,823**
NET BENEFIT													
Total Net (Benefit)	**-£17,233,148**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£16,627,000**	**-£166,876,148**	**-£16,697,419**	**-£143,726,152**
Total Net Cost Business	£17,233,148	£16,627,000	£16,627,000	£16,627,000	£16,627,000	£16,627,000	£16,627,000	£16,627,000	£16,627,000	£16,627,000	£166,876,148	£16,697,419	£143,726,152

Policy Option 3 – Maintain the use of SALP only for manufacturers of Battenberg-style cake, at a reduced level of 0.4 g Al/kg in the sponge part

60. Under Option 3 we assume manufacturers of bakery products containing SALP would choose to invest in a reformulation technique similar to that of Option 2. As a result we estimate that the incremental costs and benefits to UK industry would equate to that of Option 2.

Costs

Industry

61. As per Option 2, we estimate a total cost to UK industry of approximately £906,148 over 10 years; an annual average cost of £100,419. Once these costs are discounted at a rate of 3.5% over 10 years we obtain a present value total cost of £864,379 (see table 11).

Consultation Question 9
Under policy Option 3, do you agree with our assessment of the costs to industry, and that costs resulting from a removal of the authorisation of the use of SALP (other than for Battenberg-style cakes) will be similar to the costs of reducing the limit of SALP in production? Please quantify any implications with supporting evidence in as much detail as possible.

Enforcement

62. Under policy Option 3 we envisage no incremental costs for enforcement authorities; it is our assessment that the impact on Local Authorities and the Competent Authority (FSA) would be negligible.

Consumers

63. Under Option 3, the use of SALP will be restricted to one type of product – Battenberg style-cakes. Manufacturers of scones and other spongewares will no longer be permitted to use SALP. As per Option 2, industry has indicated that the most suitable substitute for SALP is likely to be sodium acid pyrophosphate.

64. A potential risk with this option, as under Option 2, is that the use of aluminium based additives is likely to be replaced by the use of additives higher in sodium in the production of scones and spongewares; imposing a potential cost to consumer health from elevated levels of salt consumption. We have however been unable to monetise this cost to consumers.

NHS

65. As per option 2, a reduction in the permitted levels of sodium for use in bakery products is likely to lead to an increased use of additives higher in sodium. We envisage that the reformulation method adopted under option 3 will be similar to that adopted under option 2. Costs to the NHS will therefore be the same under Option 3 as under Option 2; a per annum cost to the NHS of £16.6m (see paragraph 48). Once these costs are discounted at a rate of 3.5% over 10 years we obtain a present value total cost of £142,887,596 (see Table 11).

Benefits

Industry

66. As per Option 2, we estimate a total benefit to UK industry of approximately £30,000 over 10 years; an annual average cost of £3,000. Once these costs are discounted at a rate of 3.5% over 10 years we obtain a present value total cost of £25,823 (see table 11).

Consultation Question 10

Under policy Option 3 do you agree with our assessment of the benefits to industry, and that benefits resulting from a removal of the authorisation of the use of SALP will be similar to the benefits of reducing the limit of SALP in production? Please quantify any implications with supporting evidence in as much detail as possible.

Consumers

Reduced Exposure to Aluminium

67. As per Option 2, there would be a reduction in consumer exposure to aluminium in bakery products; potentially yielding a positive public health benefit. However, due to lack of data we have been unable to monetise the benefit of a reduced dietary exposure to aluminium.

NHS

Reduced Costs for the Treatment of Illness due to High Levels of Aluminium Exposure

68. As under Option 2, the new EU Regulation could also result in a benefit to the NHS if a decrease in aluminium exposure reduces the costs of treatment of illness due to aluminium exposure exceeding the TWI. We have however been unable to monetise this benefit.

Consultation Question 11

Stakeholders are invited to provide data and supporting evidence on the likely costs resulting from a lower dietary exposure to aluminium. Data and evidence should be as detailed as possible and sources provided.

Summary and justification for preferred option

69. Consumers who eat significantly more than the average of certain food additives containing aluminium are exceeding the lowered TWI for aluminium, Reducing the use of aluminium-containing additives is likely to increase exposure to sodium containing additives. Overall the preferred option is option 3 because:

- it protects some products where industry has been unable to find an alternative to aluminium-containing raising agents;
- it is the only option where aluminium exposure of high level consumers is expected to be reduced to below the TWI;
- although this option leads to an increase in sodium exposure, there is a significant programme of work looking at other options to reduce other sodium exposures.

