

To all Interested Parties

28 April 2004

Dear Sir/Madam,

Ref: SCO/4/CHEM/15

## **UPDATE ON CONTAMINANTS ISSUES: DIOXINS, PAHs AND HEAVY METALS**

I am writing to update you on recent developments in the EU involving chemical contaminants in food.

### **Dioxins**

Commission Regulation 466/2001, as amended by Council Regulation 2375/2001, allowed a transition period for free range and semi-intensive eggs to comply with the maximum dioxin level set in the legislation. In my letter of 28 January I informed you that, due to the concerns raised by some Member States about the compliance of these products, the Commission proposed to keep the transition period in place.

A Commission Regulation extending the transition period from 1 January 2004 to 1 January 2005 was recently adopted at Standing Committee. Commission Regulation 684/2004 (*Official Journal No L106/6, 15.04.2004*) amends Regulation 466/2001 and also provides some clarification on the description of the products or the parts of the products to which the maximum levels apply.

The Interested Parties letter also referred to a draft Directive (*SANCO/0111/2003 – sampling arrangements for fish*) which proposed amendments to the text at Annexes I and II to Directive 2002/69/EC (dioxins). You will wish to be aware that Commission Directive 2004/44/EC (*Official Journal L113/17, 20.04.2004*) amends Directive 2002/69/EC in relation to the methods for sampling very large fish (Annex I) and inserts a subparagraph to Annex II (analysis). Copies of the Regulation and Directive are available from the EU web site at: [http://europa.eu.int/index\\_en.htm](http://europa.eu.int/index_en.htm).

The Agency will shortly be consulting on a draft Statutory Instrument that will make provision for the enforcement of EC Regulation 684/2004 and transpose Directive 2004/44/EC into national legislation.

## **PAHs**

Discussions continue on the Commission's proposals to set maximum levels for PAHs in foodstuffs. I attach a copy of the latest draft proposals, *SANCO/70/2003 rev 5* (Appendix D), which reflect significant changes from the last document:

- food supplements are omitted from the list;
- the proposed limit for smoked fish is now 5 µg/kg;
- separate limits are proposed for unsmoked fish (2 µg/kg) and shellfish (5µg/kg).

Requests will be made for further data by October 2006 to facilitate a review of the limits.

I also attach a copy of a draft Commission Recommendation, *SANCO/16/2004 rev 1* (Appendix C), on the further investigation into the levels of PAHs in certain foods.

## **Commission Regulation 466/2001**

As you are aware, the Commission review of the maximum levels set under Commission Regulation 466/2001, as amended, are currently under review. I attach a draft Regulation, *SANCO/15/2004 rev 1* (Appendix A), which is due to be discussed at the Working Group meeting on the 3 May. The intention of the draft Regulation is to amend Commission Regulation 466/2001 in relation to heavy metals in foodstuffs. Please note that for foods where data has been too limited to be able to draw a conclusion a separate list is provided for future investigation (Appendix B).

In my letters to Interested Parties of 28 January and 23 March, I informed you that it had been proposed to set a maximum level for lead in dried vine fruits. A proposed limit of 0.2 mg/kg was supported in principle although it was agreed at Working Group that more data was needed. In my letter of 28 January, I asked for any data on the levels that are achievable and information on consumption. At present, this food category has been included in the Annex to the draft Regulation at Section 3.1.10.2. However, the Commission has requested specific data to support its inclusion. If no data is forthcoming, dried vine fruits will be moved to the list for further investigation. I would be grateful for any comments or views as to whether this food category should be included in the legislation.

**I would be grateful for comments and views on the draft proposals to reach me by 26 May, in time for the next Working Group meeting expected in early June.**

Yours sincerely

Karen Knowles  
Novel Foods, Contaminants and Emergency Planning  
Food Standards Agency Scotland

**Appendix A**

**EN**

**EN**

**EN**

**WORKING DOCUMENT ONLY**

**TO REFLECT THE DISCUSSIONS OF THE WORKING GROUP**

**Subject: considerations towards a possible amendment to Regulation (EC) No 466/2001 as regards heavy metals in foods**

**(Text with EEA relevance)**

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food<sup>(1)</sup>, and in particular Article 2(3) thereof,

After consulting the Scientific Committee on Food and the European Food Safety Authority,

Whereas:

- (1) Commission Regulation (EC) No 466/2001<sup>(2)</sup> sets maximum levels for certain contaminants in foodstuffs.
- (2) Maximum levels are set for the heavy metals lead, cadmium and mercury in foods Regulation (EC) No 466/2001 and in the amendment Commission Regulation (EC) No 221/2002<sup>(3)</sup>.
- (3) It is essential, in order to protect public health, to keep contaminants at levels which do not cause health concerns. Maximum levels for lead, cadmium and mercury must be safe and as low as reasonably achievable (ALARA) based upon good manufacturing and agricultural/ fishery practices. On the basis of new data gathered by Member States it is necessary to revise the relevant provisions of Annex I to Regulation (EC) No 466/2001 for these contaminants in certain foods.
- (4) In view of the wide range of fish species eaten and the difficulties in determining which maximum levels are as low as reasonably achievable for which species, it has been necessary to list the main traded species. The list helps to focus on fish species most eaten and most likely to contribute to dietary intake.
- (5) Data from the Member States on mercury in food have indicated the possibility for some groups of consumers to exceed the revised Provisional Tolerable Weekly Intake level (PTWI) of 1.6 µg/kg.bodyweight/day for methyl mercury recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in June 2003. Available data has been for total mercury, although the majority of mercury in fish is methyl mercury. The European Food Safety Authority concluded in its opinion of 24 February 2004 that methyl mercury in food should be minimised,

<sup>1</sup> OJ L 37, 13.2.1993, p1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p1)

<sup>2</sup> OJ L 77, 16.3.2001, p1. Regulation as amended by Regulation (EC) No 242/2004 (OJ L42, 13.2.2004, p3)

<sup>3</sup> OJ L 37, 7.2.2002, p4.

particularly in view of risks to the neurodevelopment of the unborn child and young children. Fish are the main contributors towards dietary intake of methyl mercury. In foods other than fish and fishery products, the levels of methyl mercury are low compared to other forms of mercury which do not have the same safety implications. For ease of analysis it is appropriate to maintain maximum levels for total mercury.

- (6) Regulation (EC) No 466/2001 should be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 466/2001 is amended as set out in the Annex to this Regulation.

*Article 2*

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

It shall apply from 1 April 2005.

This regulation shall not apply to products which were placed on the market before 1 April 2005 in conformity with the provisions applicable. The burden of proving when the products were placed on the market shall be borne by the food business operator.

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

## ANNEX

Section 3. of Annex I to Regulation (EC) No 466/2001 is replaced with the following:

### **Section 3: Heavy metals**

#### **3.1 Lead (Pb)**

Product	Maximum level (mg / kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.1.4. Muscle meat of fish <sup>(4,5)</sup> <b>listed in 3.4,</b> excluding species listed in 3.1.4.1.	0,20	Directive 2001/22/EC	Directive 2001/22/EC
3.1.4.1. Muscle meat of the following fish <sup>(4,5)</sup> : common two-banded seabream ( <i>Diplodus vulgaris</i> ) eel ( <i>Anguilla anguilla</i> ) grey mullet ( <i>Mugil labrosus labrosus</i> ) grunt ( <i>Pomadasys benneti</i> ) horse mackerel or scad ( <i>Trachurus species</i> ) sardine ( <i>Sardina pilchardus</i> ) sardinops ( <i>Sardinops species</i> ) spotted seabass ( <i>Dicentrarchus punctatus</i> ) wedge sole ( <i>Dicologlossa cuneata</i> )	0,40	Directive 2001/22/EC	Directive 2001/22/EC
3.1.5. Crustaceans, excluding brown meat of crab <b>and excluding head and thorax meat of lobster and similar large crustaceans (<i>Nephropidae</i> and <i>Palinuridae</i>)</b>	0,50	Directive 2001/22/EC	Directive 2001/22/EC
<b>? 3.1.10.2. Dried vine fruits (currants, raisins, sultanas) specific data required?</b>	0,20?	Directive 2001/22/EC	Directive 2001/22/EC

<sup>4</sup> Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish.

<sup>5</sup> Muscle meat of fish as defined in the category (a), (b) and (e) of the list of Article 1 of Council Regulation (EC) N° 104/2000 (O.J. L 17, 21.1.2000, p. 22).

### 3.2. Cadmium (Cd)

Product	Maximum level (mg / kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.2.5. Muscle meat of fish <sup>(4,5)</sup> <b>listed in 3.4</b> , excluding species listed in 3.2.5.1.	0,050	Directive 2001/22/EC	Directive 2001/22/EC
3.2.5.1. Muscle meat of the following fish <sup>(4,5)</sup> : anchovy ( <i>Engraulis species</i> ) bonito ( <i>Sarda sarda</i> ) common two-banded seabream ( <i>Diplodus vulgaris</i> ) eel ( <i>Anguilla anguilla</i> ) grey mullet ( <i>Mugil labrosus labrosus</i> ) horse mackerel or scad ( <i>Trachurus species</i> ) louvar or luvar ( <i>Luvarus imperialis</i> ) sardine ( <i>Sardina pilchardus</i> ) sardinops ( <i>Sardinops species</i> ) swordfish ( <i>Xiphias gladius</i> ) tuna ( <i>Thunnus species</i> , <i>Euthynnus species</i> , <b><i>Katsuwonus pelamis</i></b> ) wedge sole ( <i>Dicologlossa cuneata</i> )	0,10	Directive 2001/22/EC	Directive 2001/22/EC

### 3.3. Mercury

Product	Maximum level (mg / kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.3.1. <b>Fishery products and muscle meat of fish</b> <sup>(4,6)</sup> , <b>excluding species listed in 3.3.1.1.</b>	0,50 mg/ kg	Directive 2001/22/EC	Directive 2001/22/EC
3.3.1.1. <u>Muscle meat of</u> the following fish <sup>(4,5)</sup> : Anglerfish ( <i>Lophius species</i> ) atlantic catfish ( <i>Anarhichas lupus</i> ) <del>bass (<i>Dicentrarchus labrax</i>)</del> <del>blue ling (<i>Molva dipterygia</i>)</del> bonito ( <i>Sarda sarda</i> ) eel ( <i>Anguilla species</i> ) emperor, orange roughly, <b>rosy soldier fish</b> ( <i>Hoplostethus species atlantius</i> ) grenadier ( <i>Coryphaenoides rupestris</i> ) halibut ( <i>Hippoglossus hippoglossus</i> ) marlin ( <i>Makaira species</i> ) pike ( <i>Esox lucius</i> ) plain bonito ( <i>Orcynopsis unicolor</i> ) portuguese dogfish ( <i>Centroscymnes coelolepis</i> ) rays ( <i>Raja species</i> ) redfish ( <i>Sebastes marinus, S. mentella, S. viviparus</i> ) sail fish ( <i>Istiophorus platypterus</i> ) scabbard fish ( <i>Lepidopus caudatus, Aphanopus carbo</i> ) shark (all species) snake mackerel or butterfish ( <i>Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens</i> ) sturgeon ( <i>Acipenser species</i> ) swordfish ( <i>Xiphias gladius</i> ) tuna ( <i>Thunnus species, Euthynnus species, Katsuwonus pelamis</i> )	1,0 mg/ kg	Directive 2001/22/EC	Directive 2001/22/EC

<sup>6</sup> Muscle meat of fish and fishery products as defined in the category (a), (b), (c), (e) and (f) of the list of Article 1 of Council Regulation (EC) N° 104/2000 (O.J. L 17, 21.1.2000, p. 22).

### 3.4. Main traded fish species

Entry Number	Common name	Latin name
1	<b>African catfish</b>	<i>Clarius gariepinus</i>
2	Anchovy	<i>Engraulis species</i>
3	Anglerfish/ monkfish	<i>Lophius species</i>
<b>4</b>	<b>Arctic charr</b>	<i>Salvelinus alpinus</i>
5	Atlantic catfish	<i>Anarhichas lupus</i>
6	Barracouda	<i>Thyrites species</i>
7	Bass	<i>Dicentrarchus species</i>
8	Blue ling	<i>Molva dipterygia</i>
9	Blue mouth/ black-belly rosefish/ jacopeer	<i>Sebastichthys capensis</i>
10	Bonito	<i>Sarda sarda</i>
11	Bream	<i>Brama species</i>
12	Carp	<b><i>Cyprinidae species</i></b>
13	Coalfish/ saithe	<i>Pollachius virens</i>
14	Cod	<i>Gadus species, Serranidae, Epinephelus, Mycteroperca species</i>
15	Conger eel	<i>Conger conger</i>
16	Cutlass fish/ hair tails	<i>Triciuridae</i>
<b>17</b>	<b>Dab</b>	<b><i>Limanda limanda</i></b>
18	Dogfish	<i>Squalus species, Scyliorhinus species</i>
19	Eel	<i>Anguilla species</i>
20	Emperor, orange roughy, rosy soldier fish	<i>Hoplostethus species</i>
21	Flounder	<i>Platichthys flesus</i>
22	Grenadier and blue grenadier	<i>Coryphaenoides rupestris, Macruronus species</i>
23	Grunt	<i>Pomadasys benneti</i>
<b>24</b>	<b>Gurnard red and grey</b>	<b><i>Triga lucerna, Eutriglia gurnardus</i></b>
25	Haddock	<i>Melanogrammus aeglefinus</i>
26	Hake	<i>Merluccius species, Urophycis species</i>
27	Halibut	<i>Hippoglossus species, Reinhardtius hippoglossoides</i>
28	Herring	<i>Clupea species</i>
29	Horse mackerel or scad	<i>Trachurus species, Caranx trachurus</i>
30	Ling	<i>Molva species</i>
31	Mackerel	<i>Scomber species</i>
32	Marlin	<i>Makaira species</i>

