

**FOOD STANDARDS AGENCY CONSULTATION**  
**UNION LIST OF SMOKE FLAVOURING PRIMARY PRODUCTS TO BE USED IN OR ON**  
**FOODS**

**CONSULTATION SUMMARY PAGE**

<b>Date consultation launched:</b>	<b>Closing date for responses:</b>
17 February 2014	21 May 2014

**Who will this consultation be of most interest to?**

Manufacturers and suppliers of smoke flavouring primary products, food business operators involved in the placing on the market of foods containing smoke flavourings including importers, distributors, wholesalers and retailers, plus enforcement authorities and consumer organisations.

**What is the subject of this consultation?**

The Union list of smoke flavouring primary products was published in the Official Journal of the European Union on 12 December 2013 and applied from 1<sup>st</sup> January 2014. The Union list contains only those primary products that have undergone a safety assessment by the European Food Safety Authority (EFSA). The Impact Assessment describes the background to the establishment of the Union list, the options considered during EU negotiations on the list and the information received from manufacturers and users of smoke flavourings.

**What is the purpose of this consultation?**

To provide interested parties with the opportunity to comment on, and express their opinions on the Impact Assessment on the Union list of smoke flavouring primary products to be used in or on foods.

**Responses to this consultation should be sent to:**

Name: Olu Adetokunbo

Division/Branch Chemical Safety Division

FOOD STANDARDS AGENCY

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**Is an Impact Assessment included with this consultation?**

Yes ☒

No ☐ See Annex A for reason.

**UNION LIST OF SMOKE FLAVOURING PRIMARY PRODUCTS TO BE USED IN OR ON**  
**FOODS**

## DETAIL OF CONSULTATION

1. The Union list of smoke flavouring primary products was published in the Official Journal of the European Union on 12 December 2013<sup>1</sup>. Commission Regulation (EU) No. 1321/2013 (“the Union list”), establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and /or for the production of derived smoke flavourings has applied from 1<sup>st</sup> January 2014. The Union list contains only those primary products that have undergone a safety assessment by the European Food Safety Authority (EFSA).
2. Smoke flavourings can be used in the production of smoked food (e.g. smoked bacon, smoked salmon) and are also used to provide a smoky/BBQ flavour to snack products and sauces.
3. We would welcome comments on the Impact Assessment (IA) at Annex B, which describes the background to the establishment of the Union list, the options considered during EU negotiations on the Union list and the information received from manufacturers and users of smoke flavourings.
4. This IA has been prepared following previous informal consultations with stakeholders and targeted questionnaires during the negotiations to gather information on the possible impacts associated with the introduction of the positive list.
5. Separate consultations will be carried out in Scotland, Wales and Northern Ireland on the Impact Assessment.

## Policy Background

### Legislation on Smoke Flavouring

6. Commission Regulation EC No. 2065/2003 established a Community procedure for the safety and authorisation of smoke flavourings intended for use in or on foods. Consequently, in 2005 secondary legislation was established in the UK to provide enforcement provisions for when the Union list came into effect – The Smoke Flavourings (England) Regulations 2005<sup>2</sup> and equivalent legislation in the devolved administrations. Hence, no further UK legislation was necessary following the publication of the Union list. The provisions are now contained in the Food Additive, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013<sup>3</sup> and equivalent legislation in the devolved administrations.

### Use of Smoke Flavourings/Smoking of Foods

7. Smoking is a preserving process traditionally applied to certain perishable foods such as fish and meat. The smoking process also results in changes to the colour, texture and flavour of such foods. Some smoke flavourings can be used to replace traditional smoking of foods since they can also alter the colour and texture of the foods as well as imparting a smoky taste.

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<sup>1</sup> OJ L 333, 12.12.2013, p. 54, full title: Commission Regulation (EU) No. 1321/2013 of 10 December 2013, establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and /or for the production of derived smoke flavourings

<sup>2</sup> SI 2005 No. 464

<sup>3</sup> SI 2013 No. 2210

8. The use of smoke flavourings is generally considered to be less of a health concern than the traditional smoking process as certain components of smoke are removed when producing the primary product. However, not all smoke flavourings can impart colour or change the texture of a food and so are not suitable alternatives for producing smoked meats or fish etc.
9. Smoke flavourings are also used to impart a smoky flavour to foods which are not traditionally smoked e.g. snack foods, sauces; normally the primary products would be spray dried to form a powder and added to seasoning and spice blends to be used in a variety of such foods. Typically smoke flavourings are used in BBQ or smoky flavoured products. Small amounts of primary products may also be added to commercial flavourings blends to add a subtle smoky note to the flavouring (e.g. in whisky or vanilla flavourings); but when this flavouring is added to foods the smoky flavour is not discernible.
10. Labelling legislation requires that the term 'smoke flavouring' must be listed in an ingredients list if the smoke flavouring has imparted a smoky taste to the food.

### **Impact on businesses and enforcement authorities**

11. As indicated in the Impact Assessment there will be a one-off cost for businesses for familiarisation and possible reformulation costs, as a result of the Union list. We also envisage that some businesses may incur costs from re-labelling their products (for business to business sales).
12. The introduction of the Union list will also result in enforcement authorities incurring one-off administration costs for familiarisation.

### **Purpose of the Consultation**

13. 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 establishment of the Union list on smoke flavourings.

#### **Consultation Questions:**

We invite stakeholders to comment on whether the overall costs summarised in the Impact Assessment are representative of the actual position. If you have specific comments on any of the following areas, please provide as much detailed information and data as possible in order to help in quantifying the impacts of the introduction of the Union list.

- The number of businesses identified by size
- The familiarisation costs to industry
- The reasonableness of the reformulation costs
- The cost of sourcing new materials
- Re-labelling costs
- Familiarisation costs to enforcement authorities
- Whether we have captured all potential costs in the Impact Assessment.

### **Proposals**

**Key proposal(s):**

- To provide interested parties with the opportunity to comment on, and express their opinions on the draft Impact Assessment associated with the Union list of smoke flavouring primary products to be used in or on foods.

**Consultation Process*****Stakeholder engagement***

14. During negotiations on the Union list, detailed discussions were held with two companies, which either manufactured or sold smoke flavourings in the UK.
15. The Food Standards Agency (FSA) also had significant engagement with various trade associations e.g. The UK Flavouring Association (UKFA), which covers flavouring suppliers in the UK and the Food and Drink Federation (FDF), whose members use flavourings. In addition, the FSA provided frequent updates to industry stakeholders via interested parties' letters.
16. In October 2012, the FSA requested businesses complete a questionnaire regarding the associated costs of the possible options under consideration at the time, i.e. a Margin of Safety (MOS) of 100 or 300. The questionnaire can be viewed at:  
  
<http://www.food.gov.uk/enforcement/regulation/europeleg/euupdates/smoke-flavourings>
17. The FSA received seven completed questionnaires and these were used to assess the impact of MOS of 300 and 100.
18. On the basis of the discussions and the information provided in the questionnaires the attached Impact Assessment has been prepared. Any comments that interested parties are able to provide in relation to the Impact Assessment would be gratefully received. In particular, should any parties and more specifically Small and Medium Enterprises consider that the Impact Assessment does not fully reflect the impact of the Union list; we would welcome further comment with supporting evidence.
19. Following the consultation, we will review the responses received and consider whether any further action is required. A summary of all comments received and the FSA's response to each will be published on the FSA's website within 3 months following the end of the consultation period.

**Other relevant documents**

20. Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings is available from the EUR Lex website at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:333:0054:0067:EN:PDF>
21. The Food Additives, Flavourings, Enzymes and Extraction solvents (England) Regulations are available on the 'legislation.gov.uk' website at:

[http://www.legislation.gov.uk/uksi/2013/2210/pdfs/uksi\\_20132210\\_en.pdf](http://www.legislation.gov.uk/uksi/2013/2210/pdfs/uksi_20132210_en.pdf)

## **Responding to the Consultation**

22. Responses are required by close of business **21<sup>st</sup> May 2014**. 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**

Regulatory Officer  
Regulation and Business Support  
Food Safety Policy

Enclosed

Annex A: Standard Consultation Information

Annex B: Impact Assessment

Annex C: Union List (Commission Regulation (EU) No. 1321/2013)

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 our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <http://www.food.gov.uk/multimedia/pdfs/dataprotection.pdf> 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 D. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
6. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.
7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation. The consultation is being held for a full 12 weeks.
8. An Impact Assessment will normally be published alongside a formal consultation. Please see the Impact Assessment at Annex B.

<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html>

9. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 0207 276 8630.

## 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.

<b>Title:</b> Union list of smoke flavouring primary products to be used in or on foods <b>IA No:</b> FOOD0023 <b>Lead department or agency:</b> Food Standards Agency <b>Other departments or agencies:</b> N/A	Impact Assessment (IA)	
	<b>Date:</b> 13/02/2014	
	<b>Stage:</b> Consultation	
	<b>Source of intervention:</b> EU	
	<b>Type of measure:</b> Other	
	<b>Contact for enquiries:</b> Wendy Dixon - 020 7276 8587 wendy.dixon@foodstandards.gsi.gov.uk	
<b>Summary: Intervention and Options</b>		<b>RPC Opinion:</b> 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, Two-Out?	Measure qualifies as
-£1.44m	-£1.42m	£0.15m	No	NA

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

Smoke used to flavour food contains carcinogenic components that are harmful to health. Whilst smoke flavourings are produced from smoke, these are purified to reduce some harmful components such as polycyclic aromatic hydrocarbons (PAHs). Smoke flavourings can be used in the production of smoked food (e.g. smoked bacon, smoked salmon) and are also used to provide a smoky/BBQ flavour to snack foods and sauces. Government intervention was required to ensure the Union list of smoke flavouring primary products offers a high level of protection of consumer health whilst ensuring the controls on the use of these substances are proportionate to the risks.

**What are the policy objectives and the intended effects?**

The policy objective was to establish harmonised EU controls on the use of smoke flavouring primary products. The UK considered that conditions of use set for primary products should take into consideration the protection of consumer health, but that any controls established should be proportionate to the risks.

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

Option 1 - Do nothing. This would mean harmonised controls, such as specific conditions of use, would not be established and new smoke flavouring primary products could not be authorised. The controls set in the Smoke Flavouring Regulation 2065/2003 would still remain in place, resulting in a state of limbo.

