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呈第 層決行

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保存年限：

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發文日期：中華民國102年3月12日

發文字號：署授食字第1021300532號

速別：

密等及解密條件或保密期限：

附件：降低食品中多環芳香族碳氫化合物含量之作業指引1份

主旨：檢送「降低食品中多環芳香族碳氫化合物含量之作業指引」1份(如附件)，請 查照。

正本：財團法人食品工業發展研究所、中華民國健康食品協會、中華民國全國商業總會、中華民國全國工業總會、財團法人台灣優良農產品發展協會、台灣罐頭食品工業同業公會、台灣區糖菓餅乾麵食工業同業公會、台灣區蜜餞工業同業公會、台灣區蔬果加工工業同業公會、台灣區冷凍食品工業同業公會、台灣區冷凍水產工業同業公會、台灣區釀造食品工業同業公會、台灣區米穀工業同業公會、台灣區胺基酸工業同業公會、台灣區植物油製煉工業同業公會、台灣區飲料工業同業公會、台灣區冷凍肉類工業同業公會、台灣區大麥類製品工業同業公會、台灣區玉米類製品工業同業公會、台灣區紅糖工業同業公會、台灣區製茶工業同業公會、台灣區冷凍蔬果工業同業公會、台灣區人造奶油工業同業公會、台灣區麥粉工業同業公會、台灣區乳品工業同業公會、台灣區製冰冷凍冷藏工業同業公會、台北市進出口商業同業公會、台灣省進出口商業同業公會聯合會、高雄市進出口商業同業公會、財團法人中央畜產會、中華民國直銷協會、財團法人中華穀類食品工業技術研究所、社團法人中華民國乳業協會、中華民國食油商業同業公會全國聯合會、中華民國家畜肉類商業同業公會全國聯合會、中華民國酵素食品發展協會、中華有機與自然食品協會、台灣省豆腐商業同業公會聯合會、台灣省食油商業同業公會聯合會、台灣省製麵商業同業公會聯合會、台灣省醬類商業同業公會聯合會、台灣省雜糧商業同業公會聯合會、各縣市衛生局、行政院農業委員會、行政院環境保護署、經濟部、經濟部



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工業局、經濟部標準檢驗局、台灣食品產業發展協會、台灣食品良好作業規範發展協會、台灣食品保護協會、行政院消費者保護處

副本：行政院衛生署食品藥物管理局南區管理中心、行政院衛生署食品藥物管理局研究檢驗組、行政院衛生署食品藥物管理局北區管理中心、行政院衛生署食品藥物管理局中區管理中心



署長 邱文達

本案依分層負責規定授權局長執行

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# 降低食品中多環芳香族碳氫化合物含量之 作業指引

## 壹、前言

- 一、多環芳香族碳氫化合物 ( polycyclic aromatic hydrocarbons, 以下簡稱 PAHs ) 為一群具有數個苯環的化學結構物，因有機質不完全燃燒或熱裂解 ( pyrolysis ) 反應所生成，環境中的 PAHs 可能達百種，來源包括森林大火、火山爆發、工業污染及食品加工等。
- 二、國際癌症研究中心 ( International Agency for Research on Cancer, IARC ) 已報告有多種 PAHs 具致突變性或致癌性，其中以苯(a)駢芘 ( benzo ( a ) pyrene, 以下簡稱 BaP ) 之致癌性最強，被列為一級致癌物。2006 年聯合國糧農組織 / 世界衛生組織食品添加物專家委員會 ( 簡稱 JECFA ) 建議可將 BaP 作為評估 PAHs 污染之監測指標。
- 三、人體暴露 PAHs 之來源，除了空氣及菸品之吸入外，最主要的就是透過食物的攝入，生鮮食品中存在之 PAHs，多來自空氣及土壤的污染或食品加工過程所產生的。許多調查報告指出，在工業區或交通頻繁區域所生產之農作物，其 PAHs 的含量有較高趨勢，顯示空氣污染是食品原料中含 PAHs 之重要來源。
- 四、在食品生產過程中，煙燻、乾燥、烘焙、燒烤等加工過程，則是另一個使 PAHs 含量增加的主因。由於食品經過上述加工，可賦予其特殊之質地、風味或口感，無法逕予禁止該等加工操作；故為了減少自食物暴露過多之 PAHs，應優先透過加工操作過程之改善，從而減少食品受 PAHs 之污染及攝食暴露之風險，以收預防重於善後處理之效；食品產業在此即扮演著第一線為食品衛生安全把關的主要角色。