<b>33</b>	<b>Megrin</b>	<i>Lepidorhombus species</i>
34	Mullet	<i>Mugil species</i>
<b>35</b>	<b>Pangasius</b>	<i>Pangasius species</i>
36	Perch and pike perch	<i>Percidae species, Sander lucioperca</i>
37	Pike	<i>Esox lucius</i>
38	Plaice	<i>Peuronectes platessa</i>
39	Plain bonito	<i>Orcynopsis unicolor</i>
40	Pollack and Alaskan pollack	<i>Pollachius pollachius, Gadus pollachius, Theregra chalcogramma</i>
41	Portuguese dogfish	<i>Centroscymnes coelolepis</i>
<b>42</b>	<b>Pouting</b>	<i>Tricopterus luscus</i>
43	Rays + skates	<i>Raja species</i>
44	Redfish	<i>Sebastes marinus, S. mentella, S. viviparus</i>
45	Sail fish	<i>Istiophorus platypterus</i>
46	Saithe	<i>Pollachius virens</i>
47	Salmon	<i>Salmo salar, Oncorhynchus species</i>
48	Sardine	<i>Sardina pilchardus</i>
49	Sardinops	<i>Sardinops species</i>
50	Scabbard fish	<i>Lepidopus species, Aphanopus carbo</i>
51	Seabream	<i>Diplodus vulgaris, Sparus aurata</i>
52	Shark	all species
<b>53</b>	<b>Snapper</b>	<i>Lutjanidae species</i>
54	Snake mackerel or butterfish	<i>Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens</i>
55	Snoek	<i>Esocidae, Gempylidae</i>
56	Sole	<i>Soleo soecies, Platichthys flesus, Microstomus kitt</i>
57	Sprat/ brisling	<i>Sprattus sprattus, Sardinella species</i>
58	Sturgeon	<i>Acipenser species</i>
59	Swordfish	<i>Xiphias gladius</i>
<b>60</b>	<b>Tilapia</b>	<i>Tilapia species, Cichlidae species</i>
<b>61</b>	<b>Torsk</b>	<i>Brosme brosme</i>
<b>62</b>	<b>Trout</b>	<i>Oncorhynchus species, Salmo trutta species</i>
63	Tuna	<i>Thunnus species, Euthynnus</i>

		<i>species, Neothunnus species, Katsuwonis pelamis</i>
<b>64</b>	<b>Turbot</b>	<b><i>Scophthalmus maximus</i></b>
65	Wedge sole	<i>Dicologlossa cuneata</i>
<b>66</b>	<b>Whitefish</b>	<b><i>Coregonus lavaretus</i></b>
67	Whiting and blue whiting	<i>Merlangius merlangus, Micromesistius species, Gadus poutassou</i>

## Appendix B

### REVIEW OF MAXIMUM LEVELS FOR HEAVY METALS: AREAS IDENTIFIED FOR FURTHER INVESTIGATION

The recent report for SCOOP task 3.2.11 on dietary exposure to metals includes data generated in the Member States largely before the maximum levels set in Regulation (EC) No 466/2001 came into force (April 2002). The impact of the maximum levels might not be reflected in the SCOOP data. In reviewing the current maximum levels some Member States have presented more recent data or data on levels in foods not covered in the SCOOP report. The Table below highlights the contaminant and the particular foods in question where further information would be necessary before discussions on maximum levels could resume:

Contaminant	Food	Comment
<i>Cadmium</i>	Potatoes	Denmark and Finland suggest that recent data shows lower levels might be achievable, but SCOOP data do not. More widespread recent data necessary.
	Rice	Sweden suggests that recent data show lower levels might be achievable, but SCOOP data do not. More widespread recent data necessary.
	Wild fungi	Cultivated fungi already covered in Reg 466/2001. Data needed on levels in wild fungi to clarify what would be reasonably achievable.
	Linseed	Germany suggests a maximum level of 0.6 mg/kg, but data is limited e.g. on natural variation of occurrence levels and intake via different foods where used as an ingredient.
	Sunflower seed	Germany suggests a maximum level of 1.0 mg/kg, but data is limited e.g. on natural variation of occurrence levels and intake via different foods where used as an ingredient.
	Other oil seeds?	Considerations of the group at the same time as linseed and sunflower seed?
<i>Lead</i>	Potatoes	Denmark suggests that recent data show lower levels are achievable, but SCOOP data do not. More widespread recent data necessary.
	Wine	Denmark suggests that recent data show lower levels are achievable, but SCOOP data do not. More widespread recent data necessary.
	Wild fungi	Cultivated fungi already covered in Regulation 466/2001. Data needed on levels in wild fungi to clarify what would be reasonably achievable.
	Food supplements	e.g. to cover chalks?
<i>Mercury</i>	Foods other than fish and fishery products	EFSA concluded that methyl mercury is not a concern at the levels found in other foods, but what are the other forms of mercury, what proportions are present and are maximum levels necessary?

Contact: Martin SLAYNE

## Appendix B

[Martin.slayne@cec.eu.int](mailto:Martin.slayne@cec.eu.int)

26 April 2004

**EN**

**WORKING DOCUMENT ONLY**

**TO REFLECT THE DISCUSSIONS OF THE WORKING GROUP**

**FOR A POSSIBLE COMMISSION RECOMMENDATION**

of [...]