Option 2 - To establish a Union list of smoke flavouring primary products which protects consumer health and is proportionate to the risks. This is the preferred option.

Whilst the preferred option was always to establish a Union list, during the negotiations on the structure of the Union List different safety factors were considered e.g. setting conditions of use based on a Margin of Safety of 100 or 300. Option 2 describes the costs associated with an MOS of 100 which the Union list is mainly based on, although with other concessions.

**Will the policy be reviewed? It will be reviewed. If applicable, set review date:** 12/2018

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.	<b>Micro</b> Yes	<b>&lt; 20</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes	<b>Large</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b> N/A		<b>Non-traded:</b> 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: \_\_\_\_\_



# Summary: Analysis & Evidence

## Policy Option 1

**Description:** Do nothing. This would mean harmonised controls, such as specific conditions of use, would not be established and new smoke flavouring primary products could not be authorised. The controls set in the Smoke Flavouring Regulation 2065/2003 would still remain in place, resulting in a state of limbo.

### FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: n/a
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)	
Low	Optional		Optional	Optional	
High	Optional		Optional	Optional	
Best Estimate	N/A		N/A	N/A	
Description and scale of key monetised costs by ‘main affected groups’ There are no monetised incremental costs associated with this option. This is the baseline against which other options are assessed.					
Other key non-monetised costs by ‘main affected groups’ There are no non-monetised incremental benefits associated with this option. This is the baseline against which other options are assessed.					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)	
Low	Optional		Optional	Optional	
High	Optional		Optional	Optional	
Best Estimate	N/A		N/A	N/A	
Description and scale of key monetised benefits by ‘main affected groups’ There are no monetised incremental benefits associated with this option. This is the baseline against which other options are assessed.					
Other key non-monetised benefits by ‘main affected groups’ There are no non-monetised incremental costs or benefits associated with this option. This is the baseline against which other options are assessed.					
Key assumptions/sensitivities/risks Assuming there is no change in policy				Discount rate (%) 3.5	

### BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: N/A	Benefits: N/A	Net: N/A	No	NA

## Summary: Analysis & Evidence

## Policy Option 2

**Description:** To establish a Union list of smoke flavouring primary products which protects consumer health and is proportionate to the risks (Estimated costs based on a Margin of Safety of 100)

### FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -£1.44

  

<b>COSTS (£m)</b>	<b>Total Transition</b> (Constant Price) Years		<b>Average Annual</b> (excl. Transition) (Constant Price)	<b>Total Cost</b> (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	£1.44		£0	£1.44

**Description and scale of key monetised costs by 'main affected groups'**  
 Industry, one-off costs: familiarisation £23,747 (PV, ten years); Reformulation £1,331,080 (PV, ten years); New raw materials £44,500 (PV, ten years); Re-labelling £20,000 (PV, ten years)  
 Enforcement, one-off costs: familiarisation £18,315 (PV, ten years).

**Other key non-monetised costs by 'main affected groups'**  
 There are no non-monetised incremental costs associated with this option.

  

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

**Description and scale of key monetised benefits by 'main affected groups'**  
 We have been unable to monetise any potential health benefits to consumers

**Other key non-monetised benefits by 'main affected groups'**  
 - Enhanced consumer protection.  
 - Facility for the authorised list of smoke flavouring primary products to be updated and amended in line with commercial considerations, particularly cross-EU trade.

  

<b>Key assumptions/sensitivities/risks</b>	<b>Discount rate (%)</b>	3.5
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All monetised costs are assumed to be subject to a transitional period of one year.  
 Some questionnaire responses were nil responses and there is therefore a risk that we have been unable to monetise some costs fully.

### BUSINESS ASSESSMENT (Option 2)

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>In scope of OIOO?</b>	<b>Measure qualifies as</b>
Costs: £0.16	Benefits: £0	Net: £0.16	No	NA

# Evidence Base (for summary sheets)

## Summary

1. The Union list of smoke flavouring primary products was voted on at the 21<sup>st</sup> October meeting of the Standing Committee on Food Chain and Animal Health (SCoFCAH). It was published in the *Official Journal* on 12 December and applied from 1<sup>st</sup> January 2014<sup>1</sup>. This positive list contains only those primary products that have undergone a safety assessment by the European Food Safety Authority (EFSA) and for which no concerns over genotoxicity were raised. The list specifies which types of food the approved primary products can be used in and maximum permitted levels.
2. This impact assessment describes the background to the establishment of the Union list, the options considered during EU negotiations on the list and the information received from manufacturers and users of smoke flavourings.
3. The Union list is mainly based on an approach using a Margin of Safety of 100 (see paragraphs 24-31), with refinements in food categories and usage levels as appropriate. However, some additional concessions were made in cases where smoke flavourings are used as a direct replacement for traditional smoking.

## Problem under consideration/Rationale for intervention

4. Smoke used to flavour food (e.g. smoked bacon, fish) contains carcinogenic components that are harmful to health. Whilst smoke flavourings are produced from smoke, these are purified and fractionated to reduce harmful components such as polycyclic aromatic hydrocarbons (PAHs). The Smoke Flavouring Regulation (EC) No 2065/2003 additionally sets limits for the level of PAHs in smoke flavourings themselves.
5. Smoke flavourings can be used in the production of smoked food (e.g. smoked bacon, ham) and are also used to provide a smoky/BBQ flavour to snack foods and sauces. Whilst the smoke flavouring Regulation (2065/2003) established the intent to develop a positive list, during negotiations on the structure of the Union list it was important to ensure the list of smoke flavouring primary products offered a high level of protection of consumer health whilst ensuring the controls for the use of these substances were proportionate to the risks.

## Policy objective/Intended effect

6. The policy objective was to establish harmonised EU controls on the use of smoke flavouring primary products. The UK considered that conditions of use set for primary products should take into consideration the protection of consumer health, but that, any controls established should be proportionate to the risks.

## Policy Background

### Legislation on smoke flavourings

7. EC Regulation 2065/2003 established a Community procedure for the safety assessment and the authorisation of smoke flavourings intended for use in or on foods. Consequently, in 2005 secondary legislation was established in the UK to provide for enforcement provisions for when the Union list came into effect - The Smoke Flavourings (England) Regulations 2005, SI 464 and equivalent legislation in devolved administrations. Therefore no further UK legislation will be necessary following publication of the Union list. The 2005 Regulations have been revoked, but the relevant provisions are now contained in "The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, SI 2210" and equivalent legislation in devolved administrations.

### Use of smoke flavourings/smoking of foods

8. Smoking is a process traditionally applied to certain perishable foods such as fish and meat for preservation purposes. The smoking process also results in changes to the colour, texture and flavour of such foods. Some smoke flavourings can be used to replace traditional smoking of foods since they can also alter the colour and texture of the foods as well as imparting a smoky taste.

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<sup>1</sup> Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:333:0054:0067:EN:PDF>

9. There are a variety of ways that smoke flavourings can be applied to meat and fish (traditionally smoked foods) including reatomisation/regeneration of the primary product to produce a 'cloud' of smoke, dipping food into a solution of smoke flavouring and injection of the smoke flavouring into the meat.
10. The use of smoke flavourings is generally considered to be less of a health concern than the traditional smoking process as certain components of smoke are removed when producing the primary product. However, not all smoke flavourings can impart colour or change the texture of a food and so are not suitable alternatives to producing smoked meats etc.
11. Smoke flavourings are also used to impart a smoky flavour to foods which are not traditionally smoked e.g. snack foods, sauces. Normally the primary product would be spray dried to form a powder and added to seasoning and spice blends to be used in a variety of such foods. Typically smoke flavourings are used in BBQ or smoky flavoured products.
12. Small amounts of primary products may also be added to commercial flavouring blends to add a subtle smoky note to the flavouring (e.g. in whisky or vanilla flavourings), but when this flavouring is added to foods the smoky flavour is not discernible.
13. Labelling legislation requires that the term "smoke flavouring" must be listed in an ingredients list if the smoke flavouring has imparted a smoky taste to the food.

#### Production of smoke flavouring primary products

14. Smoke flavouring primary products are obtained from condensed wood smoke. The condensed smoke is normally separated into a water-based primary smoke condensate, a water-insoluble high density tar phase and a water-insoluble oily phase. The water-insoluble oily phase is a by-product and unsuitable for the production of smoke flavourings unless further processed. The primary smoke condensates and the water-insoluble high-density tar phase are purified to remove some components of smoke which are most harmful to human health. The term 'primary products' includes the purified water-based primary smoke condensates and the purified fraction of the water-insoluble high-density tar fractions.
15. Primary products are considered to be safer than traditional smoking as the condensed smoke has been purified and is likely to contain lower levels of PAHs some of which are genotoxic carcinogens.
16. EC Regulation No. 2065/2003 sets limits for certain PAHs in primary products. Additionally contaminants legislation exists (Commission Regulation EC No. 1881/2006 sets maximum levels for certain contaminants in foodstuffs, as amended) which also set maximum permitted levels for PAHs in specific foods including smoked meat and fish. The levels permitted in Regulation 1881/2006 are higher than would be found in food that contained smoke flavourings.
17. The smoke flavouring manufacturing industry is very specialised and products currently on the EU market are manufactured by a handful of companies based in the EU and in the USA.

#### Evaluation process of the primary products

18. Prior to the establishment of the Union list, only smoke flavouring primary products for which a valid application was submitted before 16 June 2005, could be used in foods sold in the EU.
19. EFSA received 16 applications for primary products that were already on the market. Two of these dossiers were submitted via the UK. Of these, 14 were considered as valid applications and forwarded to EFSA for evaluation. The other two applications were not considered to be valid and therefore the primary products were withdrawn from the market. After the start of the evaluation process, applications for three notified products were withdrawn by the manufacturers and these products are no longer marketed.
20. In total, EFSA evaluated only 11 notified products, but one product was withdrawn after the opinion had been published. Therefore 10 primary products have been included on the Union list.
21. As part of EFSA's evaluation a No Observed Adverse Effect Level (NOAEL) was derived for each primary product based on safety studies submitted in the dossiers. These were typically 90-day toxicological studies in animals. EFSA also estimated the daily exposure of consumers to each primary product through the diet based on applicants' data on the likely foods the primary product was used in and the respective use levels.

22. Information on EFSA's safety evaluations of the primary products can be seen at <http://www.efsa.europa.eu/en/topics/topic/smokeflavourings.htm> and information on how the dietary exposure was calculated can be seen at <http://www.efsa.europa.eu/en/efsajournal/pub/248r.htm>. As the methods used to calculate dietary exposure were very conservative these would overestimate actual exposure to the primary products.
23. A refined exposure estimate study for primary products was carried out by the Dutch Rijksinstituut voor Volksgezondheid en Milieu (RIVM). These results showed that regardless of the exposure calculation method used, the main contributors to high intake were predominantly foods that can be traditionally smoked, such as smoked sausage and bacon. The food groups that are not traditionally smoked, such as crisps, soups and sauces, did not significantly affect the overall exposure.

#### Margin of safety (MOS)

24. In the EFSA opinions on the primary products, a margin of safety (MOS) was calculated. The MOS is the ratio of the NOAEL to the daily dietary exposure (see below).

$$\text{MOS for a primary product} = \text{NOAEL} / \text{daily dietary exposure}$$

25. EFSA recommended that a MOS of 300 would be appropriate rather than the usual safety factor of 100. A safety factor is necessary to account for variations between animals and humans and between population groups (e.g. children, elderly). EFSA decided that an additional safety factor of 3 should be used as only short term (90-day) animal toxicity studies were conducted on the primary products rather than the usual 2 year animal studies. An EFSA statement on the safety evaluation of smoke flavourings primary products: Interpretation of the Margin of Safety can be found at <http://www.efsa.europa.eu/en/efsajournal/pub/1325.htm>
26. EFSA noted that the determination of what margin of safety is acceptable may also depend on socio-political aspects to be considered by risk managers i.e. the European Commission and Member States.
27. The MOS for a primary product can be increased by altering its conditions of use. For example if the maximum permitted levels proposed by the manufacturer are lowered and/or if the use of the primary product is restricted to fewer types of foods then this would then lower the estimated daily dietary exposure and so the calculated MOS would be increased.
28. During negotiations on the Union list, the Commission and Member States considered two main approaches; whether the conditions of use should be based on a MOS of 100 (Approach 1) or on a MOS of 300 (Approach 2). It was also considered that if the acceptable MOS was set too high then the primary products may be allowed only in products that are otherwise traditionally smoked (e.g. cheese, fish and meat). Such an approach would have avoided food manufacturers being forced to switch to traditionally smoking such foods and so allow the primary product to continue to be used as a replacement for traditionally smoking meat, fish and cheeses.
29. Under Approach 2, it was considered that using a MOS of 300 to establish the restrictions in the Union list may have led to reduced competition as only a few primary products could be used in foods. Alternatively some food manufacturers may have reverted to traditionally smoking foods or using smoked food ingredients if the permitted levels for primary products were set too low to impart a smoky taste. The costs of traditionally smoked ingredients are around 10 times higher than smoke flavourings and due to the difference in taste profile and other technological issues (e.g. solubility) it may not always be possible to reformulate a snack food or sauce to use smoked ingredients. Therefore some products could potentially no longer be produced. Alternatively manufacturers may have decided that the new costs (reformulation costs and new raw material costs) would be too high to support the continued manufacturing of certain products.
30. In addition, if a MOS of 300 was selected, food companies and smoke flavouring manufacturers were concerned that the use of primary products would not be permitted in non-traditionally smoked products such as snack foods and sauces or alternatively the use levels would be set so low that it would not be possible to achieve the desired smoky/BBQ taste required. Food companies and smoke flavouring manufacturers indicated that if, in contrast, a MOS of 100 was selected (Approach 1), the effect on industry would be less as the majority of products currently on the market would not require reformulation. However, certain products would still need to be reformulated if they contain high levels of primary products e.g. strongly flavoured BBQ sauces.

31. This Impact Assessment monetises Approach 1 (MOS of 100), as Approach 2 was disregarded during negotiations. The FSA did, however, during negotiations, calculate an approximate estimate of the costs associated with a MOS of 300. The overall cost for Approach 2 was estimated to be **£2,950,793<sup>2</sup>**.

#### Manufacturers and suppliers of smoke flavouring primary products and derived smoke flavourings

32. During negotiations on the Union list detailed discussions were held with two companies which operate in the UK. Company A submitted an application for the approval of a smoke flavouring primary product on the Union list and Company B imports smoke flavourings derived from two smoke flavouring primary products. Both companies provided specific information on the market share of their products and the types of foods their primary products are used in as described below.
33. Company A stated that their primary product goes into approximately 15-20% of the smoke flavourings used in the UK. Company B smoke flavourings are used in approximately 75% of the smoke flavourings used in UK foods. A small number of smoke flavouring primary products may be imported directly from other manufacturers by UK flavouring producers.
34. Company B supplies all sectors of the food industry from international ingredient houses to small family butchers. They reported they are the only company in the UK providing this role to any significant degree.
35. Company A dries its smoke flavouring primary product and the dried derivatives go into around 200 different seasoning recipes used by the company itself and sold in the UK. These dry derivatives are also sold to other companies who use them in similar applications. Products they are used in include meat products (either internally or externally as BBQ seasonings etc.), sauces or snack applications.
36. Company A could not say exactly how many foods their approximately 300 derived seasoning blends are used in, but they themselves use them in over a thousand products.
37. Company B stated that the primary products they sell cover 75% of the UK market share and equate to 150 tonnes of smoke flavouring primary product. Foods include fish, meat (bacon, ham and sausage), crisps and snacks, sauces recipe dishes, nuts, tinned foods such as baked beans and sausages. 100,000 – 200,000 tonnes of food products in the UK are flavoured by smoke flavouring primary products each year.

#### Transitional periods

38. Transitional periods were specified in the Smoke Flavouring Regulation 2065/2003 (Article 20). This states that any foods (including compound flavourings) which contain primary products that are not on the Union list may stay on the market for 12 months after the date of application of the Union list.
39. The 12 month transitional period will allow industry time to adapt to the proposed measures and potentially reduce their impact. In addition, foods which are lawfully placed on the market before the end of transitional period may remain on the market until stocks are exhausted. Once the Union list applies, unapproved primary products cannot be sold in the EU.

#### Enforcement

40. As the primary products are complex mixtures of substances, it is unlikely that the legislation will be enforced by analysing primary products themselves, commercial flavouring blends or the foods containing primary products. Instead, we expect documentation to be checked by enforcement officers to ensure that the primary product is on the Union list, complies with the chemical specification and that the use levels are compliant with the smoke flavouring legislation. As enforcement officers must already check companies are using only smoke flavourings for which a valid application was submitted, we envisage that the introduction of the Union list will have a minimal impact on enforcement authorities.

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<sup>2</sup>The total cost was derived from: Industry, one-off costs: familiarisation £23,747 (PV, ten years); Reformulation £1,338,731 (PV, ten years); New raw materials £1,550,000 (PV, ten years); Re-labelling £20,000 (PV, ten years). The familiarisation and re-labelling costs are the same as Option 1 where the MOS is 100. Enforcement, one-off costs: familiarisation £18,315 (PV, ten years).

## **Description of options considered**

41. It should be noted that the UK's preferred option 2 – based upon a Margin of Safety (MOS) of 100 – has mainly been used by the Commission in establishing the Union list. This follows strong interventions by the UK during Commission Working Group meetings to highlight the potential impact on industry on having too large a Margin of Safety and also to highlight the conservative nature of EFSA's exposure assessments. The UK considered that a high MOS could not be justified as it would not lead to a significant increase in consumer protection. The UK worked closely with producers and users of smoke flavourings in the UK and across Europe to encourage them to provide the necessary information to the Commission and other Member States to ensure a proportionate approach was taken in developing the Union list.
42. The UK believes that the Union list is a pragmatic solution with consumers still benefiting from a high level of protection with regard to the consumption of smoke flavourings. It would also enable existing products such as smoky bacon flavour snacks and BBQ sauces to remain available on the UK market.

## **Union list of smoke flavouring primary products**

43. The maximum permitted levels set in the Union list are based on a MOS of 100. However, where smoke flavouring primary products are permitted to be used as a direct replacement for smoking meat (e.g. smoked meat or fish is produced using regenerated smoke in a smoking chamber) no numerical level is set, but they must be used according to good manufacturing practice.
44. It should be noted that the use of smoke flavourings is to some extent self-limiting as there will be a fixed amount required to obtain the desired taste profile and exceeding this amount would lead to products having an unpleasantly strong smoky taste. When multiple smoke flavouring primary products are used, the individual levels must be reduced proportionally.
45. The authorisations for the smoke flavouring primary products are company specific and the authorisation is for 10 years. However, there is a system for the renewal of authorisations.
46. During negotiations on the positive list, where the Commission considered the MOS calculated for a particular primary product had to be increased, the relevant manufacturer would have taken commercial decisions on the conditions of use to be specified in the Union list e.g. they would have decided to lower maximum permitted use levels and/or decided that the primary product would be permitted in fewer foods.

## **INDUSTRY ENGAGEMENT**

47. The Food Standards Agency had significant engagement with various trade associations (e.g. the UK Flavouring Association (UKFA) which covers flavouring suppliers in the UK and the Food and Drink Federation) and specifically with two UK based companies that either manufactured or sold smoke flavourings in the UK (see paragraph 31). In addition the FSA provided frequent updates to industry stakeholders via Interested Parties letters.
48. In October 2012, the FSA requested businesses complete a questionnaire regarding the associated costs of the possible options under consideration at the time i.e. a MOS of 100 or 300. The questionnaire can be viewed at:

<http://food.gov.uk/enforcement/regulation/europeleg/euupdates/smoke-flavourings>

49. The FSA received seven completed questionnaires and these were used to assess the impact of a MOS of 300 and 100.

## **SECTORS AND GROUPS AFFECTED**

### **Smoke Flavouring Industry**

50. The introduction of the Union list will affect manufacturers and suppliers of smoke flavouring primary products, and producers of derived smoke flavourings and/or other flavourings who may need to reformulate their products in response to the conditions of use set in the Union list. Manufacturers of foods containing derived smoke flavourings and other flavourings will be affected to a lesser extent but may need to use alternative primary products. In order to identify the businesses affected in the smoke flavouring sector, a questionnaire was developed and sent out to businesses identified by trade organisations in the sector. This generated seven responses from businesses, which were all located in England. Table 1 shows these businesses.