70. Whilst the total net cost value of option 3 (£143.7 million) appears high, this is largely due to increased costs to the NHS from the effects of increased sodium exposure. Conversely, it has not been possible to monetise the potential compensating reduced costs for treating the possible effects from aluminium exposure exceeding the TWI.

SPECIFIC IMPACT TESTS

Competition

71. We fully considered the questions posed in the Office of Fair Trading competition assessment test[1] and conclude the proposals here are unlikely to hinder the range or number of

[1] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf

businesses or the ability for operators to compete. The proposals are unlikely to significantly affect competition as the impact is likely to be minimal and will apply equally across the food additives sector. The EU Regulation, with its significant transition period, applies in its entirety within all EU Member States and the businesses that trade within them. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Small Firms

72. We have not identified any small firms which will be affected by this regulation. Two medium firms will be affected, and the impact on these forms is considered in the evidence base above.

Sustainability

73. Options 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; under this option we envisage no incremental costs for enforcement authorities; as the impact on Local Authorities and the Competent Authority (FSA) would be negligible.

Race/Gender/Disability Equality Issues

74. The FSA believes that the proposal will not have an impact on race, gender, or disability equality.

Consultation Question 12

Stakeholders are invited to comment on whether they agree with the outcome of the specific impact test analysis. If you disagree, please provide as detailed evidence as possible so that we can monetise impacts.

ANNEX A

EU Restrictions on Use of Aluminium-Containing Food Additives: Request for Information on Associated Costs Industry Questionnaire

Objective

Following the opinion of the European Food Safety Authority on the safety of aluminium from dietary intake (http://www.efsa.europa.eu/en/efsajournal/pub/754.htm) , the European Commission has discussed possible risk management measures with Member States which involve restrictions on the use of aluminium-containing food additives.

The Agency is now seeking information on the actual costs and benefits of these restrictions in order to quantify its impact on industry. All information provided in response to this questionnaire will be held securely, treated anonymously, and not disclosed to third parties. If you have any queries on this or any other aspect of the questionnaire, please contact Nasreen Shah of the Food Standards Agency's Chemical Safety Division, telephone 020 7276 8553 or e-mail < nasreen.shah@foodstandards.gsi.gov.uk >.

Structure of Questionnaire

The questionnaire is comprised of 2 sections which should take no longer than 15 minutes to complete. ***Section A: Business Profile*** *- looks to gather information on the type and scale of business currently in operation.* ***Section B: Potential Costs to Business*** *– seeks to gather data that is as up to date as possible on the extent to which the legislative changes could impact on the cost to individual businesses and industry.*

Section A: Business Profile

1. What type of food business enterprise would you describe yourself as? [*Choose as many that apply*]

A) Food Manufacturer	☐
B) Food Retailer	☐
C) Food Additive Manufacturer	☐
D) other (please specify)	

2. What is your average annual <u>turnover</u> of the business? [*Choose only one*]

A) Less than £100,000	☐
B) £100,000 - £200,000	☐
C) £200,000 - £500,000	☐
D) £500,000 - £1 million	☐
E) £1 million - £2 million	☐
F) £2 million - £ 5 million	☐
G) + £5 million	☐
H) Other (please give an approximation)	£

3. How many Full Time Equivalent employees are there in your business? [*Choose only one*]

A) Micro (9 or fewer employees)	☐
B) <20 (10- 20 employees)	☐
C) Small (21-50 employees)	☐
D) Medium (51-249 employees)	☐
E) Large (250+ employees)	☐

Section B: Potential Costs to Business

Familiarisation with restrictions

5 (a). Does your business need to familiarise itself with the changes in use of aluminium-containing food additives? [*Cross where applicable*]

Yes	☐
No	☐

If you have chosen NO to question 6(a) please go to question 6

5 (b). If yes, how much time did each member of staff need to invest in familiarising themselves with the Regulation? If possible would you be able give an indication of the number of staff involved including their grade? Please complete the table below (continued on page 5):

	Familiarisation Time [*Choose as many that apply*]		*Grade of Staff* [Please complete as many boxes that apply]			
e.g.	*15 minutes*	☒	*Senior Manager* *No. of Staff* *1*	*n/a* *No. of Staff* *n/a*	*n/a* *No. of Staff* *n/a*	*n/a* *No. of Staff* *n/a*
e.g.	*30 minutes*	☒	*Quality Control* *No. of Staff* *2*	*Production Manager* *No. of Staff* *1*	*n/a* *No. of Staff* *n/a*	*n/a* *No. of Staff* *n/a*
A	15 minutes	☐	*No. of Staff*	*No. of Staff*	*No. of Staff*	*No. of Staff*
B	30 minutes	☐	*No. of Staff*	*No. of Staff*	*No. of Staff*	*No. of Staff*

	Familiarisation Time [*Choose as many that apply*]	*Grade of Staff* [Please complete as many boxes that apply]			
C	1 hour ☐	*No. of Staff* ☐	*No. of Staff* ☐	*No. of Staff* ☐	*No. of Staff* ☐
D	Other (approximation)	*No. of Staff* ☐	*No. of Staff* ☐	*No. of Staff* ☐	*No. of Staff* ☐

6 (c). Did your business need to disseminate this information to key members of staff? [*Cross where applicable*]

Yes	☐
No	☐

If you have chosen NO to question 6(c) please go to question 7

6 (d). If yes, how much time did the business need to invest in disseminating this information to key members of staff? [*Choose only one*]

A) 15 minutes	☐
B) 30 minutes	☐
C) 1 hour	☐
D) Other (approximation)	

One -off Reformulation Costs

7 (a). Would your business need to reformulate any of its products as a result of these restrictions? [*Cross where applicable*]

Yes	☐
No	☐

If you have chosen NO to question 7(a) please go to question 9

7 (b). If yes, how many products will require re-formulation? Please explain and give approximate range below:

Insert Comments Here

7 (c). How much time will each member of staff need to invest in the reformulation process? If possible would you be able give an indication of the number of staff involved including their grade? Please complete the table below (continued on page 7):

	Reformulation Time [Choose as many that apply]	*Grade of Staff* [Please complete as many boxes that apply]			
e.g.	*1 - 3 hours* ☒	*Senior Manager* *No. of Staff* *1*	*n/a* *No. of Staff* *n/a*	*n/a* *No. of Staff* *n/a*	*n/a* *No. of Staff* *n/a*
e.g.	*3 - 5 hours* ☒	*Quality Control* *No. of Staff* *2*	*Production* *No. of Staff* *1*	*n/a* *No. of Staff* *n/a*	*n/a* *No. of Staff* *n/a*
A	1 - 3 hours ☐	*No. of Staff*	*No. of Staff*	*No. of Staff*	*No. of Staff*

	Reformulation Time [Choose as many that apply]	*Grade of Staff* [Please complete as many boxes that apply]			
B	3 - 5 hours ☐	*No. of Staff*	*No. of Staff*	*No. of Staff*	*No. of Staff*
C	5 - 7 hours ☐	*No. of Staff*	*No. of Staff*	*No. of Staff*	*No. of Staff*
D	Other (approximation	*No. of Staff*	*No. of Staff*	*No. of Staff*	*No. of Staff*

7 (d). Can you give us an indication of the cost associated with any reformulation where the level of aluminium additives exceeds the new restrictions? [*Choose only one*]

A) Less than £1, 000	☐
B) £1, 000 - £5, 000	☐
C) £5, 000 - £10, 000	☐
D) £10, 000 - £15, 000	☐
E) £20, 000 +	☐
H) Other (please give an approximation)	£

Ongoing Costs of Raw Materials

8 (a). If you responded yes to question 7 (a), will reformulation have an impact on the cost of sourcing raw materials? [*Cross where applicable*]

Yes	☐
No	☐

8 (b). If yes, can you give an estimate of the potential cost or savings associated with sourcing these raw materials? Please give approximate costs/savings below? [*Choose only one*]

	Costs	Savings
A) Less than £1, 000	☐	☐
B) £1, 000 - £5, 000	☐	☐
C) £5, 000 - £10, 000	☐	☐
D) £10, 000 - £15, 000	☐	☐
E) £20, 000 +	☐	☐
H) Other (please give an approximation)	£	£

Re-labelling Costs

9 (a). Will your business need to re-label any of its products as result of these restrictions? [*Cross where applicable*]

Yes	☐
No	☐

If you have chosen NO to question 9(a) please go to question 10

9 (b). If yes, can you give us an indication of the potential <u>cost</u> associated with any relabeling? [*Choose only one*]	
A) Less than £1, 000	☐
B) £1, 000 - £3, 000	☐
C) £4, 000 - £6, 000	☐
D) £7, 000 - £9, 000	☐
E) £10, 000 +	☐
F) Other (please give an approximation)	£

<u>Market Share and Revenue</u>

10. What impact is this restriction likely to have on the current market share of your business? Please explain and give approximate costs (potential loss of turnover/ sales revenue) below:
Insert Comments Here

<u>Other Comments</u>

11. Any other comments and/ or information you wish to provide that are relevant to the proposed possible EU Restrictions on aluminium food additives? Please explain and give approximate costs/benefits below:
Insert Comments Here

ANNEX B

Changes in sodium levels in scones and spongewares when replacing SALP with SAPP.

