COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.8.2001
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Proposal for a

COUNCIL REGULATION

amending Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs

(presented by the Commission)

EXPLANATORY MEMORANDUM

This proposal for a Regulation is a part of an overall strategy to reduce the presence of dioxins, furans and PCBs in environment, food and feed. Its purpose is to establish maximum limits for dioxins and furans in several foodstuffs.

The contamination of feed and food by dioxins, furans and polychlorinated biphenyls (PCBs) constitutes a risk to public health. Therefore, measures need to be taken to reduce their level of contamination. Already in the White Paper on Food Safety (COM(1999) 719 of 12 January 2000) the Commission identified the need to define maximum levels for dioxins throughout the chain from feed to food. Meeting in Feira in June 2000, the European Council also asked the Commission to propose harmonised rules on contaminants, in particular on dioxins. The European Parliament at its plenary session on 4 October 2000 called upon the Commission to set maximum limits for dioxins and PCBs in all feedingstuffs.

The scientific basis for setting these levels has been addressed as a matter of priority. The Commission requested the Scientific Committee for Food (SCF) and the Scientific Committee for Animal Nutrition (SCAN) to assess the risks for public health arising from the presence of dioxins and PCBs in food and feed. This included an assessment of the dietary intake of dioxins and PCBs by the EU population, identifying the main contributors. The SCF delivered its opinion on 22 November 2000 and the SCAN on 6 November 2000. The SCF updated its opinion on 30 May 2001, based on new scientific information available since the adoption of the original SCF opinion.

The SCF has established a Tolerable Weekly Intake (TWI) of 14 picograms per kilogram of bodyweight per week. This figure is in line with the provisional Tolerable Monthly Intake of 70 pg/kg bodyweight/month established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its meeting held at the beginning of June 2001. The SCF concluded that the average human intake of dioxins and dioxin-like PCBs in the European countries has been estimated to be 1.2 to 3.0 pg/kg bodyweight/day. This means that a considerable proportion of the European population is still exceeding what is considered to be tolerable from a toxicological point of view. The SCF states that this does not necessarily mean that there is an appreciable risk to the health of individuals, because the tolerable weekly intake includes a safety factor. However, exceeding this intake leads to erosion of the protection embedded in the safety factor.

Human exposure occurs mainly through food (>90 %). With the average consumption habits, food of animal origin contributes to about 90 % of the intake through food (i.e. about 80 % of the overall dioxin human exposure). Dioxins in food of animal origin derive from feedingstuffs. The contamination of feedingstuffs and foodstuffs can be the result of environmental contamination. Therefore a comprehensive strategy to reduce the presence of dioxins in the environment, feed and food is needed.

Measures to limit or to eliminate the emission of dioxins into the environment through source-directed measures are of major importance to reduce the overall contamination by dioxins. These measures will be addressed in a Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee on a Community strategy for Dioxins, Furans and PCBs. This Communication is expected to be presented by the Commission in the autumn of 2001.

This strategy will focus on two aspects:

- from the environmental side, it will focus on current and future measures to reduce the release of dioxins into the environment;

- from the feed and food safety side, it will address mainly the way to decrease the presence of dioxins in feedingstuffs and consequently in foodstuffs in order to achieve the target levels and whereby human dioxin exposure falls below the TWI (Tolerable Weekly Intake) set by SCF.

However, measures need already to be taken at the level of the food and feed chain to limit the presence of dioxins in food and feed.

The proposed measures concerning foodstuffs consist of three pillars:

- firstly, the establishment of maximum levels, taking into account the current background contamination, at a strict but feasible level;

- secondly, the establishment of action levels acting as a tool for "early warning" which triggers a proactive approach from competent authorities and operators to identify sources and pathways of contamination and to take measures to eliminate them;

- thirdly, the establishment of target levels, which are the levels to be achieved in order to bring the exposure of the large majority of the European population below the tolerable weekly intake set by the SCF.

Regarding the first pillar, the Commission proposes to establish maximum levels in food, taking into account the current background contamination. Harmonised maximum levels are a necessary tool for management and to ensure uniform application across the EU.

In order to ensure that all operators in the food and feed chain continue to make efforts and to take all the necessary measures to reduce the presence of dioxins in feed and food, a revision clause is foreseen with the aim to set lower levels by the year 2006.

From a toxicological point of view, maximum levels should include dioxins and dioxin-like PCB. However, as the data on the occurrence of dioxin-like PCBs are still very limited, this approach may lead to unrealistic maximum levels because the contribution of the dioxin-like PCBs to the total contamination load is variable according to the available limited data. But not acting immediately for dioxin-like PCBs should not prevent immediate action for dioxins and furans. Therefore measures are proposed for dioxins and furans, awaiting more comprehensive data for dioxin-like PCBs combined with an active approach to obtain these data.

The second pillar consists in setting action levels designed to trigger a proactive approach from competent authorities and operators to identify sources and pathways of contamination and to take measures to eliminate them. Indeed, permanent monitoring of the presence of dioxins and PCBs in feed and food across the EU is necessary. In case of an abnormal increase in the level of dioxins and dioxin-like PCBs, sources and/or pathways of contamination have to be identified. Once identified, measures to prevent or reduce future contamination from such sources should be defined and implemented.