**Subject: on the further investigation into the levels of polycyclic aromatic hydrocarbons in certain foods**

Whereas:

- (8) Commission Regulation (EC) No 466/2001 as amended by Regulation (EC) No [...] 2004 sets maximum levels for polycyclic aromatic hydrocarbons (PAH), specifically benzo(a)pyrene, in certain foods. In view of remaining uncertainties on levels of carcinogenic PAH in foods the Regulation provides for a review of the measures by 30 April 2007. Information is required to inform that review.
- (9) The Scientific Committee on Food concluded in its opinion of 4 December 2002 that a number of polycyclic aromatic hydrocarbons (PAH) are genotoxic carcinogens. In view of the non-threshold effects of genotoxic substances the levels of PAH in foods should be reduced to as low as reasonably achievable. The Scientific Committee on Food concluded that benzo(a)pyrene could be used as a marker for the occurrence and effect of carcinogenic PAH in food, as listed in the Annex. Further analyses of the relative proportions of these PAH in foods is necessary to inform a future review of the suitability of maintaining benzo(a)pyrene as a marker. Methods are available to test for multiple PAH.
- (10) PAH can be formed in foods during heating and drying processes which allow combustion products to come into direct contact with the food substance. Direct fire-drying and heating processes used during the production of food oils, for example olive-residue oil, can result in high levels of PAH. Active carbon can be used to remove benzo(a)pyrene during the refining of oils. Whether refining processes effectively remove all PAH of concern requires further investigation. Production and processing methods should be used which prevent the initial contamination of oils with PAH,

HEREBY RECOMMENDS THAT MEMBER STATES:

1. Investigate the respective levels of benzo(a)pyrene and other polycyclic aromatic hydrocarbons (PAH) highlighted to be carcinogenic by the Scientific Committee on Food, as listed in the Annex. Assess the relative proportions of these PAH in the foods listed in Regulation (EC) No [...] /2004. Investigate also the levels of PAH in other foods that can contain high levels of PAH, such as smoked meats and smoked meat products, dried fruits and food supplements. Communicate the results of the investigations to the

Commission by 31 October 2006, to inform a future review of the maximum levels and the suitability of maintaining benzo(a)pyrene as a marker.

2. Investigate the production methods used for food oils produced on their national territory. Where food oils are produced using methods that may cause PAH contamination in the crude oil, such as direct fire drying and heating processes, investigate with the producers alternative methods that would avoid the initial formation of PAH. Report to the Commission by 31 October 2006 on findings and on progress to replace problematic methods that can cause contamination of the crude oil.

3. Investigate with industry the presence and prevention of PAH in cocoa butter and report findings by 31 October 2006, with a view to planning for the end of the derogation presently listed in Regulation (EC) No [...] /2004.

## ANNEX

Polycyclic aromatic hydrocarbons (PAH) highlighted to be carcinogenic by the Scientific Committee on Food (1), for which further investigation of the relative levels in certain foods is required:

benz(a)anthracene  
benzo(b)fluoranthene  
benzo(j)fluoranthene  
benzo(k)fluoranthene  
benzo(g,h,i)perylene  
benzo(a)pyrene  
chrysene  
cyclopenta(c,d)pyrene  
dibenz(a,h)anthracene  
dibenzo(a,e)pyrene  
dibenzo(a,h)pyrene  
dibenzo(a,i)pyrene  
dibenzo(a,l)pyrene  
indeno(1,2,3-cd)pyrene  
5-methylchrysene

**EN**

**WORKING DOCUMENT ONLY**

**TO REFLECT THE DISCUSSIONS OF THE WORKING GROUP**

**Subject: towards a possible amendment to Regulation (EC) No 466/2001 as regards polycyclic aromatic hydrocarbons in foods**

**(Text with EEA relevance)**

Whereas:

