FOOD STANDARDS AGENCY SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

To Interested Parties

23 March 2004 Ref. SCO/4/CHEM/15

Dear Sir/Madam

UPDATE ON EU DISCUSSIONS ON CHEMICAL CONTAMINANTS

First, I would like to take this opportunity to thank those respondents who have submitted information and data to help inform the UK position on the European Commission's proposals so far.

You will also wish to be aware that ***Commission Regulation (EC) No. 242/2004*** amending Regulation (EC) No 466/2001 as regards inorganic tin in foods and ***Commission Directive 2004/16/EC*** laying down the sampling methods and methods of analysis for the official control of the levels of tin in canned foods, were published on the 12 February 2004. Copies of the legislation can be obtained from the European Union web-site at the following address: http://europa.eu.int/eur-lex/en/index.html. We shall also shortly be consulting on the introduction of enforcement legislation for these two measures.

Finally, as you may be aware, two Commission Working Group meetings were held on 16 and 26-27 February and I am now writing to update you on the progress of discussions on the following contaminants: -

- Dioxins and PCBs
- Polycyclic Aromatic Hydrocarbons
- Brominated Flame Retardants
- Heavy Metals (lead, cadmium and mercury)

The Commission has requested that Member States prepare initial positions on the introduction of PCBs into the Regulations for the next Working Group meeting on dioxins and PCBs.

We are always keen to receive comments and/or data from stakeholders to help inform the UK negotiating position. If you would like to submit comments and/or data on any of

these topics for consideration at the next round of meetings, these should reach me by **25 April 2004.**

1. Dioxins and PCBs

Dioxins, Dioxin-like PCBs and Non-dioxin like PCBs in food

The Commission presented the final results of a report that considered the impact of introducing maximum limits for **dioxin-like PCBs** in food. The report highlights the food groups where significant problems are likely to be encountered if the contribution of PCBs to the TEQ were to be added to dioxins without any adjustment to the limit, notably fish and eels, fish oils and possibly eggs and liver. A central issue was whether the new Regulation would contain separate limits for dioxins and dioxin-like PCBs or a limit on the total TEQ. The Commission stated that it would be preferable to retain separate limits for dioxins and PCBs, so that the new Regulation did not appear to be a rise in limits and envisaged two options:

- To maintain the current dioxin limits and add an increment for dioxin-like PCBs (but only regulate on the basis of the total TEQ)
- To reduce dioxin limits where possible on the basis of current data and apply the ratio to the reduced limit to derive the limit for PCBs, again regulating on the total TEQ.

I would be grateful for any comments and/or data on how PCBs might be brought into the legislation.

2. Polycyclic Aromatic Hydrocarbons (PAHs)

Discussions on possible future legislation for PAHs (SANCO/70/2003 rev 4)

I attach a copy of above document, which was discussed at the Working Group meeting. Points raised on the document included:

i. The Commission is to review any BaP limits agreed and extend controls to additional PAHs by 1 April 2007. **Cocoa butter** is likely to granted a derogation until then (this will not be extended to cocoa butter substitutes).

ii. The limits for **smoked meat** will refer to the **'edible part'**, with a proposed limit of between **2** and **5µg/kg**. Although a limit has not yet been agreed, some Member States favour limits of **1µg/kg** or **2µg/kg** which are in line with their national limits.

iii. The Commission has proposed a limit of between **2** and **5µg/kg** for **smoked fish**. However, there was some argument from Member States for a limit of **2µg/kg** in **smoked fish**, although no consensus was reached.

iv. The UK also proposed that there should be a separate limit for **shellfish** since data showed that a limit of **2µg/kg**, even for unsmoked shellfish, would be difficult to meet.

Commission Decision on Monitoring and Process Investigations (draft SANCO/16/2004)

The Commission presented a first draft of a proposal for Member States to monitor the food supply for BaP and other PAHs.

Sampling and Analysis (draft SANCO/14/2004)

I attach a copy of the above initial draft paper on sampling and analysis, which was discussed at the Working Group meeting. Points raised during the discussion included:

i. The number of incremental samples in section 4.1 of **Annex I** and the amount of sample required, since a 30g sample may be insufficient for some analytical methods.
ii. The limit of detection and limit for qualification in **Annex II** seemed high.
iii. The proposed maximum standard uncertainty value of 0.1C in section 4.3.1 of **Annex II** will be changed to value of 0.2C.