## 貳、目的

本指引係提供食品產業自訂預防或改善產品受 PAHs 污染之品質管理工作時，可參考之監測指標及行動準則，以落實食品產業自主管理之精神，確保食品安全、兼顧產業發展。

## 參、國際管理現況

- 一、國際食品法典委員會(Codex)對食品中檢出污染物質之處理原則，係對污染物含量與環境或食品中正常背景值比較，分析是否有遭受污染情形，如有偏高且經科學評估證實涉有民眾健康風險者，則依據評估結果決定適當解決方案，包括：
  - (一)採取相關管制措施 (例如污染食品回收、改善加工方式或儲存條件管理等)。
  - (二)考量有無必要建立食品中之限量。
  - (三)當相關措施不足以排除該污染物對健康之危害時，必須考慮給予飲食建議 (dietary recommendations)。
- 二、針對食品中含有 PAHs 之管制措施，Codex 於 2009 年即已制定「煙燻食品及直接乾烘食品之多環芳香族碳氫化合物污染減量控制操作規範 (Code of practice for the reduction of contamination of food with polycyclic aromatic hydrocarbons (PAH) from smoking and direct drying processes)」，提供源頭生產端業者依據該規範自主檢視，改善其加工操作過程，以減少食品受 PAHs 污染之風險。
- 三、歐盟原於 2006 年公告的 1881 號指令中，即已針對油脂類、煙燻肉製品、煙燻魚肉製品、煙燻雙殼貝類及嬰兒食品等訂有 BaP 之限值，於 2011 年又以 835 號指令更新。依據歐盟最新報告指出，PAH4 (即 BaP、BaA、BbF、chrysene) 為更適合做為監測 PAHs 之指標，故

除了過去單獨以 BaP 作為監測指標外，歐盟亦另外增訂 PAH4 總和於食品中之限量規定，並將於 2014 年起調降煙燻肉製品、煙燻魚肉製品之限值(如附錄)。

#### 肆、我國管理現況

- 一、我國對於食品中所含污染物質之管理原則，與 Codex 相同：在缺乏充分之科學依據時，不宜草率訂定限量或標準，而應蒐集更多食品中的含量資料以及不同群眾的食品攝取量數據進行統計分析，依據污染物含量對消費者飲食總暴露量有顯著意義之食品種類優先制定標準。
- 二、對於如重金屬、戴奧辛、真菌毒素及 PAHs 等污染物質，係來自環境、或因食品生產、加工及貯存過程期間產生，並非基於食品加工需要蓄意添加者，我國之管理，是針對暴露風險較高之特定食品優先訂定限量；未訂限量者，如經檢驗出，則依風險評估原則決定個案管理措施。必要時，也可依消保法第 10 條暫停販售具有風險之產品。

#### 伍、減少 PAHs 污染食品之操作原則

##### 一、一般原則

- (一) 食品業者應確認所用以進行加工、調配或製造之食品原料不致含有過量之 PAHs，以減少可能自原料帶入之污染。
- (二) 食品業者應自主檢視產品生產過程之各階段，尤其是煙燻、乾燥等經高溫處理的步驟，所使用之設備、環境、各項加工條件(如熱源、時間、溫度)等，是否易大量產生 PAHs，必要時應經實地試驗，以分析結果為依據，調整並確認適當之 PAHs 減量操作條件。
- (三) 食品業者所採取之 PAHs 減量操作，必須維護其他基本衛生安全條件，例如微生物含量及可能含有其他污

染物的風險；至於其他產品價值條件(如外觀、風味、口感、營養成分等)，亦可為評價相關減量操作可行性之參考依據。

- (四) 食品業者應定期採取監測檢驗工作，以檢視 PAHs 減量管制措施之成效。

## 二、煙燻處理之 PAHs 減量操作原則

(一) 燃料之選擇：如係使用木頭當燃料，必須避免使用經防水、防火或樹脂等化學處理的木頭，以免產生其他污染物質；松柏類木頭因含高木質素，不建議使用；含水量低木頭會快速燃燒，亦容易產生較多 PAHs。另外，不建議使用木材或植物材料以外之燃料，如柴油、橡膠(廢輪胎)或廢油等。