**Table 1: Businesses Affected by the Regulation**

	Micro	Small	Medium	Large	Total
England	1	2	1	3	7
Scotland	0	0	0	0	0
Wales	0	0	0	0	0
NI	0	0	0	0	0
<b>UK</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>3</b>	<b>7</b>

Data source: industry responses to questionnaire

### Enforcement Authorities

51. Local authorities are responsible for enforcement of current legislation on flavourings. Previously when consulting the Local Authority Coordinators of Regulatory Services (LACORS, which has been disbanded) to determine the costs involved in the enforcement of the UK Regulations (2005 SI 464), we were advised that any additional costs of enforcing these provisions will be minimal. There will however be familiarisation costs to enforcement as Local Authorities will need to read and familiarise themselves with the provisions of the new Union list. Table 2 below shows the number of enforcement authorities in the UK.

**Table 2: Number of Enforcement Authorities in the UK**

	England	Scotland	Wales	NI	UK
LAs & PHAs	354	32	23	26	435

### Consumers

52. There are potential health benefits from introducing the Union list. Consumers are unable to assess the risk of consuming smoke flavouring products and the list will ensure that such products have passed the appropriate processes and evaluations before being placed on the market.

## Option Appraisal

### Option 1: Do nothing.

#### Costs and benefits

53. There are no costs or benefit associated with this option as it is the baseline against which all other options are appraised.

**Option 2: To establish a Union list of smoke flavouring primary products which protects consumer health and is proportionate to the risks.**

### Costs

#### **Costs to Industry**

##### Familiarisation Costs to Industry (One-Off Costs)

54. There will be a one-off cost to businesses in the smoke flavouring industry from reading and familiarising themselves with the new Regulations. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the person carrying it out.
55. Responses to our industry survey questionnaire suggest that the time required for familiarisation and dissemination is substantially different between businesses, ranging from negligible costs for some businesses to substantial for other businesses.
56. Business 1 (small) responded that it would take the equivalent of 1 senior manager 3 hours for familiarisation and the equivalent of 1 sales staff 126 hours for familiarisation. Multiplying the median hourly wage rate of a senior manager (£24.1) by the number of hours (3), and the median hourly



wage rate of sales occupations (£8.9) by the number of hours (126) and summing up across occupations generates a total familiarisation cost to Business 1 of **£1,194**.<sup>3</sup>

57. Business 2 (large) responded that it would take the equivalent of 1 senior manager 25 hours (wage rate £24.1); the equivalent of 1 production manager 9 hours (wage rate £26.4); the equivalent of 1 R&D staff 50 hours (wage rate £28.6); the equivalent of 1 technical staff 25 hours (wage rate £18.9); the equivalent of 1 staff working in commercial 25 hours (wage rate £17.2); and the equivalent of 1 regulatory staff 40 hours (wage rate £29.5) for familiarisation. Multiplying the wage rates by the number of hours required and summing up across professions generates a total cost of familiarisation to Business 2 of **£4,353**.<sup>4</sup>
58. Business 3 (medium) responded that it would take the equivalent of 1 senior manager 3 hours for familiarisation. Multiplying the median hourly wage rate of a manager (£24.1) by the number of hours (3) generates a total familiarisation cost to Business 3 of **£72**.<sup>5</sup>
59. Business 4 (large) responded that it would take the equivalent of a manager 20 hours (wage rate £24.1); the equivalent of 1 technical staff 60 hours (wage rate £18.9); the equivalent of 1 regulatory staff 8 hours (wage rate £29.5); and the equivalent of 1 sales staff 20 hours (wage rate £8.9) for familiarisation. Multiplying wage rates by hours required and summing up across all staff required generates a total familiarisation cost to this business of **£2,030**.<sup>6</sup>
60. Business 5 (micro) responded that it would take 1 manager the equivalent of 32 hours (wage rate £24.1) and the equivalent of 1 legal staff 140 hours (wage rate £29.5). Multiplying wage rates by hours required and summing up across all staff generates a total familiarisation cost to this business of **£4,901**.<sup>7</sup>
61. Business 6 (small) responded that it would take the average of 1 senior manager 2 hours (wage rate £24.1) for familiarisation and the equivalent of 1 supplier 104,000 hours (or 100 suppliers 6 months) (wage rate £14<sup>8</sup>) for familiarisation. Multiplying wage rates by numbers of hours would generate a total familiarisation cost to this business of £1,456,000. We note this potential cost to this business. We also note that the cost of familiarisation to this business is substantially higher than to other businesses in the sector. Businesses have been aware for a long time of the introduction of the Union list. We therefore believe that familiarisation costs (the reading and understanding of the changes in policy) may have been misinterpreted by this business. We have therefore assumed that this business will incur the average familiarisation cost to businesses in the sector (**£3,392**)<sup>9</sup>.
62. Business 7 (large) responded that it would take the equivalent of 1 senior manager 96 hours (wage rate of £24.1), and the equivalent of 1 product developer 192 hours (wage rate of £28.6<sup>10</sup>) for

<sup>3</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Managers, Directors and Senior Officials', which has been uprated by 30% to account for overheads: £18.6\*1.3=£24.1.

<sup>4</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Managers, Directors and Senior Officials', which has been uprated by 30% to account for overheads: £18.6\*1.3=£24.1; median hourly wage rate of 'Production managers and directors in manufacturing', uprated by 30% to account for overheads: £20.3\*1.3=£26.4; median hourly wage rate of 'Research and development managers', uprated by 30% to account for overheads: £22\*1.3=£28.6; median hourly wage rate of 'Associate professional and technical occupations', uprated by 30% to account for overheads: £14.5\*1.3=£18.9; median hourly wage rate of 'Marketing associate professionals', uprated by 30% to account for overheads: £13.2\*1.3=£17.2; median hourly wage rate of 'legal professions', uprated by 30% to account for overheads: £22.7\*1.3=£29.5.

<sup>5</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Managers, Directors and Senior Officials', which has been uprated by 30% to account for overheads: £18.6\*1.3=£24.1;

<sup>6</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Managers, Directors and Senior Officials', which has been uprated by 30% to account for overheads: £18.6\*1.3=£24.1; median hourly wage rate of 'Associate professional and technical occupations', uprated by 30% to account for overheads: £14.5\*1.3=£18.9; median hourly wage rate of 'Legal professions', uprated by 30% to account for overheads: £22.7\*1.3=£29.5; median hourly wage rate of 'Sales occupations', uprated by 30% to account for overheads: £6.87\*1.3=£8.9;

<sup>7</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Managers, Directors and Senior Officials', which has been uprated by 30% to account for overheads: £18.6\*1.3=£24.1; median hourly wage rate of 'Legal professions', uprated by 30% to account for overheads: £22.7\*1.3=£29.5;

<sup>8</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Transport and distribution clerks', which has been uprated by 30% to account for overheads: £10.8\*1.3=£14.

<sup>9</sup> (1,194 + 4,353 + 72 + 2,030 + 4,901 + 7,805) / 6 = £3,392

<sup>10</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcmm%3A77-280149>). Median hourly wage rate of 'Research and development managers', which has been uprated by 30% to account for overheads: £21.98\*1.3=£28.6.

familiarisation. Multiplying wage rates by numbers of hours required and summing up across professions generates a total familiarisation cost to this business of **£7,805**.

63. Summing up familiarisation costs across all businesses that responded to the questionnaire then generates a total familiarisation cost to industry of £23,747. Table 3a below shows this total familiarisation cost to industry.

**Table 3a: Familiarisation Costs to Industry**

	Micro	Small	Medium	Large	Total
England	£4,901	£4,586	£72	£14,187	£23,747
Scotland	£0	£0	£0	£0	£0
Wales	£0	£0	£0	£0	£0
NI	£0	£0	£0	£0	£0
UK	£4,901	£4,586	£72	£14,187	£23,747

64. 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.<sup>11</sup> The total one-off familiarisation cost to UK industry in this proposal is £23,747 which yields an equivalent annual cost of £2,759 over a ten year period. Table 3b shows the EAC for UK.

**Table 3b: Familiarisation Annual Equivalent Costs (EACs) to industry**

	England	Scotland	Wales	NI	UK
EAC	£2,759	£0	£0	£0	£2,759

#### Reformulation Time Costs (One-Off Costs)

65. We envisage that the introduction of a Union list will result in some costs associated with the reformulation of products if businesses can no longer use certain ingredients and therefore need to spend time on developing new ingredients and products. Industry questionnaire responses indicated that reformulation time costs differ substantially between businesses. Whilst two businesses indicated that they would not incur any such costs, one firm gave a nil response, one firm responded that the data was confidential, and one firm gave us the numbers of hours required per smoke flavouring, but did not provide us with the number of smoke flavourings requiring reformulation. Only two businesses provided us with data on these costs that could be used to quantify any costs.
66. Out of the two businesses providing costs, Business 1 (large) responded that it would take the equivalent of 1 R&D staff 39,000 hours (wage rate £32); the equivalent of 1 commercial staff 4,325 hours (wage rate £18) and the equivalent of 1 regulatory staff 160 hours (wage rate £30) for reformulation.<sup>12 13</sup> Multiplying wage rates by hours required results in a total reformulation time cost to Business 1 of **£1,330,650**.
67. Out of the two businesses providing costs, Business 2 (large) responded that it would take the equivalent of 1 manager 4 hours (wage rate £24); the equivalent of 1 technologist 16 hours (wage rate £19); and the equivalent of 1 regulatory staff 1 hour (wage rate £30) spent on reformulation. Multiplying wage rates by hours required generates a total reformulation time cost to Business 2 of **£430**.
68. For the business that responded that their data was confidential, and the business that gave a nil response, we envisage that they may incur some time costs arising from time spent on reformulation. We have however been unable to monetise these costs due to lack of data. We can also not assume the industry average cost as an indicative estimate due to the fact that Business 1 is an outlier in the sense that its products are on the high end of the smoky taste spectrum – their products are highly

<sup>11</sup> 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:

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

concentrated barbeque seasonings or barbeque sauces, and the business would therefore incur substantially higher costs of reformulation than other businesses in the sector. We were also unable to calculate costs for the business that did not provide us with the number of flavourings affected.

69. Summing up reformulation time costs across the industry generates a total reformulation time cost to industry of £1,331,080, which yields an equivalent annual cost (see paragraph 63 above) of £154,639 per annum. Table 4a shows the reformulation time cost to industry, whilst Table 4b shows the reformulation time cost EAC.

**Table 4a: Reformulation time costs to industry**

	Micro	Small	Medium	Large	Total
England	£0	£0	£0	£1,331,080	<b>£1,331,080</b>
Scotland	£0	£0	£0	£0	<b>£0</b>
Wales	£0	£0	£0	£0	<b>£0</b>
NI	£0	£0	£0	£0	<b>£0</b>
UK	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£1,331,080</b>	<b>£1,331,080</b>

**Table 4b: Reformulation Time EACs to industry**

	England	Scotland	Wales	NI	UK
EAC	£154,639	£0	£0	£0	£154,639

#### Sourcing of New Raw Materials (One-Off Cost)

70. There may be costs to businesses from the sourcing of new raw materials as a result of the introduction of the Union list, for example in terms of finding new suppliers and setting up new contracts. Out of the seven businesses responding to the questionnaire, three businesses gave a nil response, one provided us with cost estimates per seasoning - but not the number of seasonings affected, whilst the other three businesses indicated that they would incur such costs.
71. Business 1 (large) responded that they would incur a total one-off cost of £1,500, Business 2 (micro) that they would incur a total one-off cost of £23,000, and Business 3 (large) that they would incur a total one-off cost of £20,000 associated with sourcing new raw materials. This gives a total cost to these three businesses of £44,500, with a corresponding EAC (see paragraph 63 above) of £5,170. Tables 5a and 5b below show these costs to industry.
72. For the businesses that gave a nil response we do not know if the lack of response was because they are unlikely to incur such costs, or because they are uncertain about whether they will, or will not, incur costs associated with new raw materials. We have therefore been unable to monetise any such costs to these businesses. We were also unable to monetise costs for the business that did not provide us with data on the number of seasonings affected. The numbers presented in Table 5a and 5b below may therefore be an underestimate.

**Table 5a: Costs to industry from the sourcing of new raw materials**

	Micro	Small	Medium	Large	Total
England	£23,000	£0	£0	£21,500	<b>£44,500</b>
Scotland	£0	£0	£0	£0	<b>£0</b>
Wales	£0	£0	£0	£0	<b>£0</b>
NI	£0	£0	£0	£0	<b>£0</b>
UK	<b>£23,000</b>	<b>£0</b>	<b>£0</b>	<b>£21,500</b>	<b>£44,500</b>

<sup>1212</sup> These figures have been derived from the firm response that it would take 25 R&D staff 6-12 months each – we have assumed 9 months in our calculations (39 weeks); and that it would take 25 commercial staff 1 month each; and that it would take 2 regulatory staff 1 month each in time costs associated with reformulation. We have assumed a work week consisting of 40 hours. The business also responded that it would take 25 'customers' 1 month each for reformulation. We have omitted the cost to 'customers' in this calculation as we assume that familiarisation costs incurred by the firms' customers are not costs to the business itself.

<sup>13</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>). Median hourly wage rate of 'Research and development managers', which has been uprated by 30% to account for overheads: £24.3\*1.3=£32; median hourly wage rate of 'marketing associate professionals', uprated by 30% to account for overheads: £13.7\*1.3=£18; median hourly wage rate of 'Legal professions', uprated by 30% to account for overheads: £23.4\*1.3=£30.

**Table 5b: Costs to industry from the sourcing of new raw materials**

	England	Scotland	Wales	NI	UK
EAC	£5,170	£0	£0	£0	£5,170

**Cost of Re-labelling (One-Off Cost)**

73. We envisage that some businesses may incur costs from re-labelling their products (for business to business sales) as a result of the introduction of the Union list. In response to the industry questionnaire, only one business (large) indicated that they will have re-labelling costs where products require reformulation, and that this cost would be approximately £20,000. Out of the remaining businesses, two businesses indicated that they would incur no or minimal re-labelling costs, one business indicated that it would incur costs but did not provide us with any estimates, whilst three businesses gave a nil response. We do not know if the businesses that gave a nil response did so because they wouldn't have any costs or because they were uncertain about such costs. We have therefore been unable to monetise this cost to the remaining firms in the sector. The total monetised cost to industry from re-labelling changes is therefore £20,000, with a corresponding EAC of £2,324. Table 6a and 6b show these costs to industry.

**Table 6a: Re-labelling costs to industry**

	Micro	Small	Medium	Large	Total
England	£0	£0	£0	£20,000	<b>£20,000</b>
Scotland	£0	£0	£0	£0	<b>£0</b>
Wales	£0	£0	£0	£0	<b>£0</b>
NI	£0	£0	£0	£0	<b>£0</b>
<b>UK</b>	<b>£0</b>	<b>£0</b>	<b>£0</b>	<b>£20000</b>	<b>£20,000</b>

**Table 6b: Re-labelling EACs to industry**

	England	Scotland	Wales	NI	UK
EAC	£2,324	£0	£0	£0	£2,324

**Costs to Enforcement Authorities****Familiarisation Costs (One-Off Cost)**

74. The introduction of the Union list will result in administrative costs to enforcement authorities that will need to read and understand the changes in the regulations. Familiarisation costs can be monetised as a time cost, by multiplying the time required for enforcement officers to read and understand changes by the wage rate of the official carrying out the familiarisation. We have assumed that it would be the responsibility of an Environmental Health Officer (EHO) to familiarise themselves with the changes and that it would take one EHO per authority approximately 2 hours to familiarise themselves with the changes and to disseminate this information within their organisation.

75. Multiplying the median hourly wage rate of an EHO (£21.1<sup>14</sup>) by the number of hours required and the number of enforcement authorities (see Table 2) generates a total cost to enforcement in the UK of £18,315 (EAC £2,128), as shown in Table 7a and 7b below. We have calculated costs to the whole of the UK, since although we have been unable to identify any smoke flavouring producers outside of England, these authorities will still need to be aware of the regulations if producers start to produce smoke flavourings within their areas.

<sup>14</sup> Wage rates obtained from the Annual Survey of Hours and Earnings (ASHE 2012) (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>). Median hourly wage rate of 'Health and safety officers', which has been uprated by 30% to account for overheads: £16.25\*1.3=£21.1.

**Table 7a: Familiarisation costs to Enforcement Authorities**

	England	Wales	Scotland	NI	UK
LAs and PHAs	£14,939	£928	£1,350	£1,097	£18,315

**Table 7b: Familiarisation EACs to Enforcement**

	England	Scotland	Wales	NI	UK
EAC	£1,736	£108	£157	£127	£2,128

**Consultation Question**

We invite stakeholders to comment on whether the overall costs summarised in this Impact Assessment are representative of the actual position. If you have specific comments on any of the following areas please provide as detailed information and data as possible in order to help in quantifying the impacts of the introduction of the Union list.

- The number of businesses identified by size (Table 1)
- The familiarisation costs to industry (Table 3a)
- The reasonableness of the reformulation costs (Table 4a)
- The cost of sourcing of new materials (Table 5a)
- Relabelling costs (Table 6a)
- Familiarisation costs to enforcement authorities (Table 7a)
- Whether we have captured all potential costs in this Impact Assessment

## Benefits

### Benefits to Consumers

76. There are potential health benefits from introducing the Union list as the list will include strict conditions of use for the approved primary products and only authorised primary products can be used in foods. In addition the primary products must meet specific purity criteria (including limits for heavy metals) set in the Union list. It is however very difficult to monetise these benefits and we have therefore been unable to do so. As mentioned previously, whilst smoke flavourings are produced from smoke, these are purified to reduce some harmful components such as polycyclic aromatic hydrocarbons (PAHs) and so are considered safer than the traditional smoking of foods.

## Summary of Total Costs and Benefits under Option 2

77. Under Option 2, which endorses the Union List based on a margin of safety of 100, the total cost to society is £1,437,642 (PV, ten years), whilst the total cost to Industry is £1,419,327 (PV, ten years). Since we have been unable to monetise any benefits in terms of consumer health, this means that the net impact (cost) on the economy is £1,437,642 (NPV, ten years) and the net impact (cost) to industry is £1,419,327 (NPV, ten years), see Table 8 below. As there is only a one year transitional period the costs will occur in the first year.

**Table 8: Summary of Total Cost under Option 2**

COSTS	Year 0	1	2	3	4	5	6	7	8	9	Total	EAC/p.a.	PV
<b>INDUSTRY</b>													
Familiarisation	23,747	0	0	0	0	0	0	0	0	0	23,747	2,759	23,747
Reformulation time	1,331,080	0	0	0	0	0	0	0	0	0	1,331,080	154,639	1,331,080
New Materials	44,500	0	0	0	0	0	0	0	0	0	44,500	5,170	44,500
Relabeling	20,000	0	0	0	0	0	0	0	0	0	20,000	2,324	20,000
<b>Total costs</b>	<b>1,419,327</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1,419,327</b>	<b>164,891</b>	<b>1,419,327</b>
<b>ENFORCEMENT</b>													
Familiarisation	18,315	0	0	0	0	0	0	0	0	0	18,315	2,128	18,315
<b>BENEFITS</b>	<b>Year 0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>Total</b>	<b>EAC/p.a.</b>	<b>PV</b>
<b>CONSUMERS</b>													
Health	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
<b>NET (COST)</b>	<b>Year 0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>Total</b>	<b>EAC/p.a.</b>	<b>PV</b>
Total Net Cost	1,437,642	0	0	0	0	0	0	0	0	0	1,437,642	167,018	1,437,642
Net Business	1,419,327	0	0	0	0	0	0	0	0	0	1,419,327	164,891	1,419,327

## Statutory Review

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



## **SPECIFIC IMPACT TESTS**

### **Competition Assessment**

79. Consideration has been given to the OFT guidance<sup>15</sup>. It has been established that the preferred policy option is unlikely to have any material negative impact on competition. This policy will not limit the number or range of current suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously. Companies are able to submit applications for the approval of new smoke flavouring primary products as set out in Commission Regulation (EC) No. 2065/2003.
80. Since 2006 food manufacturers could only use primary products for which a valid application had been submitted and so only those primary products that will be authorised on the positive list are currently being used by UK companies. We acknowledge that there are a limited number of primary products that will be authorised – 10 in total and that all authorisations will be company specific. However, primary products can be blended with each other and/or with other flavourings to prepare a large variety of smoke flavourings.