3. Brominated Flame Retardants (BFRs)

A number of Member States indicated that they have work currently underway on BFRs and the Commission had requested to be updated. Regulatory limits may well be forthcoming.

4. Review of Commission Regulation 466/2001- Heavy Metals

Heavy Metals and proposed revision of Section 3 of Annex I to Regulation 466/2001 (Draft SANCO/15/2004)

The Commission produced the proposed revised section of Annex I, Section 3 to Regulation 466/2001. The following points were raised by the Working Group:

i. Section 3.1.4 **lead** and **cadmium** in **fish and crustaceans**. **Gastropods** (marine and land) will now not be included with molluscs due to the absence of any data.
ii. Section 3.1.9.1 **fungi**. Either a single limit should be set for lead and cadmium in fungi, or a higher limit set for certain species rather than trying to distinguish cultivated from wild fungi. The Commission will also consider setting limits based on **dry weight rather than wet**.

iii. Section 3.1.10.2 **dried vine fruits**. A limit for lead of **0.2mg/kg** in dried vine fruits was proposed. The proposal was supported in principal although it was agreed that more data was needed for lead and cadmium in dried fruit.

iv. Section 3.2.5 and Section 3.1.4 **fish**. There have been a number of changes to the fish categories and the list has been modified to include a list of the main traded species.

v. Section 3.2.5.1 Discussions on **Swordfish** being added to the higher limit for **cadmium** of **0.1mg/kg** continue.

vi. **New proposed section**. Limits for **lead** in **food supplements**, including chalks have been suggested. There was support for limits with some Member States suggesting a limit of **1mg/kg**.

vii. Section 3.2.12 **linseed**. New limits for **cadmium** of **0.6mg/kg** in linseed were discussed.

viii. Section 3.2.13 **sunflower seeds.** New limits for **sunflower seeds** of **1.0mg/kg** were also discussed and received general support.

ix. Section 3.2.11.2 **vegetables and fruits**. A reduction to the **0.1mg/kg** limit has been suggested for **cadmium** in **potatoes**.

x. Section 3.2.9 **cereals**. A reduction to the limit for cadmium in rice was also proposed.

I would be grateful for any comments and/or data to inform the UK position on the proposals for a reduction to the limits for cadmium in rice and potatoes.

Yours sincerely

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Draft SANCO/14/2004

DRAFT WORKING DOCUMENT ../…/EC

of […]

laying down the sampling methods and the methods of analysis for the official control of the levels of benzo(a)pyrene in foods

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption[1], and in particular Article 1 thereof,

Whereas:

(1) Commission Regulation (EC) N° 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs[2], as last amended by Regulation ../../EC[3] fixes maximum limits for benzo(a)pyrene in foods and makes reference to measures laying down the sampling and analysis methods to be used.

(2) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs[4] introduces a system of quality standards for laboratories entrusted by the Member States with the official control of foodstuffs.

(3) It seems necessary to fix general criteria, which the method of analysis has to comply with in order to ensure that laboratories, in charge of the control, use methods of analysis with comparable levels of performance. It is also of major importance that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach across the European Union. These interpretation rules are of application for the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the national rules apply.

[1] O.J. L 372, 31.12.1985, p. 50.
[2] OJ L 77, 16.3.2001, p.1
[3] OJ L , .3.2002, p.
[4] O.J. L 290, 24.11.1993, p. 14.

(4) The provisions for the sampling and methods of analysis have been drawn up on the basis of present knowledge and they may be adapted to take account of advances in scientific and technological knowledge.

(5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Member States shall take all measures necessary to ensure that the sampling for the official control of the levels of benzo(a)pyrene in foods is carried out in accordance with the methods described in the Annex I of this Directive.

Article 2

The Member States shall take all measures necessary to ensure that sample preparation and methods of analyses used for the official control of the levels of benzo(a)pyrene in foods comply with the criteria described in the Annex II of this Directive.

Article 3

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive by 31 July 2005. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.
When Member States adopt those provisions, their provisions shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.
This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
David BYRNE
Member of the Commission

ANNEX I

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF BENZO(A)PYRENE IN FOODS.

1. Purpose and Scope

Samples intended for official checking of the levels of benzo(a)pyrene in foods shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots. Compliance with maximum levels laid down in Commission Regulation (EC) 466/2001 shall be established on the basis of the levels determined in the laboratory samples.

2. Definitions

Lot:	an identifiable quantity of a food commodity delivered at one time and having been determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings
Sublot:	designated part of a lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable
Incremental sample:	a quantity of material taken from a single place in the lot or sublot
Aggregate sample:	the combined total of all the incremental samples taken from the lot or sublot
Laboratory sample:	sample intended for the laboratory

3. General provisions

3.1. Personnel

Sampling shall be performed by an authorised person as specified by the Member States.

3.2. Material to be sampled

Each lot which is to be examined must be sampled separately.

3.3. Precautions to be taken

In the course of sampling and preparation of the samples precautions must be taken to avoid any changes, which would affect the benzo(a)pyrene content, adversely affect the analytical determination or make the aggregate samples unrepresentative.

3.4. Incremental samples

As far as possible incremental samples should be taken at various places distributed throughout the lot or sublot. Departure from this procedure must be recorded in the record.

3.5. Preparation of the aggregate sample

The aggregate sample is made up by uniting all incremental samples. This aggregate sample is homogenised in the laboratory.

3.6. Replicate laboratory samples

Replicate laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample unless this conflicts with Member States' rules on sampling.

3.7. Packaging and transmission of samples

Each sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample, which might arise during transportation or storage.

3.8. Sealing and labelling of samples

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member State's regulations.

A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

4. Sampling plans

The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

4.1. Number of incremental samples

In the case of oils, for which a homogeneous distribution of benzo(a)pyrene can be assumed within a given lot, it is sufficient to take three incremental samples per lot to form the aggregate sample. Reference to the lot number shall be given. A similar approach can be taken for food supplements.

For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The incremental samples shall be of similar weight, no less than 100g each, resulting in an aggregate sample of no less than 300g (see point 3.5). The incremental samples for food supplements shall be no less than 10g each, resulting in an aggregate sample of no less than 30g.

Table 1: Minimum number of incremental samples to be taken from the lot

Weight of lot (in kg)	Minimum number of incremental samples to be taken
< 50	3
50 to 500	5
> 500	10

If the lot consists of individual packages, then the number of packages which shall be taken to form the aggregate sample is given in Table 2.

Table 2: Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units in the lot or sublot	Number of packages or units to be taken
1 to 25	1 package or unit
26 to 100	About 5%, at least 2 packages or units
> 100	About 5%,at maximum 10 packages or units

4.2 Sampling at retail stage

Sampling of foodstuffs at the retail stage should be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage can be used provided that they ensure sufficient representativeness for the sampled lot.

5. Compliance of the lot or sublot with the specification

The control laboratory shall analyse the laboratory sample for enforcement in at least two independent analyses, and calculate the mean of the results.

The lot is accepted if the mean does not exceed the respective maximum level (as laid down in Regulation (EC) No 466/2001) taking into account the measurement uncertainty and correction for recovery.

The lot is non-compliant with the maximum level (as laid down in Regulation (EC) 466/2001) if the mean exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.

ANNEX II

SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CHECKING OF THE LEVELS OF BENZO(A)PYRENE IN FOODS

1. Precautions and general considerations for benzo(a)pyrene in food samples

The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.

The analyst should ensure that samples do not become contaminated during sample preparation. Containers should be rinsed with high purity acetone or hexane (p.A., HLPC grade or equivalent) before use to minimise the risk of contamination. Wherever possible, apparatus coming into contact with the sample should be made of inert materials e.g. aluminium, glass or polished stainless steel. Plastics such as polypropylene, PTFE etc. should be avoided because the analyte can adsorb onto these materials.

All of the sample material received by the laboratory is to be used for the preparation of test material. Only very finely homogenised samples give reproducible results.

There are many satisfactory specific sample preparation procedures which may be used, for example, ISO/WD 15753:2001 for oils (1).

2. Treatment of the sample as received in the laboratory

Finely grind (where relevant) and mix thoroughly the complete aggregate sample using a process that has been demonstrated to achieve complete homogenisation.

3. Subdivision of samples for enforcement and defence purposes

The replicate samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised material unless this conflicts with Member States' rules on sampling.