(二) 煙燻室(間)之設置：

1. 火源與食材距離越近，食物吸附 PAHs 粒子的量越多，故應保持火源與食材適當之距離。
2. 為減少食材油脂滴落而產生更多 PAHs，必要時可於火源與食材間加裝有孔的擋板阻隔。
3. 以間接煙燻取代直接煙燻，將更能顯著降低食物受 PAHs 之污染。
4. 使用濾網等設備協助移除燻煙中之顆粒物質，降低可能之 PAHs 污染。
5. 應確認有適當之氧氣供應，氧氣不足造成燃燒不完全，或氧氣過多造成溫度太高，均會增加 PAHs 之生成。應適當調控溫度以降低 PAHs 之生成量。

(三) 煙燻時間應越短越好。

(四) 食材煙燻後可透過適當清(浸)洗(魚類產品不宜)、去皮(如魚類產品)或刮除表面煙燻處(如：柴魚)等方式，顯著降低 PAHs 之含量。

### 三、乾燥處理之 PAHs 減量操作原則

- (一) 透過風吹或日曬等暴露於室外或露天之乾燥法，應避免靠近可能有污染源之區域，例如有燃燒氣體之工業區域、焚化爐、水泥廠或緊鄰交通密集的道路，必要時可使用有蓋之乾燥器，以減少污染。
- (二) 其他透過加熱方式進行乾燥之相關注意事項，得比照煙燻處理者。
- (三) 合併脫水及乾燥等操作方式，可增加乾燥效率、減少乾燥時間，間接減少 PAHs 之污染。
- (四) 穀類與油籽(榨油原料)乾燥時，應避免與熱源直接接觸，尤其避免以火源直接乾燥種籽；油品精製過程可透過使用活性炭，以減少 PAHs 之污染含量。
- (五) 可透過監視燃燒氣體中之一氧化碳、火焰溫度或煙燻累積量等，確認燃料是否完全燃燒。
- (六) 以間接乾燥取代直接乾燥，能顯著降低 PAHs 的污染。

### 四、燒烤處理之 PAHs 減量操作原則

(比照煙燻及乾燥法之操作重點)

### 陸、PAHs 監測指標值

為考量食品產業自主品管量能，衛生署優先依據 PAHs 指標化學物 BaP 之相關評估資料，倡議監測指標值如附件 1，以提供食品產業遵循；未來並將依據科學資訊之更新及實務需求，評估修正 BaP 之監測指標值或提出其他 PAHs 之監測指標。

### 柒、異常處理

加工食品檢驗其 BaP 含量之結果，如超過本指引之監測指標時，應分別採取以下異常處理措施：

一、經依附件 2 之風險評估計算結果，其暴露限值(MOE)在

10,000 以上者：應自行加強產品之品管監測頻率。

二、經依附件 2 之風險評估計算結果，其暴露限值(MOE)未達 10,000 者：應採取以下處理程序：

- (一)清查異常產品之範圍及數量，控管異常產品之出貨/販售，必要時應有產品回收措施。
- (二)就異常產品之原料及製程全面檢視，釐清 PAHs 之可能污染原因。
- (三)針對污染原因提出改善方案，並進行測試，確認排除異常或減少產品 PAHs 含量至監測指標值以下。
- (四)保留異常處理過程之完整紀錄備查。
- (五)檢討並加強品管抽驗。

## 捌、結語

由於 PAHs 可於多種加工操作過程中產生，屬於加工食品中無法避免之污染物質，故如何降低該等污染物之含量應為企業進行品質安全管理之重點；另外，對於複合多種食品原料之加工食品，其 PAHs 多來自於原料之污染，故源頭管理(包括原材料之採購驗收等)亦應為管制重點之一。

本指引將提供食品產業界進行產品品質管制及確認製程條件之參考，針對食品原料或產品之安全性所提供之監測指標值，亦可提供食品產業進行自主品管分析之結果是否採取異常處理措施之指標，衛生署將於本指引實施一年後，參酌食品產業管理成效，進一步評估是否訂定相關法規標準。



## 附件 1-PAHs 監測指標值

(單位：μg/kg, ppb)