Calculation provided by industry[2] taking account of sodium content in: SALP or SAPP; sodium bicarbonate; and salt. This gives the following changes in sodium content for scones and spongewares :

	Scone mix using SALP	Scone mix using SAPP	Increase in moving to SAPP.
Total sodium content in baked scone (mg/100g)	680	1048	368
	Sponge mix using SALP	Sponge mix using SAPP	Increase in moving to SAPP.
Total sodium content in baked sponge (mg/100g)	395	675	280

Average increase in sodium in scones/ spongewares from moving to SAPP: 324 mg sodium/100 g[3].

National Diet and Nutrition Survey Data[4] shows that the average weekly intake of scones and cake for adults is 127.7 g, which corresponds to a daily intake of 18.2 g.

In the absence of data assume that one third of the scones and spongewares on the market are currently using SALP which is 6.1 g, and that all re-formulated products will use SAPP rather than other raising agents[5].

Therefore average increase in sodium for adults each day is 19.8 mg[6].

[2] Association of Bakery Ingredient Manufacturers, Spring 2011

[3] (368+280)/2=324

[4] *Consultation with the Department of Health May 2012*

[5] (1/3)*18.2=6.1

[6] (324/100)*6.1=19.8 (20mg rounded)

ANNEX C

DH calculation of the increase in NHS health care costs from a 20mg/day increase in sodium consumption in an average adult consumer

Assuming that replacing SALP with SAPP will result in an average increase in sodium for adults of 20mg (see Annex B)

20mg sodium equates to 0.05g salt (1g sodium = 2.5g salt)

In 2006, the total cost to UK health care of cardiovascular disease was £14.4bn[7].

DH estimates that a 1g reduction in salt will result in 2% reduction in cardiovascular disease (CVD), and a cost saving of 2% of current health care costs of CVD (£14.4bn in 2006), i.e. 288m.[8]

Assuming proportionality, therefore a 0.05g decrease in salt will result in a 0.10%[9] decrease in CVD and a decrease in costs equal to 0.10% of current health care costs (£14.4bn in 2006), i.e. £14.4 million

Assuming that an increase in salt will have the same proportional response as a decrease, therefore a 0.05g increase in salt will result in an increase in health care costs of £14.4m.

Converting this figure to 2012 prices using the most recent HMT GDP deflators[10] gives a value of £16.6m. (There are no more recent estimates of the cost to UK health care for the treatment of cardiovascular disease)

[7] NICE (2010), Prevention of cardiovascular disease. Costing Report. Implementing NICE Guidance. http://www.nice.org.uk/nicemedia/live/13024/49325/49325.pdf, accessed on 10/09/2012

[8] This estimate has been obtained from direct communication with DH.

[9] 0.02 * 0.05 = 0.05%

[10] http://www.hm-treasury.gov.uk/data_gdp_fig.htm

ANNEX D

Sensitivity Analysis of the increase in health care costs from the policy

Lower Bound Estimate

Assuming proportionality, and given that 0.05g is 5% of 1g, then if 1g reduction in salt results in 1% drop in 14.4bn, then 0.05g reduction results in 0.05%[11] drop in 14.4bn, which is 7.2m[12].

Higher Bound Estimate

Assuming proportionality, and given that 0.05g is 5% of 1g, then if 1g reduction in salt results in 3% drop in 14.4bn, then 0.05g reduction results in 0.15%[13] drop in 14.4bn, which is 21.6m[14].

[11] Five percent of one percent (0.01*0.05=0.05%)

[12] 0.0005*14.4bn=7.2m

[13] Five percent of one percent (0.03*0.05=0.15%)

[14] 0.0015*14.4bn=21.6m

Annex D

Interested Parties List

A J H Consulting
British Retail Consortium
Food Additives and Ingredients Association (FAIA)
Food and Drink Federation
Map Technologies
NATCOL (The Natural Food Colours Association)
Phytone
Sensient Technologies
Trading Standards Institute