4. Method of analysis to be used by the laboratory and laboratory control requirements

4.1. Definitions

A number of the most commonly used definitions that the laboratory will be required to use are given below:

r =	Repeatability, the value below which the absolute difference between 2 single test results obtained under repeatability conditions (i.e., same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95%) and hence $r = 2.8 \times s_r$.
s_r =	Standard deviation, calculated from results generated under repeatability conditions.

RSD_r= Relative standard deviation, calculated from results generated under repeatability conditions [(s_r / $\bar{x}$) x 100], where $\bar{x}$ is the average of results over all laboratories and samples.

R = Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e., on identical material obtained by operators in different laboratories, using the standardised test method), may be expected to lie within a certain probability (typically 95%); R = 2.8 x s_R.

s_R = Standard deviation, calculated from results under reproducibility conditions.

RSD_R = Relative standard deviation calculated from results generated under reproducibility conditions [(s_R / $\bar{x}$) x 100].

$HORRAT_r$ = the observed RSD_r divided by the RSD_r value estimated from the Horwitz equation using the assumption r = 0.66R.

$HORRAT_R$ = the observed RSD_R value divided by the RSD_R value calculated from the Horwitz equation (2).

U = the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95%.

4.2. General requirements

Methods of analysis used for food control purposes must comply with the provisions of items 1 and 2 of the Annex to Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption[5].

4.3. Specific requirements

Where no specific methods for the determination of benzo(a)pyrene in foods are prescribed at Community level, laboratories may select any validated method provided the selected method meets the performance criteria indicated in Table 2. The validation should ideally include a certified reference material.

Table 2: Performance criteria for methods of analysis for benzo(a)pyrene

Parameter	**Value/Comment**
Applicability	Foods specified in Regulation (EC) N° …/2003
Detection limit	No more than 0.3 µg/kg
Limit of quantification	No more than 0.9 µg/kg
Precision	$HORRAT_r$ or $HORRAT_R$ values of less than 1.5 in the validation collaborative trial

[5] OJ L 372 of 31.12.85, p. 50.

Recovery	70% - 120%
Specificity	Free from matrix or spectral interferences, verification of positive detection

4.3.1. Performance Criteria - Uncertainty Function Approach

However, an uncertainty approach may also be used to assess the suitability of the method of analysis to be used by the laboratory. The laboratory may use a method which will produce results within a maximum standard uncertainty. The maximum standard uncertainty can be calculated using the following formula:

$$Uf = \sqrt{(LOD/2)^2 + (0.1C)^2}$$

where:

Uf is the maximum standard uncertainty

LOD is the limit of detection of the method

C is the concentration of interest

If an analytical method provides results with uncertainty measurements less than the maximum standard uncertainty the method will be equally suitable to one which meets the performance characteristics given in Table 2.

4.4. Recovery calculation and reporting of results

The analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery is used for checking compliance (see Annex I, point 5).

The analyst should note the 'European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation'(3).

The analytical result has to be reported as *x* +/- U whereby *x* is the analytical result and U is the measurement uncertainty.

4.5. Laboratory quality standards

Laboratories must comply with Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs.

4.6. Other considerations for the analysis

Proficiency testing

Participation in appropriate proficiency testing schemes which comply with the 'International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories'(4) developed under the auspices of IUPAC/ISO/AOAC.

Internal quality control

Laboratories should be able to demonstrate that they have internal quality control procedures in place. Examples of these are the 'ISO/AOAC/IUPAC Guidelines on Internal Quality Control in Analytical Chemistry Laboratories'(5).

REFERENCES

1. ISO/WD 15753:2001 (*full details to add*)
2. W Horwitz, "Evaluation of Analytical Methods for Regulation of Foods and Drugs", Anal. Chem., 1982, **54**, 67A - 76A.
3. European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation, 2004 (SANCO website address).
4. ISO/AOAC/IUPAC International Harmonised Protocol for Proficiency Testing of (Chemical) Analytical Laboratories, Edited by M Thompson and R Wood, Pure Appl. Chem., 1993, **65**, 2123 - 2144 (Also published in J. AOAC International, 1993, **76**, 926).
5. ISO/AOAC/IUPAC International Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories, Edited by M Thompson and R Wood, Pure Appl. Chem., 1995, **67**, 649 - 666.

Draft SANCO/15/2004

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food([6]), 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([7]) 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([8]).

(3) It is essential, in order to protect public health, to keep contaminants at levels which are toxicologically acceptable. 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 it is necessary to revise the relevant provisions of Annex I to Regulation (EC) No 466/2001 for these contaminants in certain foods. The revisions maintain a high level of consumer health protection.

(4) In view of the wide range of fish species eaten and the difficulties in determining which maximum levels for heavy metals are as low as reasonably achievable for which species, it has been necessary to list the main traded species. This list helps to focus on the species most eaten and most likely to contribute to dietary intake.

[6] 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)

[7] OJ L 77, 16.3.2001, p1. Regulation as amended by Regulation (EC) No 242/2004 (OJ L42, 13.2.2004, p3)

[8] OJ L 37, 7.2.2002, p4.

(5) The European Food Safety Authority concluded in its opinion of 24 February 2004 that methyl mercury in food… (*should be a low as possible? – opinion will be available shortly*). Fish are the main contributor towards dietary intake of methyl mercury. Data from the Member States have indicated that it is possible for some groups of consumers to exceed the revised provisional tolerable weekly intake level (PTWI) of 1.6 ug/kg.body weight/day recommended by the Joint Expert Committee on Food Additives (JECFA). The available data has been on total mercury, although the majority of mercury in fish is methyl mercury. 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.

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

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
3.1.1. Cow's milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Council Directive 92/46/EEC)	0,02	Directive 2001/22/EC	Directive 2001/22/EC
3.1.2. Infant formulae and follow-on formulae as defined in Directive 91/321/EEC[9]	0,02	Directive 2001/22/EC	Directive 2001/22/EC
3.1.3. Meat of bovine animals, sheep, pig and poultry as defined in Article 2 (a) of Council Directive 64/433/EEC[10], as last amended by Council Directive 95/23/EC[11], and Article 2 (1) of Council Directive 71/118/EEC[12], as last amended by Council Directive 97/79/EC[13], excluding offal as defined in Article 2 (e) of Council Directive 64/433/EEC and Article 2 (5) of Council Directive 71/118/EEC	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.3.1. Edible offal of cattle, sheep, pig and poultry as defined in Article 2 (e) of Council Directive 64/433/EEC and Article 2 (5) of Council Directive 71/118/EEC	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.1.4. Muscle meat([14]) of fish **listed in 3.4 and** as defined in the category (a), (b) and (e) of the list of Article 1 of Council Regulation (EC) N° 104/2000[15], excluding fish species listed in 3.1.4.1.	0,2	Directive 2001/22/EC	Directive 2001/22/EC

9 Maximum level applies to the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.
10 O.J. B 121, 29.7.1964, p. 2012.
11 O.J. L 243, 11.10.1995, p. 7.
12 O.J. L 55, 8.3.1971, p. 23.
13 O.J. L 24, 30.1.1998, p. 31.
14 Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish
15 O.J. L 17, 21.1.2000, p. 22.

3.1.4.1. Muscle meat([3]) of: ~~bonito (*Sarda sarda*)~~ common two-banded seabream (*Diplodus vulgaris*) eel (*Anguilla anguilla*) grey mullet (*Mugil labrosus labrosus*) grunt (*Pomadasys benneti*) horse mackerel or scad (*Trachurus* ***species*** ~~*trachurus*~~) sardine (*Sardina pilchardus*) sardinops (*Sardinops species*) spotted seabass (*Dicentrarchus punctatus*) ~~tuna (*Thunnus species* and *Euthynnus species*)~~ wedge sole (*Dicologoglossa cuneata*)	0,4	Directive 2001/22/EC	Directive 2001/22/EC
3.1.4.2 Species of fish not listed in 3.4	0,4	Directive 2001/22/EC	Directive 2001/22/EC
3.1.5. Crustaceans, excluding brown meat of crab	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.1.6. Bivalve molluscs **+ gastropods?**	1,5	Directive 2001/22/EC	Directive 2001/22/EC
3.1.7 Cephalopods (without viscera)	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.1.8. Cereals (incl. buckwheat), legumes and pulses	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.9. Vegetables as defined in Article 1 of Council Directive 90/642/EEC[16], as last amended by Directive 2000/48/EC[17], excluding brassica, leafy vegetables, fresh herbs and all fungi. In case of potatoes the maximum level applies to peeled potatoes.	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.9.1 Brassica, leafy vegetables and all cultivated fungi **(including cultivated wild-type fungi)** ***or all cultivated and wild fungi***	0,3	Directive 2001/22/EC	Directive 2001/22/EC
3.1.10. Fruits as defined in Article 1 of Council Directive 90/642/EEC, excluding berries and small fruits.	0,1	Directive 2001/22/EC	Directive 2001/22/EC

[16] O.J. L 350, 14.12.1990, p. 71.
[17] O.J. L 197, 3.8.2000, p. 26.

3.1.10.1 Berries and small fruits as defined in Article 1 of Council Directive 90/642/EEC	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.10.2. Dried vine fruits (currants, raisins, sultanas)	**0,2?**	**Directive 2001/22/EC**	**Directive 2001/22/EC**
3.1.11. Fats and oils, including milk fat	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.1.12. Fruit juices, concentrated fruit juices (for direct consumption) and fruit nectars as defined in Council Directive 93/77/EEC[18]	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.1.13. Wines as defined in Council Regulation (EC) N° 1493/1999[19] (including sparkling wines and excluding liqueur wines), aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails as defined in Council Regulation (EEC) N° 1601/91[20], and ciders, perry and fruit wines. Maximum level applies to products produced from the fruit harvest 2001 onwards.	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.1.14. ***Food supplements? E.g. to cover chalks etc?***			

[18] O.J. L 244, 30.9.1993, p. 23.
[19] O.J. L 179, 14.7.1999, p. 1.
[20] O.J. L 149, 14.6.1991, p. 1.

3.2. Cadmium (Cd)

Product	Maximum level (mg / kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
3.2.1. Meat of bovine animals, sheep, pig and poultry as defined in Article 2 (a) of Council Directive 64/433/EEC and Article 2 (1) of Council Directive 71/118/EEC excluding offal as defined in Article 2 (e) of Council Directive 64/433/EEC and Article 2 (5) of Council Directive 71/118/EEC	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.2.2. Meat of horse	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.3. Liver of cattle, sheep, pig and poultry	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.2.4. Kidney of cattle, sheep, pig and poultry	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.2.5. Muscle meat([3]) of fish **listed in 3.4 and** as defined in the category (a), (b) and (e) of the list of Article 1 of Council Regulation (EC) N° 104/2000, excluding fish species listed in 3.2.5.1.	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.2.5.1. Muscle meat([3]) of: anchovy **(*Engraulis species*)** bonito (*Sarda sarda*) common two-banded seabream (*Diplodus vulgaris*) eel (*Anguilla anguilla*) grey mullet (*Mugil labrosus labrosus*) horse mackerel or scad (*Trachurus* ***species*** ~~*trachurus*~~) louvar or luvar (*Luvarus imperialis*) sardine (*Sardina pilchardus*) sardinops (*Sardinops species*) **swordfish (Xiphias gladius** tuna (*Thunnus* and *Euthynnus species*) wedge sole (*Dicologoglossa cuneata*)	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.2.5.2 Species of fish not listed in 3.4	0,1	Directive 2001/22/EC	Directive 2001/22/EC

3.2.6. Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*)	0,5	Directive 2001/22/EC	Directive 2001/22/EC
3.2.7. Bivalve molluscs **+ gastropods?**	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.2.8. Cephalopods (without viscera)	1,0	Directive 2001/22/EC	Directive 2001/22/EC
3.2.9. Cereals, excluding bran, germ, wheat grain and rice	0,1	Directive 2001/22/EC	Directive 2001/22/EC
3.2.9.1 Bran, germ, wheat grain and rice	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.10. Soybeans	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.11. Vegetables and fruits as defined in Article 1 of Council Directive 90/642/EEC, excluding leafy vegetables, fresh herbs, all fungi, stem vegetables, root vegetables and potatoes	0,05	Directive 2001/22/EC	Directive 2001/22/EC
3.2.11.1 Leafy vegetables, fresh herbs, celeriac and all cultivated fungi **(including cultivated wild-type fungi)** ***or all cultivated and wild fungi?***	0,2	Directive 2001/22/EC	Directive 2001/22/EC
3.2.11.2 Stem vegetables, root vegetables and potatoes, excluding celeriac. In case of potatoes the maximum level applies to peeled potatoes (***is a lower level achievable for potatoes?***).	0,1	Directive 2001/22/EC	Directive 2001/22/EC
? 3.2.12. Linseed	**0,6?**	Directive 2001/22/EC	Directive 2001/22/EC
? 3.2.13. Sunflower seeds	**1,0?**	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. **Fishery products and muscle meat([3]) of fish as listed in 3.4 and as defined in the category (a), (b) and (e) of the list of Article 1 of Council Regulation (EC) N° 104/2000, excluding fish species listed in 3.3.1.1.**	0,5 mg/ kg	Directive 2001/22/EC	Directive 2001/22/EC
3.3.1.1. Muscle meat([3]) of: Anglerfish (*Lophius species*) atlantic catfish (*Anarhichas lupus*) bass (*Dicentrarchus labrax*) blue ling (*Molva dipterygia*) bonito (*Sarda sarda*) eel (*Anguilla species*) emperor or orange roughy (*Hoplostethus atlanticus*) grenadier (*Coryphaenoides rupestris*) halibut (*Hippoglossus hippoglossus*) marlin (*Makaira species*) pike (*Esox lucius*) plain bonito (*Orcynopsis unicolor*) portuguese dogfish (*Centroscymnes coelolepis*) rays (*Raja species*) redfish (*Sebastes marinus, S. mentella, S. viviparus*) sail fish (*Istiophorus platypterus*) scabbard fish (*Lepidopus caudatus, Aphanopus carbo*) shark (all species) snake mackerel or butterfish (*Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens*) sturgeon (*Acipenser species*) swordfish (*Xiphias gladius*) tuna (*Thunnus species and Euthynnus species*)	1,0 mg/ kg	Directive 2001/22/EC	Directive 2001/22/EC
3.3.1.2. Species of fish not listed in 3.4	1,0 mg/kg	Directive 2001/22/EC	Directive 2001/22/EC

3.4. Main traded fish species

Entry Number	Common name	Latin name
1	Anchovy	*Engraulis species*
2	Anglerfish/ monkfish	*Lophius species*
3	Atlantic catfish	*Anarhichas lupus*
4	Barracouda	*Thyrites species*
5	Bass	*Dicentrarchus species*
6	Blue ling	*Molva dipterygia*
7	Blue mouth/ black-belly rosefish/ jacopever	*Sebastichthys capensis*
8	Bonito	*Sarda sarda*
9	Bream	*Brama species*
10	Carp	
11	Coalfish/ saithe	*Pollachius virens*
12	Cod	*Gadus species, Serranidae, Epinephelus, Mycteroperca species*
13	Conger eel	*Conger conger*
14	Cutlass fish/ hair tails	*Triciuridae*
15	Dogfish	*Squalus species, Scyliorhinus species*
16	Eel	*Anguilla species*
17	Emperor or orange roughy	*Hoplostethus atlanticus*
18	Flounder	*Platichthys flesus*
19	Grenadier and blue grenadier	*Coryphaenoides rupestris, Macruronus novaezealandiae*
20	Grunt	*Pomadasys benneti*
21	Haddock	*Melanogrammus aeglefinus, Gladus aeglefinus*
22	Hake	*Merluccius species, Urophycis species*
23	Halibut	*Hippoglossus species,*

		Reinhardtius hippoglossoides
24	Herring	*Clupea species*
25	Horse mackerel or scad	*Trachurus species, Caranx trachurus*
26	Ling	*Molva species*
27	Mackerel	*Scomber species*
28	Marlin	*Makaira species*
29	Mullet	*Mugil species*
30	Perch	*Percidae*
31	Pike	*Esox lucius*
32	Plaice	*Peuronectes platessa*
33	Plain bonito	*Orcynopsis unicolor*
34	Pollack and Alaskan pollack	*Pollachius pollachius, Gadus pollachius, Theregra chalcograma*
35	Portuguese dogfish	*Centroscymnes coelolepis*
36	Rays	*Raja species*
37	Redfish	*Sebastes marinus, S. mentella, S. viviparus*
38	Sail fish	*Istiophorus platypterus*
39	Salmon	*Salmo salar, Oncorhynchus species*
40	Sardine	*Sardina pilchardus*
41	Sardinops	*Sardinops species*
42	Scabbard fish	*Lepidopus species, Aphanopus carbo*
43	Seabream	*Diplodus vulgaris*
44	Shark	all species
45	Snake mackerel or butterfish	*Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens*
46	Snoek	*Esocidae, Gempylidae*