管制項目 食品類別	苯(a)駢芘 (Benzo(a)pyrene, BaP)
油脂類(直接供食用或作為食品原料使用)	2.0
煙燻肉製品	5.0
煙燻魚肉製品、煙燻甲殼類製品(煙燻鯡魚及其罐頭、雙殼貝類及煙燻雙殼貝類除外)，煙燻甲殼類的最高限量適用於附屬物及腹部肌肉，蟹類或類似蟹的甲殼類含腹部及肢節之肌肉	5.0
柴魚*	30*
煙燻雙殼貝類	6.0
穀類加工食品	1.0
嬰兒及較大嬰兒配方食品	1.0
*暫行指標，將於蒐集更完整之含量背景值及相關風險評估資訊後，再行評估是否修正。	

※備註：

- 1.本表之監測指標值，係供食品產業自主品管監測產品之參考。
- 2.食品經檢驗 BaP 含量之結果，如有超出本表所訂之監測指標值，應另依本指引第柒節，進行暴露限值評估(計算範例如附件 3)及視評估結果採取適當之異常處理措施。
- 3.本表中未明列之食品類別，食品業者仍可自主管理，依本指引第柒節之風險評估原則，及不同產品之加工屬性，自訂品管指標，加強預防 BaP 之污染。

## 附件 2-食品中檢出 BaP 之健康風險評估

### 暴露限值評估模式(margin of exposure, MOE)

※某物質對動物產生不良反應之劑量與人類膳食攝入量之比值，如該引起不良反應之劑量與人類攝取量越接近，則計算結果(MOE 值)便越低，代表對健康危害的影響越大。

※係用以評定其健康風險之關注程度，而非量化風險。可作為釐定風險管理措施的優先順序。

※計算公式：

$$\text{MOE} = \text{BMDL} \div \text{膳食攝入量}$$

- BMDL：每日每公斤體重 0.1 毫克(0.1 mg /kg bw per day)，誘發人類癌症發病率增加 10% 的基準劑量可信下限。(WHO, 2005)
- 膳食攝入量：每人平均每日攝入量，依不同食品之攝取量推估

※評估：

- MOE 在 10,000 以上(含 10,000)→低關注等級，加強品管抽驗
- MOE 未達 10,000 →採取異常處理措施

### 附件 3-風險評估計算範例

1. 假設柴魚片每日攝食量為 5 g，經檢出含 BaP 30  $\mu\text{g}/\text{kg}$ 。經分別以 60 kg 體重成人及 20 kg 體重兒童為例，其 MOE 之計算結果：

(1) 每日 BaP 之攝入量(檢出量 $\times$ 每日攝食量)： $0.030 \text{ mg}/\text{kg} \times 0.005 \text{ kg} = 0.00015 \text{ mg}$

(2) MOE 成人 =  $(0.1 \times 60) \div 0.00015 = 40000$

(3) MOE 幼兒 =  $(0.1 \times 20) \div 0.00015 = 13333$

(4) 評估： $(40000 \text{ 或 } 13333) > 10000$ ，A 食品之 BaP 含量，尚屬低健康危害風險關注程度。

2. 假設以柴魚片熬煮高湯(20g 柴魚片加入 2000 mL 高湯)，再假設柴魚片所含之 BaP 全部溶入湯水中。若柴魚片檢出含 BaP 30  $\mu\text{g}/\text{kg}$ ，每日飲用量 500 mL，經以 20 kg 體重兒童為例，其 MOE 之計算結果：

(1) 每日 BaP 之攝入量(檢出量 $\times$ 每日攝食量)： $(0.030 \text{ mg}/\text{kg} \times 0.020 \text{ kg}) \div 4 = 0.00015 \text{ mg}$

(2) MOE =  $(0.1 \times 20) \div 0.00015 = 13333$

(3) 評估： $13333 > 10000$ ，尚屬低健康危害風險關注程度。

3. 假設每日食用泡麵 3 包，泡麵調味包(每包 10g)經檢出 BaP 之含量為 5  $\mu\text{g}/\text{kg}$ ，以 60 kg 體重成人為例，其 MOE 之計算結果：

(1) 每日 BaP 之攝入量(檢出量 $\times$ 每日攝食量)： $(0.005 \text{ mg}/\text{kg} \times 0.010 \text{ kg}) \times 3 = 0.00015 \text{ mg}$

