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**SANCO/00305/2005**  
**(ex SANCO/0072/2004)**

**WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT  
THE COMMISSION’S VIEWS**

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,  
SANCO/0305/2005  
(ex SANCO/0072/2004)

Draft

**COMMISSION REGULATION (EC) ...**

**of [...]**

**amending Commission Regulation (EC) No 466/2001 setting maximum levels for certain  
contaminants in foodstuffs as regards dioxins and dioxin-like PCBs**

**[Text with EEA relevance]**

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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<sup>1</sup>, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 466/2001<sup>2</sup> sets maximum levels for certain contaminants in foodstuffs.
- (2) The term ‘dioxins’, as referred to in this Regulation, covers a group of 75 polychlorinated dibenzo-p-dioxin (‘PCDD’) and 135 polychlorinated dibenzofuran (‘PCDF’) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (‘PCBs’), are group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often termed ‘dioxin-like PCBs’. The other PCBs do not exhibit dioxin-like toxicity but they have a different toxicological profile.
- (3) Each congener of dioxins or dioxin-like PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (‘TEFs’) has been introduced to facilitate risk assessment and regulatory control. This means that the analytical results relating to all 17 individual dioxin congeners and to the 12 dioxin-like PCB congeners are expressed in terms of quantifiable unit: ‘TCDD toxic equivalent concentration’ (TEQ).

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<sup>1</sup> OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>2</sup> OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) 684/2004 (OJ L 106, 15.4.2004, p. 6).

- (4) Although, from a toxicological point of view any level should apply to dioxins and dioxin-like PCBs maximum levels were set only for dioxins and not for dioxin-like PCBs given the very limited data available at that moment on the prevalence of the dioxin-like PCBs. However in the meantime more data on the presence of dioxin-like PCBs have been made available.
- (5) According to Regulation (EC) No 466/2001, the Commission shall review the provisions as regards dioxins for the first time by 31 December 2004 at the latest in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set
- (6) All operators in the food and feed chain must continue to make all possible efforts and to do all that is necessary to limit the presence of dioxins in feed and food. Therefore, it was provided by Commission Regulation (EC) No 466/2001 that the maximum levels applicable should be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels and possibly laying down maximum levels for other foodstuffs. Taking into account the time required to to obtain sufficient monitoring data to determine these significant lower levels, it is appropriate to slightly postpone this date.
- (7) It is proposed to set maximum levels for the sum of dioxins and dioxin-like PCBs expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs as this is the most appropriate approach from a toxicological point of view. In order to ensure a smooth transition, it is appropriate to keep for a transitional period the existing levels for dioxins applicable in addition to the newly set levels for sum of dioxins and dioxin-like PCBs
- (8) In order to stimulate a pro-active approach to reduce the presence of dioxins and dioxin-like PCBs in food and feed, action levels have been set by Commission Recommendation 2002/201/EC of 4 March 2002 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs<sup>3</sup>. These action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. Given that different sources of contamination exist for the presence in food of dioxins on the one hand and of dioxin-like PCBs on the other hand, it is important that separate action levels are determined for dioxins on the one hand and for dioxin-like PCBs on the other hand. Commission Recommendation 2002/201/EC will therefore be amended.

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<sup>3</sup> OJ L67, 9.3.2002, p.69

- (9) A derogation has been granted to Sweden and Finland to place on the market fish originating from the Baltic region, which is intended for consumption in their territory with dioxin levels higher than those set in point 5.2 of section 5 of Annex I. A possibility for such a derogation has been foreseen for Estonia in the Accession Treaty. Finland and Sweden have fulfilled the conditions as regards the information to the consumers on dietary recommendations and have yearly communicated to the Commission the results of their monitoring of the levels of dioxins in fish from the Baltic region and have reported on the measures to reduce human exposure to dioxins from the Baltic region.

