

## I

(Acts whose publication is obligatory)

**COUNCIL REGULATION (EC) No 2375/2001**  
**of 29 November 2001**  
**amending Commission Regulation (EC) No 466/2001 setting maximum levels for certain**  
**contaminants in foodstuffs**  
 (Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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,

Having regard to the proposal from the Commission,

Whereas:

- (1) Commission Regulation (EC) No 466/2001 <sup>(2)</sup> stipulates that foodstuffs should not, when placed on the market, contain higher contaminant levels than those specified in that Regulation.
- (2) The term 'dioxins' covers a group of 75 polychlorinated dibenzo-p-dioxin ('PCDD') and 135 polychlorinated dibenzofuran ('PCDF') congeners, of which 17 are of toxicological concern. The most toxic congener is 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD) classified by the International Agency for Research on Cancer and other reputable international organisations as a known human carcinogen. The Scientific Committee for Food ('SCF'), in line with the World Health Organisation ('WHO'), concluded that the carcinogenic effect of dioxins does not occur at levels below a certain threshold. Other adverse effects, such as endometriosis, neurobehavioural and immunosuppressive effects occur at much lower levels and are therefore considered relevant for determining a tolerable intake.
- (3) Polychlorinated biphenyls, ('PCBs'), are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties to dioxins and

are therefore often termed 'dioxin-like PCBs'. The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile.

- (4) 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 a single quantifiable unit: 'TCDD toxic equivalent concentration' (TEQ).
- (5) Dioxins and PCBs are extremely resistant to chemical and biological degradation and therefore persist in the environment and accumulate in the feed and food chain.
- (6) More than 90 % of human dioxin exposure derives from foodstuffs. Foodstuffs of animal origin normally contribute to approximately 80 % of overall exposure. The dioxin burden in animals derives mainly from feedingstuffs. Therefore feedingstuffs, and in some cases soil, raise concerns as potential sources of dioxins.
- (7) The SCF adopted an opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food on 30 May 2001, an update based on new scientific information which has become available since the adoption of the SCF opinion on this matter on 22 November 2000. The SCF fixed a tolerable weekly intake ('TWI') for dioxins and dioxin-like PCBs of 14 pg WHO-TEQ/kg body weight. Exposure estimates indicate that a considerable proportion of the Community population has a dietary intake in excess of the TWI. Certain population groups in some countries could be at higher risk due to particular dietary habits.

<sup>(1)</sup> OJ L 37, 13.2.1993, p. 1.

<sup>(2)</sup> OJ L 77, 16.3.2001, p. 1.