### **Small Firms Impact Test**

81. Small businesses are not exempt from the proposal whose aim is to ensure consumer safety for foods in which smoke flavourings are used. We do not consider the impact on small businesses to be significant as the preferred option 2 (with a MoS of 100) has been agreed in establishing maximum permitted levels for smoke flavouring primary products and there are also extra concessions as described in paragraph 42. This view has been confirmed by the one micro business we are aware of that sells smoke flavouring primary products and derived smoke flavourings in the UK.

### **Sustainability**

82. Impacts under the three pillars of sustainable development (environment, economic and social) have been and continue to be considered in the preparation of this Impact Assessment. Option 2 is the preferred option as it will have less effect on businesses. This is the option which has been agreed with the Commission in deriving the Union list of smoke flavouring primary products.
83. Information from the European Snack Association states that traditional smoking requires 15-20 kg of sawdust per ton of product. It also requires 4-5 times more chemical cleaners and landfill. In contrast, products smoked with smoke condensate require 3-5 kg of sawdust from sustainable forestry practices and all by-products of smoke condensate manufacturing processes are recycled within the factory. Using smoke flavourings instead of traditional smoking can lead to a reduction in greenhouse gas emissions CO<sub>2</sub> by 61-84% compared to traditional smoking. (Report provided by Red Arrow). Therefore the use of smoke flavourings could have a benefit to the environment, but we are unable to quantify this in detail.

### **Race/Gender/Disability/Equality Issues**

84. The FSA has considered the impact of the Union list on different groups in the community. The foods containing smoke flavourings are consumed by all groups in the community and so no specific group will be particularly affected by the introduction of the Union list. The main impacts will be to flavouring producers/suppliers and so consumers are unlikely to be aware of any changes resulting from the introduction of the list. As a proportionate approach was taken in developing the list, foods that are not traditionally smoked (e.g. BBQ sauces and smoky tasting crisps) will continue to be permitted to contain smoke flavourings and so consumer choice is not significantly affected.

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<sup>15</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876con.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876con.pdf)

**COMMISSION IMPLEMENTING REGULATION (EU) No 1321/2013****of 10 December 2013****establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings****(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 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended to be used in or on foods <sup>(1)</sup>, and in particular Article 6 thereof,

Whereas:

- (1) Article 10(2) of Regulation (EC) No 2065/2003 provides for the initial establishment of a Union list of authorised smoke flavouring primary products (hereinafter referred to as 'primary products'). That list is to be established on the basis of applications for authorisation submitted by business operators and the opinion issued by the European Food Safety Authority ('the Authority') on the relevant primary product.
- (2) In accordance with Article 10 of Regulation (EC) No 2065/2003, the Authority received 14 valid applications for authorisation of primary products before 16 June 2005. Three applications have been withdrawn. Therefore the Authority has evaluated in total 11 primary products. One evaluated application has been withdrawn after completion of the evaluation.
- (3) According to Article 4(1) of Regulation (EC) No 2065/2003 the authorisation of smoke flavourings may be subject to specific conditions of use and according to Article 9(3) of that Regulation authorisations should be granted for 10 years, renewable in accordance with Article 12 of that Regulation.
- (4) Primary products and derived smoke flavourings are used in or on food to impart a smoke taste or to complement another flavour without imparting smoke flavour. They are also used to smoke meat, fish and dairy products. The refined exposure study carried out by Rijksinstituut

voor Volksgezondheid en Milieu (RIVM) <sup>(2)</sup> shows that regardless of the exposure calculation method used, the main contributors to the high intake are predominantly foods that used to be traditionally smoked, such as cooked smoked sausage and bacon. The food groups that are not traditionally smoked, such as crisps, soups and sauces, do not significantly affect exposure. Because primary products are produced from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be of less health concern than the use of smoke that is made by burning wood or by heating saw dust or small wood chips <sup>(3)</sup>.

- (5) The safety assessment of the Authority on the primary product Scansmoke PB1110, adopted on 26 March 2009 <sup>(4)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However the uses and use levels as originally proposed by the applicant would provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product Scansmoke PB1110 should therefore be authorised subject to specific conditions of use.
- (6) The safety assessment of the Authority on the primary product Zesti Smoke Code 10, adopted on 29 January 2009 <sup>(5)</sup> and on 6 July 2011 <sup>(6)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product Zesti Smoke Code 10 should therefore be authorised subject to specific conditions of use.
- (7) The safety assessment of the Authority on the primary product Smoke Concentrate 809045, adopted on 29 January 2009 <sup>(7)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. The uses and use levels as proposed by the applicant do not give rise to safety concern. The primary product Smoke Concentrate 809045 should therefore be authorised subject to specific conditions of use.

<sup>(1)</sup> OJ L 309, 26.11.2003, p. 1.

<sup>(2)</sup> 'Refined exposure assessment of smoke flavouring primary products with use levels provided by the industry. A pilot study into data collection of use levels,' RIVM Letter report 320026003.

<sup>(3)</sup> EFSA Journal 2008; 724, 1-114.

<sup>(4)</sup> EFSA Journal 2009; ON-1056, 1-23.

<sup>(5)</sup> EFSA Journal 2009; ON-982, 1-24.

<sup>(6)</sup> EFSA Journal 2011; 9(7):2307.

<sup>(7)</sup> EFSA Journal 2009; ON-981, 1-19.



- (8) The safety assessment of the Authority on the primary product Scansmoke SEF 7525, adopted on 14 May 2009 <sup>(1)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. The uses and use levels as proposed by the applicant do not give rise to safety concern. The primary product Scansmoke SEF 7525 should therefore be authorised subject to specific conditions of use.
- (9) The safety assessment of the Authority on the primary product SmokEz C-10, adopted on 14 May 2009 <sup>(2)</sup> and on 4 July 2012 <sup>(3)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product SmokEz C-10 should therefore be authorised subject to specific conditions of use.
- (10) The safety assessment of the Authority on the primary product SmokEz Enviro-23, adopted on 14 May 2009 <sup>(4)</sup> and on 4 July 2012 <sup>(5)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product SmokEz Enviro-23 should therefore be authorised subject to specific conditions of use.
- (11) The safety assessment of the Authority on the primary product Tradismoke™ A MAX, adopted on 26 November 2009 <sup>(6)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product Tradismoke™ A MAX should therefore be authorised subject to specific conditions of use.
- (12) The safety assessment of the Authority on the primary product Scansmoke R909, adopted on 26 November 2009 <sup>(7)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The applicant notified to the Commission on 26 November 2012 that the name of the primary product had been changed to proFagus-Smoke R709. The primary product proFagus-Smoke R709 should therefore be authorised subject to specific conditions of use.
- (13) The safety assessment of the Authority on the primary product Fumokomp, adopted on 24 September 2009 <sup>(8)</sup> and on 6 July 2011 <sup>(9)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. The uses and use levels as proposed by the applicant do not give rise to safety concern. The primary product Fumokomp should therefore be authorised subject to specific conditions of use.
- (14) The safety assessment of the Authority on the primary product AM 01, adopted on 26 November 2009 <sup>(10)</sup> and on 2 February 2012 <sup>(11)</sup>, concludes that the data provided by the applicant is sufficient to eliminate the concerns over its genotoxicity. However, the uses and use levels as originally proposed by the applicant provide an insufficient margin of safety. The uses and the use levels have been revised to take into account this opinion. The primary product AM 01 should therefore be authorised subject to specific conditions of use.
- (15) In respect of each authorised primary product, the Union list should provide a unique product code, the name of the product, the name and address of the authorisation holder, a description and characterisation of the product, the conditions of its use in or on specific foods or food categories, the date from which the product is authorised and the date until which the product is authorised. For the purpose of this Regulation, the food categories as laid down in Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(12)</sup>, should be referred to.
- (16) Conditions for the production of primary products are laid down in Annex I of the Regulation (EC) No 2065/2003 including maximum content of polycyclic aromatic hydrocarbons.
- (17) When authorised smoke flavourings are used in or on food, their use must be in accordance with the conditions of use, including maximum levels, set in the Annex to this Regulation. When authorised smoke flavourings are used in combination, the individual levels should be reduced proportionally.

<sup>(1)</sup> EFSA Journal 2009; 1224, 1-24.

<sup>(2)</sup> EFSA Journal 2009; 1225, 1-28.

<sup>(3)</sup> EFSA Journal 2012; 10(7):2830.

<sup>(4)</sup> EFSA Journal 2009; 1226, 1-26.

<sup>(5)</sup> EFSA Journal 2012; 10(7):2829.

<sup>(6)</sup> EFSA Journal 2010; 8(1):1394.

<sup>(7)</sup> EFSA Journal 2010; 8(1):1395.

<sup>(8)</sup> EFSA Journal 2009; 7(9):1343.

<sup>(9)</sup> EFSA Journal 2011; 9(7):2308.

<sup>(10)</sup> EFSA Journal 2010; 8(1):1396.

<sup>(11)</sup> EFSA Journal 2012; 10(2):2580.

<sup>(12)</sup> OJ L 354, 31.12.2008, p. 16.

- (18) Smoking by regenerated smoke is a process of treating food by exposing it to smoke which is regenerated by atomizing smoke flavourings in a smoking chamber under the time and temperature conditions similar to those for hot or cold smoking. In that case it is difficult to estimate how much of the smoke flavourings will be present in the final food as marketed due to loss of smoke flavouring during smoking. Therefore, the use should be in accordance with good manufacturing practices.
- (19) Unless subject to further restrictions, an authorised smoke flavouring may be present in food, other than by direct addition, as a result of carry-over from an ingredient in which the smoke flavouring was permitted, provided that the level of the smoke flavouring in the final food is no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice.
- (20) The Union list of smoke flavourings should apply without prejudice to other provisions laid down in sector specific legislation.
- (21) Since smoke flavourings are already on the market in the Member States, provisions have been made to ensure that the transition to a Union authorisation procedure is smooth. To this effect transitional periods have been laid down in Article 20 of Regulation (EC) No 2065/2003.
- (22) Pursuant to Article 12 of Regulation (EC) No 2065/2003, authorisations are renewable for 10-year periods on application to the Commission by the authorisation holder. The application must be accompanied by the documents listed in Article 12(2) of that Regulation. Those documents must include any available information concerning toxicological data following the advice of Authority given in its guidance document of 7 October 2004 or its latest update.
- (23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

The list of the smoke flavouring primary products authorised to the exclusion of all others in the Union for use in or on foods and/or for the production of derived smoke flavourings, as referred to in Article 6 of Regulation (EC) No 2065/2003, is laid down in the Annex to this Regulation.