(2) MOE =  $(0.1 \times 60) \div 0.00015 = 40000$

(3) 評估： $40000 > 10000$ ，尚屬低健康危害風險關注程度。

## COMMISSION REGULATION (EU) No 835/2011

of 19 August 2011

amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs <sup>(2)</sup> sets maximum levels for benzo(a)pyrene in a range of foodstuffs.
- (2) Benzo(a)pyrene belongs to the group of polycyclic aromatic hydrocarbons (PAH) and is used as a marker for the occurrence and effect of carcinogenic PAH in food based on a scientific opinion of the former Scientific Committee on Food (SCF) <sup>(3)</sup>. In its opinion of December 2002, the SCF recommended that further analyses of the relative proportions of these PAH in foods would be necessary for a future review of the suitability of maintaining benzo(a)pyrene as a marker.
- (3) New data on occurrence of carcinogenic PAH in foodstuffs have been collected by the Member States in the framework of Commission Recommendation 2005/108/EC <sup>(4)</sup>. The Commission asked the European Food Safety Authority (EFSA) to review the SCF opinion taking into account the new occurrence data, other relevant new scientific information as well as the Margin of Exposure (MOE) approach. Within this review, EFSA was asked to re-assess the suitability of maintaining benzo(a)pyrene as a marker.
- (4) The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of EFSA adopted an opinion on Poly-

cyclic Aromatic Hydrocarbons in Food on 9 June 2008 <sup>(5)</sup>. In this opinion EFSA concluded that benzo(a)pyrene is not a suitable marker for the occurrence of polycyclic aromatic hydrocarbons in food and that a system of four specific substances (PAH4 <sup>(6)</sup>) or eight specific substances (PAH8 <sup>(7)</sup>) would be the most suitable indicators of PAH in food. EFSA also concluded that a system of eight substances (PAH8) would not provide much added value compared to a system of four substances (PAH4).

- (5) Furthermore, the CONTAM Panel concluded, using the Margin of Exposure (MOE) approach, that there is low concern for consumer health at the average estimated dietary exposures. However, for high level consumers the MOEs were close to or less than 10 000, which indicates a potential concern for consumer health.
- (6) Based on the conclusions of EFSA, the current system of using benzo(a)pyrene as the only marker for the group of polycyclic aromatic hydrocarbons, can not be maintained. An amendment of Regulation (EC) No 1881/2006 is therefore necessary.
- (7) New maximum levels for the sum of four substances (PAH4) (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) should be introduced, whilst maintaining a separate maximum level for benzo(a)pyrene.
- (8) Such system would ensure that PAH levels in food are kept at levels that do not cause health concern and that the amount of PAH can also be controlled in those samples in which benzo(a)pyrene is not detectable, but where other PAH are present.
- (9) The separate maximum level for benzo(a)pyrene is maintained to ensure comparability of previous and future data. After a certain time of implementation of this amendment and on basis of new data that will be generated in future, the need for retaining a separate maximum level for benzo(a) pyrene should be re-assessed.

<sup>(1)</sup> OJ L 37, 13.2.1993, p. 1.<sup>(2)</sup> OJ L 364, 20.12.2006, p. 5.<sup>(3)</sup> Opinion of the Scientific Committee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food (expressed on 4 December 2002).<sup>(5)</sup> *The EFSA Journal* (2008) 724, 1-114.<sup>(6)</sup> Benzo(a)pyrene, Chrysene, Benz(a)anthracene, benzo(b)fluoranthene.<sup>(7)</sup> Benzo(a)fluorene, Chrysene, Benz(a)anthracene, benzo(b)fluoranthene.