47	Sole	*Soleo soecies, Platichthys flesus*
48	Sprat/ brisling	*Sprattus sprattus, Sardinella species*
49	Sturgeon	*Acipenser species*
50	Swordfish	*Xiphias gladius*
51	Tuna	*Thunnus species, Euthynnus species, Neothunnus species, Katsuwonis pelamis*
52	Wedge sole	*Dicologoglossa cuneata*
53	Whiting and blue whiting	*Merlangius merlangus, Micromesistius species, Gadus poutassou*

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Draft SANCO/16/2004

WORKING DOCUMENT FOR POSSIBLE COMMISSION DECISION

of […]

Subject: provisions for monitoring and further investigation into the levels of polycyclic aromatic hydrocarbons in certain foods

Whereas:

(1) Commission Regulation (EC) No 466/2001 as amended by Regulation (EC) No […] 2004 sets maximum levels for benzo(a)pyrene in certain foods.

(2) 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, listed in the Annex to this Decision. Further analyses of the relative proportions of these PAH in foods is necessary to inform a future review of the suitablility of maintaining benzo(a)pyrene as a marker. Methods are available to test for multiple PAH.

(3) 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.

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

Article 1

The Member States shall investigate and monitor the levels of benzo(a)pyrene and other polycyclic aromatic hydrocarbons highlighted to be carcinogenic by the Scientific Committee on Food (1), listed in the Annex to this Decision. The Member States shall assess the relative proportions of these PAH in the foods listed in Regulation (EC) No […]/2004. The results of the monitoring should be communicated 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.

Article 2

The Member States shall investigate the production methods used for food oils produced on their national territory. Where food oils are produced using direct fire drying and heating processes, which may cause contamination with PAH, the Member States shall investigate with the producers alternative methods that would avoid the initial formation of PAH in the crude oil. The Member States shall report to the Commission by 31 October 2006 on the methods of production and on the progress to replace methods which cause contamination of the crude oil.

This Decision is addressed to the Member States.

Done at Brussels, […]

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

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 polycyclic aromatic hydrocarbons in foods

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food([21]), and in particular Article 2(3) thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) Commission Regulation (EC) No 466/2001([22]) sets maximum levels for certain contaminants in foodstuffs, including foods intended for infants and young children, covered by Commission Directive 91/321/EEC of 14 May 1991 on infant formula and follow-on formula([23]) and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children([24]).

(2) 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.

(3) 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

[21] 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)
[22] OJ L 77, 16.3.2001, p1. Regulation as amended by Regulation (EC) No 242/2004 (OJ L42, 13.2.2004, p3)
[23] OJ L 175, 4.7.1991, p35. Directive as amended by Directive 1999/50/EC (OJ L139, 2.6.1999, p29)
[24] OJ L 49, 28.2.1996, p17. Directive as amended by Directive 1999/39/EC (OJ L124, 18.5.1999, p8)

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 suitablility of maintaining benzo(a)pyrene as a marker.

(4) 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.

(5) In order to protect public health, maximum levels are needed 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.

(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, 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.

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

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 (ìg/ kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
7.1 Benzo(a)pyrene ([1])			
7.1.1 Oils and fats intended for direct human consumption or use an as ingredient in foods (*achievability in cocoa butter to be determined*)	2.0	Directive 2003/…/EC	Directive 2003/…/EC
7.1.2 Food supplements([2])	2.0		
7.1.4 Foods for infants and young children	1.0	Directive 2003/…/EC	Directive 2003/…/EC
7.1.4.1 Baby foods and processed cereal-based foods for infants and young children([3])			
7.1.4.2 Infant formulae and follow-on formulae, including infant milk and follow-on milk([4])			
7.1.4.3 Dietary foods for special medical purposes([5]) intended specifically for infants.			
7.1.5. Smoked meats and smoked meat products	2.0-5.0?		
7.1.6. Smoked fish and smoked fishery products ([6])	2.0-5.0?		
7.1.7. Fish and fishery products, other than smoked products listed in 7.1.6.	1.0?		

([1]) 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.

([2]) Described in Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 10.6.2002, p51).

([3]) 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.

([4]) 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.

([5]) 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.

([6]) The maximum level applies to the edible portion and excludes the skin of fish.

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