*Article 2*

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

The list of the authorised smoke flavourings is established with the effect from 1 January 2014.

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

Done at Brussels, 10 December 2013.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

**Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings**

*Note 1:* Maximum levels refer to levels in or on food as marketed. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted the maximum levels shall apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor. If primary products are used for the production of the derived smoke flavourings, the maximum levels shall be adjusted accordingly.

*Note 2:* When combinations of smoke flavourings are used in or on foodstuffs, the individual levels shall be reduced proportionally.

*Note 3:* In case smoke flavourings are permitted to be used in processed meat (food category 8.2) or in processed fish and fishery products (food category 9.2) and these foods are smoked in a smoking chamber by regenerating smoke by using these permitted smoke flavourings, the use shall be in accordance with good manufacturing practices.

*Note 4:* The presence of a smoke flavouring shall be permitted:

- (a) in a compound food other than as referred to in the Annex, where the primary product is permitted in one of the ingredients of the compound food;
- (b) in a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with this Regulation.

This shall not apply to infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children as referred to in Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses <sup>(1)</sup>.

Unique code	SF-001	
Name of the product	Scansmoke PB 1110	
Name of the authorisation holder	Azelis Denmark A/S	
Address of the authorisation holder	Lundtoftegaardsvej 95 2800 Lyngby DENMARK	
Description and characterisation of the product	1. Source materials: 90 % beech ( <i>Fagus sylvatica</i> ), 10 % oak ( <i>Quercus alba</i> ) 2. Specifications: — pH: 2,1 – 2,9 — Water: 47,0 – 56,0 % — Acid % (expressed as acetic acid): 8 – 12 % — Carbonyl compounds: 17 – 25 % — Phenols (as syringol, mg/g): 10,5 – 20,1 3. Purity criteria: — Lead: < 5,0 mg/kg — Arsenic: < 3,0 mg/kg — Cadmium: < 1,0 mg/kg — Mercury: < 1,0 mg/kg	
Conditions of use	Food category	Maximum level g/kg
	1.7. Cheese and cheese products	2,0
	2. Fats and oils and fat and oil emulsions	0,002
	3. Edible ices	0,005
	5. Confectionery	0,05

<sup>(1)</sup> OJ L 124, 20.5.2009, p. 21.

	8.1.2. Meat preparations as defined by Regulation (EC) No 853/2004 of the European Parliament and of the Council <sup>(1)</sup>	2,0
	8.2. Processed meat	2,0
	9.2. Processed fish and fishery products including crustaceans and molluscs	2,0
	9.3. Fish roe	2,0
	12.2. Herbs, spices, seasonings	2,3
	12.5. Soups and broths	0,23
	12.6. Sauces	1,0
	12.7. Salads and savoury based sandwich spreads	0,23
	14.1. Non-alcoholic beverages	0,02
	14.2. Alcoholic beverages, including alcohol-free and low-alcohol counterparts	0,02
	15. Ready-to-eat savouries and snacks	2,0
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 55.

Unique code	SF-002	
Name of the product	Zesti Smoke Code 10	
Name of the authorisation holder	Mastertaste	
Address of the authorisation holder	Draycott Mills Cam Dursley Gloucestershire GL11 5NA UNITED KINGDOM	
Description and characterisation of the product	1. Source material: 50 – 60 % of hickory ( <i>Carya ovata</i> ), 40 – 50 % oak ( <i>Quercus alba</i> ) 2. Specifications: — pH: 2,0 – 2,5 — Water: 62,3 – 65,7 % — Acid % (expressed as acetic acid): 10,5 – 11 % — Carbonyl compounds (g/100 ml): 15 – 25 — Phenols (mg/ml): 12 – 22 3. Purity criteria: — Lead: < 5,0 mg/kg — Arsenic: < 3,0 mg/kg — Cadmium: < 1,0 mg/kg — Mercury: < 1,0 mg/kg	
Conditions of use	Food category	Maximum level g/kg
	1.7. Cheese and cheese products	0,50
	1.8. Dairy analogues, including beverage whiteners	0,50

	4.2. Processed fruits and vegetables	0,30
	8.1.2. Meat preparations as defined by Regulation (EC) No 853/2004	2,5
	8.2. Processed meat	2,5
	9.2. Processed fish and fishery products including crustaceans and molluscs	2,0
	9.3. Fish roe	2,0
	12.2. Herbs, spices, seasonings	3,0
	12.5. Soups and broths	0,30
	12.6. Sauces	1,0
	12.9. Protein products, excluding products covered in category 1.8	1,0
	15. Ready-to-eat savouries and snacks	3,0
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	
Unique code	SF-003	
Name of the product	Smoke Concentrate 809045	
Name of the authorisation holder	Symrise AG	
Address of the authorisation holder	Mühlenfeldstraße 1 37603 Holzminden GERMANY	
Description and characterisation of the product	1. Source material: Beech ( <i>Fagus sylvatica</i> ) 2. Specifications: — pH: 2 – 3 — Water: 5 – 15 % — Acid % (expressed as acetic acid): 8 – 15 % — Carbonyl compounds: 10 – 20 % — Phenols: 0,2 – 0,6 % 3. Purity criteria: — Lead: < 5 mg/kg — Arsenic: < 3 mg/kg — Cadmium: < 1 mg/kg — Mercury: < 1 mg/kg	
Conditions of use	Food category	Maximum level g/kg
	1. Dairy products and analogue	0,50
	4.2. Processed fruits and vegetables	0,30
	6.4.5. Fillings of stuffed pasta (ravioli and similar)	1,0
	7.1. Breads and rolls	0,60
	7.2. Fine bakery wares	0,60
	8. Meat	0,60

	9.2. Processed fish and fishery products including crustaceans and molluscs	0,60
	9.3. Fish roe	0,60
	12.2. Herbs, spices, seasonings	3,0
	12.5. Soups and broths	0,60
	12.6. Sauces	4,0
	12.7. Salads and savoury based sandwich spreads	1,0
	12.9. Protein products, excluding products covered in category 1.8	1,0
	15. Ready-to-eat savouries and snacks	3,0
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	
Unique code	SF-004	
Name of the product	Scansmoke SEF 7525	
Name of the authorisation holder	Azelis Denmark A/S	
Address of the authorisation holder	Lundtoftegaardsvej 95 2800 Lyngby DENMARK	
Description and characterisation of the product	1. Source materials: 35 % red oak ( <i>Quercus rubra</i> ), 35 % white oak ( <i>Quercus alba</i> ), 10 % maple ( <i>Acer saccharum</i> ), 10 % beech ( <i>Fagus grandifolia</i> ) and 10 % hickory ( <i>Carya ovata</i> ). 2. Specifications: — Water: 0,3 – 0,9 wt. % — Acid (expressed as acetic acid): 0,09 – 0,25 meq/g — Carbonyl compounds: 1,2 – 3,0 wt. % — Phenols: 8 – 12 wt. % 3. Purity criteria: — Lead: < 5,0 mg/kg — Arsenic: < 3,0 mg/kg — Cadmium: < 1,0 mg/kg — Mercury: < 1,0 mg/kg	
Conditions of use	Food category	Maximum level g/kg
	1. Dairy products and analogue	0,16
	2. Fats and oils and fat and oil emulsions	0,05
	4.2. Processed fruits and vegetables	0,05
	5. Confectionery	0,08
	6. Cereals and cereal products	0,05
	7.1. Breads and rolls	0,08
	7.2. Fine bakery wares	0,08
	8. Meat	0,16

	9.2. Processed fish and fishery products including crustaceans and molluscs	0,16
	9.3. Fish roe	0,16
	10.2. Processed eggs and egg products	0,05
	12.2. Herbs, spices, seasonings	0,18
	12.5. Soups and broths	0,05
	12.6. Sauces	0,05
	12.7. Salads and savoury based sandwich spreads	0,05
	12.9. Protein products, excluding products covered in category 1.8	0,05
	14.1. Non-alcoholic beverages	0,05
	14.2. Alcoholic beverages, including alcohol-free and low-alcohol counterparts	0,05
	15. Ready-to-eat savouries and snacks	0,08
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	
Unique code	SF-005	
Name of the product	SmokEz C-10	
Name of the authorisation holder	Red Arrow Products Company LLC	
Address of the authorisation holder	P.O. Box 1537 633 South 20th street Manitowoc, WI 54221- 1537 USA	
Description and characterisation of the product	<p>1. Source materials: Maple (<i>Acer saccharum</i>): 25 – 60 % Oak (<i>Quercus alba</i>): 10 – 40 % Hickory (<i>Carya ovata</i>): 10 – 25 % Ash (<i>Fraxinus americana</i>), birch (<i>Betula papyrifera</i> and <i>Betula alleghanisensis</i>), cherry (<i>Prunus serotina</i>), beech (<i>Facus grandifolia</i>): 0 – 15 % (in total)</p> <p>2. Specifications: — pH: 2,15 – 2,6 — Water: 60,7 – 65,1 % — Acid % (expressed as acetic acid): 10,5 – 12,0 wt. % — Carbonyl compounds: 12,0 – 17,0 wt. % — Phenols: 10,0 – 15,0 mg/ml</p> <p>3. Purity criteria: — Lead: &lt; 5,0 mg/kg — Arsenic: &lt; 3,0 mg/kg — Cadmium: &lt; 1,0 mg/kg — Mercury: &lt; 1,0 mg/kg</p>	
Conditions of use	Food category	Maximum level g/kg
	1.7. Cheese and cheese products	0,20
	8.1.2. Meat preparations as defined by Regulation (EC) no 853/2004	2,5