- (10) As regards the sum of the four substances (PAH4), lower bound concentrations should be used as the basis for compliance decisions.
- (11) Maximum levels for polycyclic aromatic hydrocarbons must be safe and as low as reasonably achievable (ALARA) based upon good manufacturing and agricultural/fishery practices. The new PAH occurrence data show that background levels of PAH are lower than previously thought in some food commodities. Benzo(a)pyrene maximum levels have therefore been adapted to reflect more realistic lower background levels in fresh and smoked bivalve molluscs.
- (12) Data for smoked fish and smoked meat have also shown that lower maximum levels are achievable. Nevertheless, adaptations of current smoking technology may be necessary in some cases. Therefore, a two step procedure should be established for smoked meat and smoked fish which grants a transition of two years from the date of application of this Regulation before lower maximum levels become applicable.
- (13) Smoked sprats and canned smoked sprats have been found to contain higher levels of PAH than other smoked fish. Specific maximum levels should be established for smoked sprats and canned smoked sprats in order to reflect what is achievable in these foodstuffs.
- (14) Previously a maximum level for benzo(a)pyrene in "muscle meat of fish other than smoked fish" was established as an indicator for potential environmental pollution. Nevertheless, it has been shown that PAH are quickly metabolised in fresh fish and do not accumulate in the muscle meat. Therefore, maintaining a maximum level for PAH in fresh fish is no longer appropriate.
- (15) High levels of PAH have been found in some types of heat treated meat and heat treated meat products sold to the final consumer. These levels are avoidable if appropriate processing conditions and equipment are used. It is therefore appropriate to establish maximum levels for PAH in meat and meat products that have undergone a heat treatment process known to potentially result in formation of PAH, i.e. only grilling and barbecuing.
- (16) Cocoa butter was temporarily exempted from the existing maximum level for benzo(a)pyrene in oils and fats under Regulation (EC) No 1831/2006 and a review of the appropriateness of setting a maximum level for PAH in cocoa butter was foreseen by 1 April 2007. The review was then postponed pending the result of the then ongoing scientific re-assessment of PAH by EFSA.
- (17) Cocoa butter contains higher levels of PAH than other oils and fats. This is mainly due to inappropriate drying practices of the cocoa beans and the fact that cocoa butter can not be refined as other vegetable oils and fats. Cocoa butter is a main constituent of cocoa raw products (e.g. cocoa beans, cocoa mass, cocoa nibs or cocoa liquor) and is present in chocolate and other cocoa products often consumed by children. It thereby contributes to human exposure, in particular to exposure of children. It is therefore necessary to establish maximum levels for PAH in cocoa beans and derived products, thereby also including cocoa butter.
- (18) Maximum levels for PAH in cocoa beans should be established at levels as low as reasonably achievable and taking into account the current technological possibilities of producing countries. They should be established on a fat basis since PAH concentrate in the fat fraction, the cocoa butter. To allow producing countries to make technological improvements in order to adapt to these maximum levels, the date of application of the maximum levels for cocoa beans and derived products should be deferred. Furthermore, initially a higher maximum level for the sum of the four substances should apply to these products. After a transition period of two years a lower maximum level should apply. The levels of PAH in cocoa beans and derived products should be regularly monitored with a view to assessing the possibility for further decreasing the maximum levels in future.
- (19) Data have shown that coconut oil can contain higher amounts of PAH4 than other vegetable oils and fats. This is due to the proportionally higher presence of benz(a)anthracene and chrysene which can not be easily removed during refinement of coconut oil. Specific maximum levels for coconut oil should therefore be set at levels as low as reasonably achievable and taking into account the current technological possibilities of producing countries. As technological improvements in producing countries are expected, the levels of PAH in coconut oil should be regularly monitored with a view to assessing the possibility for setting lower levels in future.
- (20) Current occurrence data on PAH in cereals and vegetables are limited. The available data indicate that cereals and vegetables contain rather low levels of PAH. The low levels seen in the currently available occurrence data do not justify the immediate setting of maximum levels. Nevertheless, EFSA identified cereals and vegetables as being important contributors to human exposure due to their high consumption. Therefore, PAH levels in these two product groups should be further monitored. On the basis of further data, the need for setting maximum levels will be evaluated.

- (21) High levels of PAH have been found in some food supplements. Nevertheless, the levels are variable and depend on the specific type of food supplements. Further data on food supplements are needed and should be collected. Once these data become available, the need for setting maximum levels for PAH in food supplements will be evaluated.
- (22) Member States and food business operators should be allowed time to adapt to the maximum levels established by this Regulation. The date of application of this Regulation should therefore be deferred. A transitional period should be provided for the products already placed on the market before the date of application of the amendments introduced by this Regulation.
- (23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them.

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

*Article 2*

1. Foodstuffs not complying with the maximum levels applicable from 1 September 2012 pursuant to Section 6 "Polycyclic aromatic hydrocarbons" of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are

lawfully placed on the market prior to 1 September 2012, may continue to be marketed after that date until their date of minimum durability or use-by-date.