Taking into account this information, it is appropriate to limit the derogation granted to Sweden and Finland and the possibility for derogation for Estonia, (*Poland, Latvia and Lithuania*) to Baltic Salmon, Baltic Sea herring (*Clupea harengus*), river lamprey, trout (*Salmo trutta*), Char (*Salvelinus umbla*) and roe of Vendace (*Coregonus albula*) originating from the Baltic region. Based on the information provided, it is appropriate to grant the derogation without expiry date. This derogation applies to the maximum levels of dioxins and to the maximum levels for the sum of dioxins and dioxin-like PCBs set in point 5.2 of section 5 of Annex I.

- (10) Regulation (EC) No 466/2001 should therefore be amended accordingly.
- (11) 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 DIRECTIVE:

#### *Article 1*

Regulation (EC) No 466/2001 is amended as follows :

**1. In Article 1, paragraphs 1a and 1b are replaced by the following :**

“1a. By way of derogation from paragraph 1, Sweden and Finland are authorised to place on their market Baltic Salmon, Baltic Sea herring (*Clupea harengus*), river lamprey, trout (*Salmo trutta*), Char (*Salvelinus umbla*) and roe of Vendace (*Coregonus albula*), originating from the Baltic region, which is intended for consumption in their territory with levels of dioxins and/or levels of the sum of dioxins and dioxin-like PCBs higher than those set in point 5.2. of section 5 of Annex I, provided that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on the consumption of these fish species from the Baltic region by identified vulnerable groups of the population in order to avoid potential health risks.

1b. By way of derogation from paragraph 1, the Commission may authorise Estonia (*Poland, Latvia and Lithuania*) authorised to place on their market Baltic Salmon, Baltic Sea herring (*Clupea harengus*), river lamprey, trout (*Salmo trutta*), Char (*Salvelinus umbla*) and roe of Vendace (*Coregonus albula*), originating from the Baltic region, which is intended for consumption in its territory with levels of dioxins and/or levels of the sum of dioxins and dioxin-like PCBs higher than those set in point 5.2. of section 5 of Annex I. This derogation will be granted in accordance with the procedure laid down in Article 8 of Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food. To this end, Estonia (*Poland, Latvia and Lithuania*) shall demonstrate that human exposure to dioxins and dioxin-like PCBs in Estonia (*Poland, Latvia and Lithuania*) is not higher than the highest average level in any of the Member States of the Community as constituted on 30 April 2004.

Estonia (*Poland, Latvia and Lithuania*) will further demonstrate that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on the consumption of fish from the Baltic region by identified vulnerable groups of the population in order to avoid potential health risks.”

**2. In Article 1, paragraph 2 is replaced by the following**

“2. The maximum levels specified in the Annex I shall apply to the edible part of the foodstuffs concerned, unless otherwise specified in the Annex.”

**3. Article 4a is replaced by the following**

*“Article 4a*

With regard to dioxins and dioxin-like PCBs in products referred to in section 5 of Annex I, it shall be prohibited:

(a) to mix products complying with the maximum levels with products exceeding these maximum levels;

(b) to use products, which do not comply with the maximum levels as an ingredient for the manufacture of other foodstuffs.”

**4. In Article 5, paragraph 3 is replaced by the following**

“3. The separate maximum level for dioxins (PCDD/F) shall cease to apply on 1 January 2008. Until 1 January 2008, the foodstuffs indicated in section 5 of Annex I must comply with maximum levels for dioxins and with the maximum levels for the sum of dioxins and dioxin-like PCBs.

The Commission shall review section 5 of Annex I by 31 December 2007 at the latest with the aim of significantly reducing the maximum levels for the sum of dioxins and dioxin-like PCBs and possibly laying down maximum levels for other foodstuffs.

As regards the establishment of maximum levels for other foodstuffs by 31 December 2007, particular attention will be paid to the necessity of setting specific lower maximum levels for dioxins and dioxin-like PCBs in foods for infants and young children taking into account the monitoring data obtained through the monitoring programmes 2005, 2006 and 2007 on dioxins and dioxin-like PCBs in foods for infants and young children.”

**5. Annex I is amended in accordance with the Annex to this Regulation**

*Article 2*

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

It shall apply from 1 July 2005.