- (11) Commission Regulation (EC) No 466/2001<sup>(7)</sup> sets maximum levels for certain contaminants in foodstuffs, including foods intended for infants and young children, as described by Commission Directive 91/321/EEC of 14 May 1991 on infant formula and follow-on formula<sup>(8)</sup> and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children<sup>(9)</sup>.
- (12) Some Member States have adopted maximum levels for polycyclic aromatic hydrocarbons (PAH) in certain foods. In view of the disparities between Member States and the consequent risk of distortion of competition, Community measures are necessary in order to ensure market unity whilst abiding by the principle of proportionality.
- (13) The Scientific Committee on Food concluded in its opinion of 4 December 2002 that a number of PAH are genotoxic carcinogens. In laboratory studies the levels found to induce experimental tumours were several fold higher than those expected to be found in food and consumed. However, in view of the non-threshold effects of genotoxic substances the levels of PAH in foods should be reduced to as low as reasonably achievable. The Scientific Committee on Food concluded that benzo(a)pyrene could be used as a marker for the occurrence and effect of carcinogenic PAH in food, including also benz(a)anthracene, benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(k)fluoranthene, benzo(g,h,i)perylene, chrysene, cyclopenta(c,d)pyrene, dibenz(a,h)anthracene, dibenzo(a,e)pyrene, dibenzo(a,h)pyrene, dibenzo(a,i)pyrene, dibenzo(a,l)pyrene, indeno(1,2,3-cd)pyrene and 5-methylchrysene. Further analyses of the relative proportions of these PAH in foods would be necessary to inform a future review of the suitability of maintaining benzo(a)pyrene as a marker.
- (14) PAH can be formed in foods during heating and drying processes which allow combustion products to come into direct contact with the food substance. Direct fire-drying and heating processes used during the production of food oils, for example olive-residue oil, can result in high levels of PAH. Active carbon can be used to remove benzo(a)pyrene during the refining of oils. Whether refining processes effectively remove all PAH of concern requires further investigation.

<sup>7</sup> OJ L 77, 16.3.2001, p1. Regulation as amended by Regulation (EC) No 683/2004 (OJ L106, 15.4.2004, p3)

<sup>8</sup> OJ L 175, 4.7.1991, p35. Directive as amended by Directive 1999/50/EC (OJ L139, 2.6.1999, p29)

<sup>9</sup> OJ L 49, 28.2.1996, p17. Directive as amended by Directive 1999/39/EC (OJ L124, 18.5.1999, p8)

Production and processing methods should be used which prevent the initial contamination of oils with PAH.

- (15) In order to protect public health, maximum levels are necessary for benzo(a)pyrene in certain foods containing fats and oils and in foods where smoking or drying processes might cause high levels of contamination. Separate lower maximum levels are necessary in foods for infants, which are achievable through the strictly controlled manufacturing and packaging of infant formulae, follow-on formulae, baby foods and processed cereal-based foods for infants and young children. For some foods, high levels of benzo(a)pyrene can be found, but the available data is inconclusive regarding what levels are reasonably achievable, in particular for smoked meats and smoked meat products and also for dried fruits. Further investigation is needed to clarify achievable levels in these foods.
- (16) Regulation (EC) No 466/2001 should be amended accordingly.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 466/2001 is amended as set out in the Annex to this Regulation, introducing Section 7 for polycyclic aromatic hydrocarbons with maximum levels for benzo(a)pyrene.

*Article 2*

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

It shall apply from 1 April 2005.

This regulation shall not apply to products which were placed on the market before 1 April 2005 in conformity with the provisions applicable. The burden of proving when the products were placed on the market shall be borne by the food business operator.

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

## ANNEX

In Annex I to Regulation (EC) No 466/2001 the following Section 7 is added:

### **“Section 7: Polycyclic aromatic hydrocarbons (PAH)**

Product	Maximum level (µg/ kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
<b>7.1 Benzo(a)pyrene</b> <sup>(1)</sup>			
7.1.1 Oils and fats intended for direct human consumption or use as an ingredient in foods <sup>(2)</sup>	2.0	Directive 2004/.../EC	Directive 2004/.../EC
7.1.2 Foods for infants and young children	1.0	Directive 2004/.../EC	Directive 2004/.../EC
7.1.2.1 Baby foods and processed cereal-based foods for infants and young children <sup>(3)</sup>			
7.1.2.2 Infant formulae and follow-on formulae, including infant milk and follow-on milk <sup>(4)</sup>			
7.1.2.3 Dietary foods for special medical purposes <sup>(5)</sup> intended specifically for infants			
7.1.3. Muscle meat of smoked fish and smoked fishery products <sup>(6)</sup>	5.0	Directive 2004/.../EC	Directive 2004/.../EC
7.1.4. Muscle meat of fish <sup>(7)</sup> , other than smoked fish	2.0	Directive 2004/.../EC	Directive 2004/.../EC
7.1.5. Bivalve molluscs, crustaceans, cephalopods, other than smoked	5.0	Directive 2004/.../EC	Directive 2004/.../EC

<sup>(1)</sup> The Commission shall review the maximum levels for benzo(a)pyrene in the listed food categories foods by 1 April 2007, taking into account the progress in scientific and technological knowledge on the occurrence of benzo(a)pyrene and other carcinogenic polycyclic aromatic hydrocarbons in food.

<sup>(2)</sup> Cocoa butter is excluded from this category whilst investigations into the presence of benzo(a)pyrene in cocoa butter are made. This derogation will be reviewed by 1 April 2007 with a view to include cocoa butter.

<sup>(3)</sup> Baby foods and processed cereal-based foods for infants and young children as defined in Article 1 of Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children, as last amended by Commission Directive 1999/39/EC. The maximum level refers to the product as sold.