- (8) The reduction of human exposure to dioxins through food consumption is therefore important and necessary to ensure consumer protection. Particularly high levels of dioxin have been observed in certain food groups. As food contamination is directly related to feed contamination, an integrated approach must be adopted to reduce dioxin incidence throughout the food chain, i.e. from feed materials through food-producing animals to humans.
- (9) The SCF has recommended that continuing efforts should be made to limit environmental releases of dioxins and related compounds to the lowest levels feasible. This is the most effective and efficient way to reduce the presence of dioxins and similar substances in the food chain and to ensure continued reduction of the human body burden. The SCF has noted that recent investigations on human milk and blood seem to indicate that dioxin levels are no longer decreasing.
- (10) Maximum levels for dioxins and dioxin like PCBs are an appropriate tool to prevent unacceptably high exposure of the human population and to prevent the distribution of unacceptably highly contaminated foodstuffs e.g. from accidental pollution and exposure. Furthermore, the setting of maximum levels is indispensable for the implementation of a regulatory control system and to ensure uniform application.
- (11) Measures based solely on establishing maximum levels for dioxins and dioxin-like PCBs in foodstuffs would not be sufficiently effective in reducing human exposure to dioxins unless the levels were set so low that a large part of the food supply would have to be declared unfit for human consumption. It is generally recognised that, in order to actively reduce the presence of dioxins in foodstuffs, maximum levels should be accompanied by measures stimulating a pro-active approach, including action levels and target levels for foodstuffs in combination with measures to limit emissions. Target levels indicate the levels to be achieved in order to ultimately bring human exposure for the majority of the population down to the TWI set by the Scientific Committee. 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 not only in the event of non-compliance with the provisions of this Regulation, but also where significant levels of dioxins above the normal background levels are found in foodstuffs. This approach will result in a gradual reduction of dioxin levels in foodstuffs and the target levels will ultimately be achieved. A Recommendation from the Commission on this issue is therefore being addressed to the Member States.
- (12) Although, from a toxicological point of view, any level should apply to dioxins, furans and dioxin-like PCBs, for the time being, the maximum levels are set only for dioxins and furans and not for dioxin-like PCBs, given the very limited data available on the prevalence of the latter. However, monitoring will continue, in particular on the presence of dioxin-like PCBs, with a view to including these substances in the maximum levels.
- (13) The unacceptability of the dioxin content of foodstuffs should be assessed in the light of the current background levels of contamination, which differ from foodstuff to foodstuff. The maximum level should be fixed, taking account of background contamination, at a strict but feasible level.
- (14) In order to ensure that all operators in the food and feed chain continue to make all possible efforts and to do all that is necessary to limit the presence of dioxins in feed and food, the maximum levels applicable should be reviewed within a defined period of time with the objective to set lower maximum levels. An overall reduction of at least 25 % of the human exposure to dioxins should be achieved by the year 2006.
- (15) Maximum levels are stipulated mainly for foodstuffs of animal origin. None currently apply to products such as horsemeat, goat meat, rabbit meat and eggs from ducks, geese and quails. Only limited data are available on the prevalence of dioxins in these foodstuffs. Moreover, they are of limited significance from an intake point of view, no maximum level has been laid down for the time being. Nor does any maximum level currently apply to cereals, fruits and vegetables, as these food items have generally low levels of contamination and are therefore only a minor contributory factor in overall human exposure to dioxins. However, it is appropriate that the levels of dioxins and dioxin-like PCBs in these foodstuffs are monitored regularly.
- (16) Vegetable oils normally do not contain significant levels of dioxins or dioxin-like PCBs. As vegetable oils are regularly put on the market or used as ingredient in foodstuffs as a mixture with animal fats, it is appropriate to establish a maximum level for vegetable oils for reasons of control.
- (17) The data currently available do not allow maximum levels to be laid down for different categories of fish and fishery products. The maximum level of dioxins in feedingstuffs for fish means that, farmed fish have significantly lower dioxin levels. Once more data is available, it may in future be appropriate to lay down different levels for the various categories of fish and fishery products or exempt categories of fish, insofar they are of limited significance from an intake point of view.

- (18) Certain fish species originating from the Baltic region may contain a high level of dioxin. A significant part of the Baltic fatty fish, such as Baltic herring and Baltic salmon, will not comply with the maximum level and would therefore be excluded from the Swedish and Finnish diet. There are indications that the exclusion of fish from the diet may have a negative health impact in Sweden and Finland. Sweden and Finland have a system in place which has the capacity to ensure that consumers are fully informed of the dietary recommendations concerning restrictions on consumption of fish from the Baltic region by identified vulnerable groups of the population in order to avoid potential health risks.
- (19) Monitoring data indicate that free range or semi-intensive eggs contain higher levels of dioxins than battery eggs. Measures may be taken to ensure that the dioxin levels in these eggs are reduced. It is therefore appropriate to provide for a transition period before the maximum levels apply to free range or semi-intensive eggs.
- (20) It is important to reduce the overall dioxin contamination in foodstuffs. It is therefore necessary to prohibit the mixing of foodstuffs complying with the maximum levels with foodstuffs exceeding these maximum levels.
- (21) In view of the disparities between Member States and the consequent risk of distortion of competition, Community measures are required in order to protect public health and ensure market unity while adhering to the principle of proportionality.
- (22) Regulation (EC) No 466/2001 should therefore be amended accordingly.
- (23) The SCF has been consulted, in accordance with Article 3 of Regulation (EEC) No 315/93, on the provisions liable to affect public health.
- (24) The Standing Committee for Foodstuffs did not deliver a favourable opinion. The Commission has therefore been unable to adopt the provisions it envisaged according to the procedure laid down in Article 8 of Council Regulation (EEC) 315/93,

HAS ADOPTED THIS REGULATION:

#### Article 1

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

1. in Article 1 the following paragraph shall be inserted:

'1a. By way of derogation from paragraph 1, Sweden and Finland are authorised for a transitional period, up to 31 December 2006, 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, provided that a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on consumption of fish from the Baltic region by identified vulnerable groups of the population in order to avoid potential health risks.