As regards the maximum levels for the sum of dioxins and dioxin-like PCBs, this Regulation shall not apply to products, which were placed on the market before 1 July 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*  
*Markos KYPRIANOU*  
*Member of the Commission*

## ANNEX

### Section 5 Dioxins of Annex I is replaced by the following:

“5. Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997) and sum of dioxins and dioxin like PCBs (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997 (\*))

| FOOD  | MAXIMUM LEVELS<br>SUM OF DIOXINS AND FURANS<br>(WHO-PCDD/F-TEQ) <sup>4</sup>     | MAXIMUM LEVELS<br>SUM OF DIOXINS, FURANS<br>AND DIOXIN-LIKE PCBs<br>(WHO-PCDD/F-PCB-TEQ) <sup>4</sup> | METHODS OF SAMPLING AND<br>PERFORMANCE CRITERIA FOR<br>METHODS OF ANALYSIS |
|---|--|---|--|
| 5.1.1. Meat and meat products <sup>5</sup> originating from<br>— Ruminants (bovine animals, sheep)<br>— Poultry and farmed game<br>— Pigs | 3 pg /g fat <sup>6</sup><br>2 pg /g fat <sup>6</sup><br>1 pg /g fat <sup>6</sup> | 4.5 pg /g fat <sup>6</sup><br>4 pg /g fat <sup>6</sup><br>1.50 pg /g fat <sup>6</sup>                 | Commission Directive<br>2002/69/EC <sup>7</sup>                            |
| 5.1.2. Liver and derived products originating<br>from terrestrial animals   | 6 pg /g fat <sup>6</sup>   | 12 pg /g fat <sup>6</sup>   |  |
| 5.2 Muscle meat of fish and fishery products and<br>products thereof <sup>8,9</sup>   | 4 pg /g fresh weight   | 8 pg /g fresh weight  | Commission Directive<br>2002/69/EC   |
| 5.3. Milk <sup>10</sup> and milk products, including butter<br>fat  | 3 pg /g fat <sup>6</sup>   | 6 pg /g fat <sup>6</sup>  | Commission Directive<br>2002/69/EC   |

<sup>4</sup> Upperbound concentrations: Upperbound concentrations are calculated assuming that all the values of the different congeners less than the limit of determination are equal to the limit of determination

<sup>5</sup> Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.04.2004., Corrigendum published in OJ L226, 25.6.2004, p. 22) , excluding edible offal as defined in Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.04.2004., Corrigendum published in OJ L226, 25.6.2004, p. 22)

<sup>6</sup> The maximum levels are not applicable for food products containing < 1 % fat.

<sup>7</sup> OJ L 209, 6.8.2002, p. 5. As last amended by Commission Directive 2004/44/EC of 13 April 2004 (OJ L 113, 20.4.2004, p. 17)

<sup>8</sup> Muscle meat of fish and fishery products as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p. 22). The maximum level applies to crustaceans excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (*Nephropidae* and *Palinuridae*) and to cephalopods without viscera.

<sup>9</sup> Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish



| <b>FOOD</b>   | <b>DIOXINS + FURANS (WHO-TEQ)</b>   | <b>TOTAL WHO-TEQ<br/>(SUM OF DIOXINS, FURANS<br/>AND DIOXIN-LIKE PCBs<br/>(WHO-TEQ)<sup>4</sup></b>  | <b>METHODS OF SAMPLING<br/>AND METHODS OF ANALYSIS</b> |
|---|---|--|--|
| 5.4. Hen eggs and egg products <sup>11</sup>  | 3 pg /g fat <sup>6</sup>  | 6 pg /g fat <sup>6</sup>   | Commission Directive<br>2002/69/EC                     |
| 5.5. Oils and fats<br>— Animal fat<br>— from ruminants<br>— from poultry and farmed game<br>— from pigs<br>— mixed animal fats<br><br>— Vegetable oil and fats<br>— marine oil (fish body oil, fish liver oil and oils<br>from other marine organisms intended for human<br>consumption ) | 3 pg /g fat <sup>6</sup><br>2 pg /g fat <sup>6</sup><br>1 pg /g fat <sup>6</sup><br>2 pg /g fat <sup>6</sup><br><br>0,75 pg /g fat <sup>6</sup><br>2 pg /g fat <sup>6</sup> | 4.5 pg /g fat <sup>6</sup><br>4 pg /g fat <sup>6</sup><br>1.5 pg /g fat <sup>6</sup><br>3 pg /g fat <sup>6</sup><br><br>1.5 pg /g fat <sup>6</sup><br>10 pg /g fat <sup>6,12</sup> | Commission Directive<br>2002/69/EC                     |
|   |   |  |  |