<sup>(4)</sup> Infant formulae and follow-on formulae as defined in Article 1 of Commission Directive 91/321/EEC on infant formulae and follow-on formulae, as last amended by Commission Directive 1999/50/EC. The maximum level refers to the product as sold.

<sup>(5)</sup> Dietary foods for special medical purposes as defined in Article 1(2) of Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29). The maximum level refers to the product as sold.

<sup>(6)</sup> Muscle meat of fish and fishery products as defined in the category (a), (b), (c), (e) and (f) of the list of Article 1 of Council Regulation (EC) N° 104/2000 (O.J. L 17, 21.1.2000, p. 22).

<sup>(7)</sup> Muscle meat of fish as defined in the category (a), (b) and (e) of the list of Article 1 of Council Regulation (EC) N° 104/2000 (O.J. L 17, 21.1.2000, p. 22).”



## **CIRCULATION LIST: 28 April 2004**

A.B.P.Scotland	Dundas Brothers Ltd.
Aberdeen Buttery Co.Ltd	Dundee City Council
Aberdeen City Council	East Ayrshire Council
Aberdeen Fish Curers & Merchants Association	East Dunbartonshire Council
Aberdeen Fish Producers Organisation Ltd	East Renfrewshire Council
Aberdeen Scotch Meat Ltd	Express Dairies Direct Service
Aberdeen Smoked Salmon Co.	Eyemouth Port Development Association Ltd
Aberdeen University	Falkirk Council Development Services
Aberdeenshire Council	Farming & Wildlife Advisory Group
Adgen Ltd.	Fencebay Fisheries
Alex Spink and Sons	Fife Council
Allan and Dey Ltd	Fife Fish producers
Allied Distillers	Fife NHS Board
Aquascot	Food Certification Scotland Ltd
Arbroath Fishermans assosiation	Food Industry Forum
Argyll & Bute Council	Food Microbiology and Fish Handling and Processing
ARK Computing Solutions	Food Training & Consultants Company
Arran Smoked Products	Forth Valley Health Board
Association of Public Analysts	Fresh Catch td
Association of Scottish Shellfish Growers	FRS Marine Laboratory
Ayrshire & Arras Health	Fynefish Products
Barony Country Foods	G.A. & M.A. MacIver
Barratlantic Ltd	Galloway Smokehouse
BASC Scotland	Glagow Scientific Services
Beef Assurance Scheme	Glanbia Foods
Belhaven Trout Company	Glasgow Caledonian University
Biodon International	Glasgow City Council
Biomathematics & Statistics Scotland	Glasgow College of Food Technology
Biomedical Research Centre	Glasgow Scientific Services
British Marine Finfish Association	Glasgow University Veterinary School
Brown Brothers (Manufacturing) Ltd	Glasogow Caledonian University
Burnside Farm Foods	Glen Fisheries
Caledonian Cheese Co	Glenrothes College
Campbell's Prime Meat	Grampian Country Food Group
Carloway Seafoods Ltd	Grampian Country Food Group Ltd
Centre for Human Ecology	Grampian Health Board
Centre for Public Health Nutrition Research	Grampian University Hospitals NHS Trust
Charis Innovative Food Services Limited	Greater Glasgow NHS Board
City of Edinburgh Council	Green City Wholefoods
Clackmannanshire Council	Greggs Scotland
Clyde Fishermens Association	Guinness UDV
Colfin Smokehouse	H.S.M.O
Comhairie Nan Eilean Siar	Hannah Research Institute
Commercial Microbiology Limited	Health and Safety Executive
Convention of Scottish Local Authorities(COSLA)	Health Education Board for Scotland (HEBS)
Craighouse Smoke House	Heriot Watt University
D and R Stevenson	Herring Buyers Association Ltd
Daniels Sweet Herring Ltd	Highland Council
Dawnfresh Seafoods	Highland Country Food Ltd
Deans of Huntly	Highland NHS Board