Any future application of this derogation will be considered in the framework of the review of section 5 of Annex I, provided for in Article 5(3).

Finland and Sweden shall communicate to the Commission by 31 December each year, the results of their monitoring of the levels of dioxins in fish from the Baltic region and report on the measures taken to reduce human exposure to dioxins from fish from the Baltic region.;

2. the following Article shall be inserted:

#### 'Article 4a

With regard to dioxins 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.;

3. in Article 5, the following paragraph shall be added:

'3. The Commission shall review section 5 of Annex I 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.

Section 5 of Annex I shall 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.;

4. Annex I shall be amended in accordance with 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 Communities*.

It shall apply from 1 July 2002.

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

Done at Brussels, 29 November 2001.

*For the Council*  
*The President*  
M. VANDERPOORTEN

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## ANNEX

In Annex I, the following section 5 is added:

**'Section 5: Dioxin (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)**

Products	Maximum levels (PCDD + PCDF) <sup>(1)</sup> (pg WHO-PCDD/F-TEQ/g fat or product)	Performance criteria for sampling	Performance criteria for the methods of analysis
5.1.1. Meat and meat products <sup>(4)</sup> originating from			
— Ruminants (bovine animals, sheep)	3 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup> <sup>(3)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— Poultry and farmed game	2 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup> <sup>(3)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— Pigs	1 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup> <sup>(3)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
5.1.2. Liver and derived products	6 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup> <sup>(3)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
5.2. Muscle meat of fish and fishery products <sup>(5)</sup> and products thereof	4 pg WHO-PCDD/F-TEQ/g fresh weight <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
5.3. Milk <sup>(6)</sup> and milk products, including butter fat	3 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup> <sup>(3)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
5.4. Hen eggs and egg products <sup>(7)</sup> <sup>(8)</sup>	3 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup> <sup>(3)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
5.5. Oils and fats			
— Animal fat			
— from ruminants	3 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— from poultry and farmed game	2 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— from pigs	1 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— mixed animal fat	2 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— Vegetable oil	0,75 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>
— fish oil intended for human consumption	2 pg WHO-PCDD/F-TEQ/g fat <sup>(2)</sup>	Directive 2001/.../EC <sup>(*)</sup>	Directive 2001/.../EC <sup>(*)</sup>

<sup>(\*)</sup> Commission Directive to be adopted before 1 July 2002.

<sup>(1)</sup> Upperbound concentrations; upperbound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.

<sup>(2)</sup> These maximum levels shall be reviewed 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 and will be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels.

<sup>(3)</sup> The maximum levels are not applicable for food products containing < 1 % fat.

<sup>(4)</sup> Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Article 2(a) of Council Directive 64/433/EEC (OJ L 121, 29.7.1964, p. 2012/64), as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p. 7) and Article 2(1) of Council Directive 71/118/EEC (OJ L 55, 8.3.1971, p. 23), as last amended by Directive 97/64/EC (OJ L 24, 30.1.1998, p.31), and Article 2(2) of Council Directive 91/495/EEC (OJ L 268, 24.9.1991, p. 41) as last amended by Directive 94/65/EC (OJ L 368, 31.12.1994, p. 10), excluding edible offal as defined in Article 2(e) of Directive 64/433/EEC and Article 2(5) of Directive 71/118/EEC.

<sup>(5)</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 to cephalopods without viscera.

<sup>(6)</sup> Milk (raw milk, milk for the manufacture of milk-based products and heat treated milk as defined in Council Directive 92/46/EEC (OJ L 268, 14.9.1992, p. 1) as last amended by Council Directive 96/23/EC (OJ L 125, 23.5.1996, p. 10)).

<sup>(7)</sup> Hen eggs and egg products as defined in Article 2 of Council Directive 89/437/EEC (OJ L 212, 22.7.1989, p. 87), as last amended by Council Directive 96/23/EC (OJ L 125, 23.5.1996, p. 10).

<sup>(8)</sup> Free-range or semi-intensive eggs as defined in Article 18 of Commission Regulation (EEC) No 1274/91 (OJ L 121, 16.5.1991, p. 11), as last amended by Commission Regulation (EC) No 1651/2001 (OJ L 220, 15.8.2001, p. 5), must comply with the maximum level laid down as from 10 January 2004.'