<sup>10</sup> Milk (raw milk, milk for the manufacture of milk-based products and heat treated milk as defined in in Annex I to Regulation (EC) N0 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.04.2004,. Corrigendum published in OJ L226, 25.6.2004, p. 22)

<sup>11</sup> Hen eggs and egg products as defined in in Annex I to Regulation (EC) N0 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.04.2004,. Corrigendum published in OJ L226, 25.6.2004, p. 22)

<sup>12</sup> Efforts have to be done by the operators to increase the capacity to remove effectively dioxins, furans and dioxin-like PCBs from marine oil. Legislation provides that all maximum levels for dioxins and dioxin-like PCBs have to be reviewed before 31 December 2007 with the aim of significantly reducing of the maximum levels. As regards marine oil, this significant lower level shall be determined based on the technical possibilities of the most effective decontamination procedure.

(\* ) Table WHO TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. *Environmental Health Perspectives*, 106(12), 775).

| Congener                                  | TEF value | Congener   | TEF value |
|---|-----------|--|-----------|
| <b><i>Dibenzo-p-dioxins ("PCDDs")</i></b> |           | <i>"Dioxin-like" PCBs Non-ortho PCBs + Mono-ortho PCBs</i> |           |
| 2,3,7,8-TCDD                              | 1         |  |           |
| 1,2,3,7,8-PeCDD                           | 1         | <b><i>Non-ortho PCBs</i></b>                               |           |
| 1,2,3,4,7,8-HxCDD                         | 0.1       | PCB 77   | 0.0001    |
| 1,2,3,6,7,8-HxCDD                         | 0.1       | PCB 81   | 0.0001    |
| 1,2,3,7,8,9-HxCDD                         | 0.1       | PCB 126  | 0.1       |
| 1,2,3,4,6,7,8-HpCDD                       | 0.01      | PCB 169  | 0.01      |
| OCDD                                      | 0.0001    | <b><i>Mono-ortho PCBs</i></b>                              |           |
| <b><i>Dibenzofurans ("PCDFs")</i></b>     |           | PCB 105  | 0.0001    |
| 2,3,7,8-TCDF                              | 0.1       | PCB 114  | 0.0005    |
| 1,2,3,7,8-PeCDF                           | 0.05      | PCB 118  | 0.0001    |
| 2,3,4,7,8-PeCDF                           | 0.5       | PCB 123  | 0.0001    |
| 1,2,3,4,7,8-HxCDF                         | 0.1       | PCB 156  | 0.0005    |
| 1,2,3,6,7,8-HxCDF                         | 0.1       | PCB 157  | 0.0005    |
| 1,2,3,7,8,9-HxCDF                         | 0.1       | PCB 167  | 0.00001   |
| 2,3,4,6,7,8-HxCDF                         | 0.1       | PCB 189  | 0.0001    |
| 1,2,3,4,6,7,8-HpCDF                       | 0.01      |  |           |
| 1,2,3,4,7,8,9-HpCDF                       | 0.01      |  |           |
| OCDF                                      | 0.0001    |  |           |

\*Abbreviations used: "T" = tetra; "Pe" = penta; "Hx" = hexa; "Hp" = hepta; "O" = octa; "CDD" = chlorodibenzodioxin; "CDF" = chlorodibenzofuran; "CB" = chlorobiphenyl.