2. Foodstuffs not complying with the maximum levels applicable from 1 September 2014 pursuant to points 6.1.4 and 6.1.5 of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are lawfully placed on the market prior to 1 September 2014, may continue to be marketed after that date until their date of minimum durability or use-by-date.

3. Foodstuffs not complying with the maximum levels applicable from 1 April 2013 pursuant to point 6.1.2 of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are lawfully placed on the market prior to 1 April 2013, may continue to be marketed after that date until their date of minimum durability or use-by-date.

4. Foodstuffs not complying with the maximum level applicable from 1 April 2015 pursuant to point 6.1.2 of the Annex to Regulation (EC) No 1881/2006, as amended by this Regulation, which are lawfully placed on the market prior to 1 April 2015, may continue to be marketed after that date until their date of minimum durability or use-by-date.

*Article 3*

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

It shall apply from 1 September 2012.

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

Done at Brussels, 19 August 2011.

For the Commission  
The President  
José Manuel BARROSO

## ANNEX

The Annex to Regulation (EC) No 1831/2006 is amended as follows:

(1) Section 6: *Polycyclic aromatic hydrocarbons* is replaced by the following:

"Section 6: *Polycyclic aromatic hydrocarbons*

Foodstuffs		Maximum levels (µg/kg)	
6.1	Benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene	Benzo(a)pyrene	Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene <sup>(13)</sup>
6.1.1	Oils and fats (excluding cocoa butter and coconut oil) intended for direct human consumption or use as an ingredient in food	2,0	10,0
6.1.2	Cocoa beans and derived products	5,0 µg/kg fat as from 1.4.2013	35,0 µg/kg fat as from 1.4.2013 until 31.3.2015 30,0 µg/kg fat as from 1.4.2015
6.1.3	Coconut oil intended for direct human consumption or use as an ingredient in food	2,0	20,0
6.1.4	Smoked meat and smoked meat products	5,0 until 31.8.2014 2,0 as from 1.9.2014	30,0 as from 1.9.2012 until 31.8.2014 12,0 as from 1.9.2014
6.1.5	Muscle meat of smoked fish and smoked fishery products <sup>(23)</sup> <sup>(24)</sup> , excluding fishery products listed in points 6.1.6 and 6.1.7. The maximum level for smoked crustaceans applies to muscle meat from appendages and abdomen <sup>(14)</sup> . In case of smoked crabs and crab-like crustaceans ( <i>Brachyura</i> and <i>Anomura</i> ) it applies to muscle meat from appendages.	5,0 until 31.8.2014 2,0 as from 1.9.2014	30,0 as from 1.9.2012 until 31.8.2014 12,0 as from 1.9.2014
6.1.6	Smoked sprats and canned smoked sprats <sup>(25)</sup> <sup>(14)</sup> ( <i>Sprattus sprattus</i> ); bivalve molluscs (fresh, chilled or frozen) <sup>(26)</sup> ; heat treated meat and heat treated meat products <sup>(16)</sup> sold to the final consumer	5,0	30,0
6.1.7	Bivalve molluscs <sup>(16)</sup> (smoked)	6,0	35,0
6.1.8	Processed cereal-based foods and baby foods for infants and young children <sup>(1)</sup> <sup>(24)</sup>	1,0	1,0
6.1.9	Infant formulae and follow-on formulae, including infant milk and follow-on milk <sup>(8)</sup> <sup>(24)</sup>	1,0	1,0

Foodstuffs		Maximum levels ( $\mu\text{g}/\text{kg}$ )	
6.1.10	Dietary foods for special medical purposes ( <sup>(1)</sup> )( <sup>(2)</sup> ) intended specifically for infants	1,0	1,0

(<sup>(1)</sup>) Lower bound concentrations are calculated on the assumption that all the values of the four substances below the limit of quantification are zero.

(<sup>(2)</sup>) Meat and meat products that have undergone a heat treatment potentially resulting in formation of PAH, i.e. only grilling and barbecuing

(<sup>(3)</sup>) For the canned product the analysis shall be carried out on the whole content of the can. As regards the maximum level for the whole composite product Art. 2(1)(c) and 2(2) shall apply."

(2) Endnote (<sup>(1)</sup>) is deleted.