The third pillar of the measures concerns the future establishment of target levels. These target levels would be the levels to be achieved in order to bring the exposure of the large majority of the European population below the Tolerable Weekly Intake recommended by the SCF. Target levels will act as the driving force for measures which are necessary to further reduce emissions into the environment. With increasing decline of emissions, the distribution of the contamination levels for the different food groups will shift towards lower levels and will come closer to the target levels. However, for the time being it is difficult to foresee accurately the impact of environmental measures on the levels in the different feed materials and in the different foodstuffs of animal origin. Accordingly, no numerical target levels can yet be set with reasonable scientific certainty.

A Commission Recommendation on action levels and target levels in food and feed, addressed to Member States, will be adopted at the same time as this Regulation.

With regard to sampling and methods of analysis, measures establishing performance criteria will be proposed shortly for adoption by the Commission.

According to the procedure laid down in Article 8 of Council Regulation (EEC) No 315/93 of 8 February 1993 concerning laying down Community procedures for contaminants in food[1], the measures of this Commission Proposal were submitted for an opinion to the Standing Committee for Foodstuffs on 25 July 2001.

The Commission, not having received a favourable opinion on the proposed draft measures, is required, according to the provisions of the above mentioned Regulation, to refer the proposed measures to Council without delay.

This proposal has no financial impact on the budget of the European Communities.

[1] OJ L 37, 13.2.1993, p. 1.

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

Having regard to the proposal from the Commission[3],

Whereas:

(1) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs[4] stipulates that foodstuffs should not when placed on the market, contain higher contaminant levels than those specified in the 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.

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2 OJ L 37, 13.2.1993, p. 1.
3 OJ C …, …, p. …
4 OJ L 77, 16.3.2001, p. 1.

(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.

(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 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) 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.

(19) 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.

(20) 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.

(21) Regulation (EC) No 466/2001 should therefore be amended accordingly.

(22) The SCF has been consulted, in accordance with Article 3 of Regulation (EEC) No 315/93, on the provisions liable to affect public health.

(23) The Standing Committee for Foodstuffs did not deliver a favourable opinion. The Commission has been therefore 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) The following Article 4a is 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."

(2) In Article 5, the following paragraph 3 is 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 of the maximum levels and possibly laying down maximum levels for other foodstuffs."

(3) 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 Communities.*

It shall apply from 1 January 2002.

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

Done at Brussels,

For the Council
The President

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)** [25] **(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 ([28]) originating from			
- Ruminants (bovine animals, sheep)	3 pg WHO-PCDD/F-TEQ /g fat[26,27]	Directive 2001/../EC	Directive 2001/../EC
- Poultry and farmed game	2 pg WHO-PCDD/F-TEQ /g fat[26,27]	Directive 2001/../EC	Directive 2001/../EC
- Pigs	1 pg WHO-PCDD/F-TEQ /g fat[26,27]	Directive 2001/../EC	Directive 2001/../EC
5.1.2 Liver and derived products	6 pg WHO-PCDD/F-TEQ /g fat[26,27]	Directive 2001/../EC	Directive 2001/../EC
5.2. Muscle meat of fish and fishery products ([29]) and products thereof	4 pg WHO-PCDD/F-TEQ /g fresh weight[26]	Directive 2001/../EC	Directive 2001/../EC
5.3. Milk ([30]) and milk products, including butter fat	3 pg WHO-PCDD/F-TEQ /g fat[26,27]	Directive 2001/../EC	Directive 2001/../EC
5.4 Hen eggs and egg products ([31,32])	3 pg WHO-PCDD/F-TEQ /g fat[26,27]	Directive 2001/../EC	Directive 2001/../EC
5.5.Oils and fats			
- Animal fat			
- from ruminants	3 pg WHO-PCDD/F-TEQ /g fat[26]	Directive 2001/../EC	Directive 2001/../EC
– from poultry and farmed game	2 pg WHO-PCDD/F-TEQ /g fat[26]	Directive 2001/../EC	Directive 2001/../EC
– from pigs	1 pg WHO-PCDD/F-TEQ /g fat[26]	Directive 2001/../EC	Directive 2001/../EC
– mixed animal fat	2 pg WHO-PCDD/F-TEQ /g fat[26]	Directive 2001/../EC	Directive 2001/../EC
- Vegetable oil	0.75 pg WHO-PCDD/F-TEQ /g fat[26]	Directive 2001/../EC	Directive 2001/../EC
- fish oil intended for human consumption	2 pg WHO-PCDD/F-TEQ /g fat[26]	Directive 2001/../EC	Directive 2001/../EC

([25]) 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

([26]) 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.

([27]) The maximum levels are not applicable for food products containing < 1% fat.

([28]) Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Article 2 (a) of Council Directive 64/433/EEC (OJ 121, 29.7.1964, p. 2012), 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 97/79/EC (OJ L 24, 30.1.1998, p.31) and Article 2(2) of Council Directive 91/495/EC (OJ 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.

([29]) 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.

([30]) 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 94/71/EC (OJ L 368, 31.12.1994, p.33)).

([31]) Hen eggs and egg products as defined in Article 2 of Council Directive 89/437/EEC (OJ L 212, 22.7.1989, p.87).

([32]) 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.1) must comply with the maximum level laid down as from 1 January 2004."