	8.2. Processed meat	2,5
	9.2. Processed fish and fishery products including crustaceans and molluscs	2,0
	9.3. Fish roe	2,0
	12.2. Herbs, spices, seasoning and condiments	3,0
	12.6. Sauces and like products	3,0
	15. Ready-to-eat savouries and snacks	3,0
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	
Unique code	SF-006	
Name of the product	SmokEz Enviro-23	
Name of the authorisation holder	Red Arrow Products Company LLC	
Address of the authorisation holder	P.O. Box 1537 633 South 20th street Manitowoc, WI 54221- 1537 USA	
Description and characterisation of the product	1. Source materials: Maple ( <i>Acer saccharum</i> ): 25 – 65 % Oak ( <i>Quercus alba</i> ): 20 – 75 % Hickory ( <i>Carya ovata</i> ), ash ( <i>Fraxinus americana</i> ), birch ( <i>Betula papyrifera</i> and <i>Betula alleghanisensis</i> ), cherry ( <i>Prunus serotina</i> ), beech ( <i>Facus grandifolia</i> ): 0 – 15 % (in total) 2. Specifications: — pH: 2,8 – 3,2 — Water: 57,0 – 64,4 % — Acid % (expressed as acetic acid): 6,0 – 7,0 wt. % — Carbonyl compounds: 16,0 – 24,0 wt. % — Phenols: 10,0 – 16,0 mg/ml 3. Purity criteria: — Lead: < 5,0 mg/kg — Arsenic: < 3,0 mg/kg — Cadmium: < 1,0 mg/kg — Mercury: < 1,0 mg/kg	
Conditions of use	Food category	Maximum level g/kg
	1.7. Cheese and cheese products	2,0
	8.1.2. Meat preparations as defined by Regulation (EC) no 853/2004	5,0
	8.2. Processed meat	5,0
	9.2. Processed fish and fishery products including crustaceans and molluscs	2,0
	9.3. Fish roe	2,0
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	



Unique code	SF-007	
Name of the product	Tradismoke™ A MAX	
Name of the authorisation holder	Nactis	
Address of the authorisation holder	36, rue Gutenberg – ZI La Marinière 91070 Bondoufle FRANCE	
Description and characterisation of the product	<p>1. Source materials: Beech (<i>Fagus grandifolia</i>)</p> <p>2. Specifications:</p> <ul style="list-style-type: none"> <li>— pH: 1,5 – 2,5</li> <li>— Water: 50 – 58 wt. %</li> <li>— Acid % (expressed as acetic acid): 13 – 16 wt. %</li> <li>— Carbonyl compounds: 17 – 22 wt. %</li> <li>— Phenols: 30 – 45 mg/ml</li> </ul> <p>3. Purity criteria:</p> <ul style="list-style-type: none"> <li>— Lead: &lt; 5,0 mg/kg</li> <li>— Arsenic: &lt; 3,0 mg/kg</li> <li>— Cadmium: &lt; 1,0 mg/kg</li> <li>— Mercury: &lt; 1,0 mg/kg</li> </ul>	
Conditions of use	Food category	Maximum level g/kg
	1.4. Flavoured fermented milk products including heat treated products	1,0
	1.6.3. Other creams	1,0
	1.7.3. Edible cheese rind	1,0
	1.7.5. Processed cheeses	1,0
	2. Fats and oils and fat and oil emulsions	1,0
	8.1.2. Meat preparations as defined by Regulation (EC) No 853/2004	4,0
	8.2. Processed meat	4,0
	9.2. Processed fish and fishery products including crustaceans and molluscs	4,0
	9.3. Fish roe	4,0
	12.2. Herbs, spices, seasonings	1,0
	12.5. Soups and broths	0,50
	12.6. Sauces	1,0
	14.1. Non-alcoholic beverages	0,10
	14.2. Alcoholic beverages, including alcohol-free and low-alcohol counterparts	0,10
	15. Ready-to-eat savouries and snacks	1,0
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	

Unique code	SF-008	
Name of the product	proFagus-Smoke R709	
Name of the authorisation holder	ProFagus GmbH	
Address of the authorisation holder	Uslarer Strasse 30 37194 Bodenfelde GERMANY	
Description and characterisation of the product	<p>1. Source materials: 90 % beech (<i>Fagus sylvatica</i>), 10 % oak (<i>Quercus alba</i>)</p> <p>2. Specifications:</p> <ul style="list-style-type: none"> <li>— pH: 2,0 – 2,5</li> <li>— Water: 76,7 – 83,5 %</li> <li>— Acid (expressed as acetic acid): 10,5 – 12,5 meq/g</li> <li>— Carbonyl compounds: 5 – 10 wt. %</li> <li>— Phenols: 5 – 10 wt. %</li> </ul> <p>3. Purity criteria:</p> <ul style="list-style-type: none"> <li>— Lead: &lt; 5,0 mg/kg</li> <li>— Arsenic: &lt; 3,0 mg/kg</li> <li>— Cadmium: &lt; 1,0 mg/kg</li> <li>— Mercury: &lt; 1,0 mg/kg</li> </ul>	
Conditions of use	Food category	Maximum level g/kg
	1.7. Cheese and cheese products	2,5
	2. Fats and oils and fat and oil emulsions	0,002
	3. Edible ices	0,005
	4.2. Processed fruits and vegetables	0,55
	5. Confectionery	0,10
	8.1.2. Meat preparations as defined by Regulation (EC) No 853/2004	2,5
	8.2. Processed meat	2,5
	9.2. Processed fish and fishery products including crustaceans and molluscs	2,5
	9.3. Fish roe	2,5
	12.2. Herbs, spices, seasonings	4,0
	12.4. Mustard	0,10
	12.5. Soups and broths	0,28
	12.6. Sauces	1,5
	12.7. Salads and savoury based sandwich spreads	0,40
	14.1. Non-alcoholic beverages	0,10
	14.2. Alcoholic beverages, including alcohol-free and low-alcohol counterparts	0,02
	15. Ready-to-eat savouries and snacks	2,5
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	

Unique code	SF-009	
Name of the product	Fumokomp	
Name of the authorisation holder	Kompozíció Kft	
Address of the authorisation holder	Kompozíció Kft 2053 Herceghalom HUNGARY	
Description and characterisation of the product	<p>1. Source materials: 85 % beech (<i>Fagus sylvatica</i>), 15 % hornbeam (<i>Carpinus betulus</i>)</p> <p>2. Specifications:</p> <ul style="list-style-type: none"> <li>— Water content: &lt; 2 w/w %</li> <li>— Acid % (expressed as acetic acid): 1 – 8 w/w %</li> <li>— Carbonyl compounds: 25 – 30 w/w %</li> <li>— Phenols: 15 – 60 w/w %</li> </ul> <p>3. Purity criteria:</p> <ul style="list-style-type: none"> <li>— Lead: &lt; 5,0 mg/kg</li> <li>— Arsenic: &lt; 3,0 mg/kg</li> <li>— Cadmium: &lt; 1,0 mg/kg</li> <li>— Mercury: &lt; 1,0 mg/kg</li> </ul>	
Conditions of use	Food category	Maximum level g/kg
	1.4. Flavoured fermented milk products including heat treated products	0,06
	1.6.3. Other creams	0,06
	1.7. Cheese and cheese products	0,06
	1.8. Dairy analogues, including beverage whiteners	0,06
	2. Fats and oils and fat and oil emulsions	0,06
	3. Edible ices	0,06
	4.2. Processed fruit and vegetables	0,06
	5. Confectionery	0,06
	6.3. Breakfast cereals	0,06
	6.4.5. Fillings of stuffed pasta (ravioli and similar)	0,06
	6.5. Noodles	0,06
	6.6. Batters	0,06
	6.7. Pre-cooked or processed cereals	0,06
	7.1. Breads and rolls	0,06
	7.2. Fine bakery wares	0,06
	8. Meat	0,06
	9.2. Processed fish and fishery products including crustaceans and molluscs	0,06
	9.3. Fish roe	0,06
	10.2. Processed eggs and egg products	0,06
	12.2. Herbs, spices, seasonings	0,06

	12.3.	Vinegar	0,06
	12.4.	Mustard	0,06
	12.5.	Soups and broths	0,06
	12.6.	Sauces	0,06
	12.7.	Salads and savoury based sandwich spreads	0,06
	12.9.	Protein products, excluding products covered in category 1.8	0,06
	13.3.	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal	0,06
	13.4.	Foodstuffs suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009 <sup>(1)</sup>	0,06
	14.1.4.	Flavoured drinks	0,06
	14.1.5.2.	Other	0,06
	14.2.	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	0,06
	15.	Ready-to-eat savouries and snacks	0,06
	16.	Desserts excluding products covered in category 1, 3 and 4	0,06
Date from which the product is authorised	1 January 2014		
Date until which the product is authorised	1 January 2024		
(1) OJ L 16, 21.1.2009, p. 3.			
Unique code	SF-010		
Name of the product	AM 01		
Name of the authorisation holder	AROMARCO, s.r.o		
Address of the authorisation holder	Mlynská 15 929 01 Dunajská Streda SLOVAKIA		
Description and characterisation of the product	1. Source materials: Beech ( <i>Fagus sylvatica</i> ) 2. Specifications: — Solvent: ethanol/water mixture (approx. 60/40 wt. %) — Acid (expressed as acetic acid): 3,5 – 5,2 g/kg — Carbonyl compounds: 6,0 – 10,0 g/kg — Phenols: 8,0 – 14,0 g/kg 3. Purity criteria: — Lead: < 5,0 mg/kg — Arsenic: < 3,0 mg/kg — Cadmium: < 1,0 mg/kg — Mercury: < 1,0 mg/kg		

Conditions of use	Food category	Maximum level g/kg
	1.4. Flavoured fermented milk products including heat treated products	0,60
	1.6.3. Other creams	0,60
	1.7. Cheese and cheese products	0,60
	1.8. Dairy analogues, including beverage whiteners	0,60
	2. Fats and oils and fat and oil emulsions	0,40
	8.1.2. Meat preparations as defined by Regulation (EC) no 853/2004	0,85
	8.2. Processed meat	0,85
	9.2. Processed fish and fishery products including crustaceans and molluscs	0,80
	9.3. Fish roe	0,80
	14.2. Alcoholic beverages, including alcohol-free and low-alcohol counterparts	0,02
	15. Ready-to-eat savouries and snacks	1,30
Date from which the product is authorised	1 January 2014	
Date until which the product is authorised	1 January 2024	

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