Devron Shellfish	Highland Smoked Salmon
Dumfries & Galloway Council	Highland Spring Ltd
Hilton Group Plc.	North Ayrshire Council
HMS Caledonia	North of Scotland Water Authority
HUSH	Nutrition and Dietetic Consultant
Hutchison Associates Ltd	Orkney Fisheries Association
Ian Hain Associates	Orkney Herring Co Ltd
Independent Farming Group Scotland	Orkney Islands Council
International Federation of Environmental Health	P and C Morris (Fish and Game) Ltd
International Fish Cannery Ltd	Pataks Frozen Food
Inverawe Smokehouses	Perth & Kinross Council
Inverclyde Council	Puremalt Products Ltd.
Island Seafare Ltd	Quality Food Producers (Aberdeen) Ltd
Isle of Skye Seafood Ltd	Quality Meat Scotland
J C Morris and Sons	Queen Margaret University College
J H Milne	R R Spink and Sons
James Finlay Ltd	Ramsay of Carluke Ltd
John Richards (Aberdeen)	Rannoch Smokery
John Ross JR (Aberdeen) Ltd	Ritchies of Rothsey
Joseph Robertson (Aberdeen) Ltd	Road Haulage Assoc Ltd
Kettle Produce Ltd.	Robert Gordon University
Kezie Ltd	Rowett Research Institute
Kilron Seafoods	Royal Alexandra Hospital
Kingdom Bakers Ltd	Royal College of Midwives
Landcatch Ltd.	Royal Environmental Health Institute for Scotland
Lees Of Scotland	RSPB Scotland
Lightbody Celebration Cakes	S.W.R.I.
Loch Fyne Oysters Ltd	SAC
Lomond & Argyll Primary Care NHS Trust	Salar Ltd
Lossie Seafoods Ltd	SASA
Lothian Health Board	Scot Campbell Marine Ltd
M.D. Longhorn & Co	Scot Trout and Salmon
Macaulay Land Research Institute	Scot Trout Ltd.
MacDonalds Smoked Produce	Scotch Whisky Research Institute
MacKenzie Smokehouse	Scottish Ass.of Meat Wholesalers
MacMillan Foods	Scottish Association For Marine Science
MacPhie of Glenbervie Ltd	Scottish Assosiation of Master Bakers
MacRae Foods Ltd.	Scottish Beekeepers Association
Macsween of Edinburgh	Scottish Borders council
Mallaig & North-West Fishermen's Association	Scottish Centre Infection & Environmental Health
Martime & Coastguard Agency	Scottish Chambers of Commerce
McIntosh Donald	Scottish Civic Forum
McIntosh Of Dyce	Scottish Committee Public Health Medicine
Microgram	Scottish Consumer Council
Midlothian Council	Scottish Crop Research Institute
Moray Seafood Ltd	Scottish Dairy Assosiation
Moredun Reasearch Institue	Scottish Egg Producer Retailers Assoc
MRC Social & Public Health Sciences Unit	Scottish Environmental Research Centre
MyInfield Research Services Ltd	Scottish Executive
Napier Univesity	Scottish Executive Health Department
National Radiological Protection Board	Scottish Fishermans Federation
NESFO	Scottish Fishermens Organisation
NFU Scotland	Scottish Food & Drink Federation

NHS Lanarkshire Board	Scottish Food Quality Certification Ltd
Nor-Sea Foods Ltd	Scottish Food Safety Officers Association
North Atlantic Fisheries College	Scottish Foodservice Project
Scottish Health Food Retailers Association	Ullapool & Assynt Boatowners Ass.
Scottish Healthcare Supplies	Unions and Lobbyists
Scottish Parliament	UNIQ Prepared Foods
Scottish Potato Trade Association	United Central Bakeries Ltd
Scottish Quality Salmon	University of Aberdeen
Scottish Retail Consortium	University of Abertay
Scottish Salmon Smokers Association	University of Dundee
Scottish Sea Farms Ltd.	University of Edinburgh
Scottish Shellfish Marketing Group Ltd.	University of Glasgow
Scottish Universities Environmental Research	University Of Paisley
Scottish White Fish Producers Association	University of Strathclyde
Seafish	Voluntary Health Scotland
Seafood Scotland	Walkers Shortbread Ltd
Seafood Shetland	Water At Work Ltd.
SEERAD	Wellington Church
SEHD	West Dunbartonshire Council
Shetland Fishermans Assosiation	West Lothian Council
Shetland Salmon Farmers Association	West of Scotland Fish Producers Organisation Ltd
Shetland Seafood Quality Control	WestCoast Sea Products Ltd
SIMBOIS	Western Isles Fishermans association
Simply Organic	Western Isles Fishermans association
Slimming Systems Ltd	
South Lanarkshire Council	
Spicemanns Ltd.	
Spitfire Resources	
Stirling Council (Catering & Cleaning)	
Stirling Environmental Group	
Strathaird Salmon Ltd	
Strathclyde University	
Strathmore Mineral Water Co Ltd	
Student Union	
Taymar International Foods Ltd	
Tayside NHS Board	
The Achiltibuie Smokehouse	
The Applecross Trust	
The Edinburgh Smoked Salmon	
The Malt Distillers Association of Scotland	
The Moray Council	
The Robert Gordon University	
The Royal Society of Edinburgh	
The Salmon Net Fishing Association of Scotland	
The Sandwich Company	
The Scotch Whisky Association	
The Scottish Food Safety Officers Association	
The Scottish Gourmet (Scotland Direct)	
The Scottish Parliament	
The Shetland Smokehouse Ltd	
The Taviot Game Fare	
Tobermoray Fish Company Ltd	

Tomburie Smokehouse
Trawlpac Seafoods Ltd
U.S.D.A.W.