Commission Regulation (EC) No 199/2006 of 3 February 2006 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs as regards dioxins and dioxin-like PCBs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 199/2006

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

(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[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 466/2001[(2)] sets maximum levels for certain contaminants in foodstuffs.

(2) 'Dioxins' as referred to in this Regulation cover a group of 75 polychlorinated dibenzo-p-dioxin (PCDD) congeners and 135 polychlorinated dibenzofuran (PCDF) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: a small number exhibit toxicological properties similar to dioxins and are therefore often termed 'dioxin-like PCBs'. The majority do not exhibit dioxin-like toxicity but 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 the individual dioxin and dioxin-like PCB congeners of toxicological concern are expressed in terms of a quantifiable unit, namely the 'TCDD toxic equivalent' (TEQ).

(4) On 30 May 2001 the Scientific Committee for Food (SCF) adopted an Opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food, updating its Opinion of 22 November 2000 on this subject on the basis of new scientific information that had become available since the latter's adoption[(3)]. The SCF fixed a tolerable weekly intake (TWI) of 14 pg WHO-TEQ/kg body weight for dioxins and dioxin-like PCBs. Exposure estimates indicate that a considerable proportion of the Community population have a dietary intake in excess of the TWI. Certain population groups in some countries could be at higher risk owing to particular dietary habits.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 199/2006. (See end of Document for details)*

(5) From a toxicological point of view, any level set should apply to both dioxins and dioxin-like PCBs, but in 2001 maximum levels were set for dioxins only and not for dioxin-like PCBs, given the very limited data available at that time on the prevalence of dioxin-like PCBs. In the meantime, however, more data on the presence of dioxin-like PCBs have become available.

(6) According to Regulation (EC) No 466/2001, the Commission was to review the provisions on dioxins 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.

(7) 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 dioxins and PCBs present in feed and food. Regulation (EC) No 466/2001 accordingly provides 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. Given the time necessary to obtain sufficient monitoring data to determine such significantly lower levels, that time-limit should be extended.

(8) 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, for a transitional period the existing levels for dioxins should continue to apply in addition to the newly set levels for the sum of dioxins and dioxin-like PCBs. The foodstuffs indicated in section 5 of Annex I must comply during that period with the maximum levels for dioxins and with the maximum levels for the sum of dioxins and dioxin-like PCBs. Consideration will be given by 31 December 2008 to dispensing with the separate maximum level for dioxins.

(9) It is of major importance that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach throughout the Community. Commission Directive 2002/69/EC of 26 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs[(4)] provides that a lot shall be considered as non-compliant with the established maximum level if the analytical result confirmed by duplicate analysis and calculated as the mean of at least two separate determinations exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty. There are different possibilities to estimate the expanded uncertainty[(5)].

(10) In order to encourage a proactive approach to reducing the dioxins and dioxin-like PCBs present in food and feed, action levels were 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[(6)]. 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 to reduce or eliminate it. Since the sources of dioxins and dioxin-like PCBs are different, separate action levels should be determined for dioxins on the one hand and for dioxin-like PCBs on the other hand. Recommendation 2002/201/EC will therefore be amended accordingly.

(11) Derogations have been granted to Finland and Sweden to place on the market fish originating in the Baltic region and intended for consumption in the territory with dioxin levels higher than those set in point 5.2 of section 5 of Annex I to Regulation (EC) No 466/2001. Those Member States have fulfilled the conditions as regards the provision of information to consumers on dietary recommendations. Every year they have communicated the results of their monitoring of the levels of dioxins in fish from the Baltic region to the Commission and have reported on the measures to reduce human exposure to dioxins from the Baltic region.

(12) On the basis of the results of monitoring of levels of dioxins and dioxin-like PCBs carried out by Finland and Sweden, the transitional period during which the derogations granted to those Member States apply should be extended, but those derogations should be limited to certain fish species. Those derogations apply to the maximum levels for 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 to Regulation (EC) No 466/2001.

(13) The reduction of human exposure to dioxins and dioxin-like PCBs through food consumption is important and necessary to ensure consumer protection. As food contamination is directly related to feed contamination, an integrated approach must be adopted to reduce dioxin and dioxin-like PCB incidence throughout the food chain, i.e. from feed materials through food-producing animals to humans. A proactive approach is followed to actively reduce the dioxins and dioxin-like PCBs in feed and food and consequently the maximum levels applicable should be reviewed within a defined period of time with the objective to set lower levels. Therefore consideration will be given by 31 December 2008 at the latest to significantly reducing the maximum levels for the sum of dioxins and dioxin-like PCBs.

(14) Operators need to make efforts to step up their capacity effectively to remove dioxins, furans and dioxin-like PCBs from marine oil. The significant lower level to which consideration shall be given by 31 December 2008, shall be based on the technical possibilities of the most effective decontamination procedure.

(15) As regards the establishment of maximum levels for other foodstuffs by 31 December 2008, particular attention shall be paid to the need to set specific lower maximum levels for dioxins and dioxin-like PCBs in foods for infants and young children in the light of the monitoring data obtained through the 2005, 2006 and 2007 programmes for monitoring dioxins and dioxin-like PCBs in foods for infants and young children.

(16) Regulation (EC) No 466/2001 should therefore 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

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

1. Article 1 is amended as follows:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 199/2006. (See end of Document for details)*

(a) Paragraph 1a is replaced by the following:

1a. By way of derogation from paragraph 1, Finland and Sweden are authorised, for a transitional period extending to 31 December 2011, to place on their market salmon (*Salmo salar*), herring (*Clupea harengus*), river lamprey (*Lampetra fluviatilis*), trout (*Salmo trutta*), char (*Salvelinus* spp.) and roe of vendace (*Coregonus albula*) originating in the Baltic region and 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 sections of the population in order to avoid potential health risks.

By 31 March each year, Finland and Sweden shall communicate to the Commission the results of their monitoring of the levels of dioxins and dioxin-like PCBs in fish from the Baltic region obtained in the preceding year and shall report on the measures taken to reduce human exposure to dioxins and dioxin-like PCBs from fish from the Baltic region. Finland and Sweden shall continue to implement the necessary measures to ensure that fish and fish products not complying with point 5.2 of Section 5 of Annex I are not marketed in other Member States.

(b) 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 that Annex.

2. Article 4a is replaced by the following:

Article 4a

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

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

(b) to use products not complying with the maximum levels as ingredients in the manufacture of other foodstuffs.

3. Article 5, paragraph 3 is deleted.

4. 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 4 November 2006.

As regards the maximum levels for the sum of dioxins and dioxin-like PCBs, this Regulation shall not apply to products that were placed on the market before 4 November 2006 in accordance 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, 3 February 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission