Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (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[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs[(2)] has been amended substantially many times. It is necessary to amend again maximum levels for certain contaminants to take into account new information and developments in Codex Alimentarius. At the same time, the text should, where appropriate, be clarified. Regulation (EC) No 466/2001 should therefore be replaced.

(2) It is essential, in order to protect public health, to keep contaminants at levels which are toxicologically acceptable.

(3) In view of disparities between the laws of Member States and the consequent risk of distortion of competition, for some contaminants Community measures are necessary in order to ensure market unity while abiding by the principle of proportionality.

(4) Maximum levels should be set at a strict level which is reasonably achievable by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food. In the case of contaminants which are considered to be genotoxic carcinogens or in cases where current exposure of the population or of vulnerable groups in the population is close to or exceeds the tolerable intake, maximum levels should be set at a level which is as low as reasonably achievable (ALARA). Such approaches ensure that food business operators apply measures to prevent and reduce the contamination as far as possible in order to protect public health. It is furthermore appropriate for the health protection of infants and young children, a vulnerable group, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for infants and young children. This strict selection of the raw materials is also appropriate for the production of some specific foodstuffs such as bran for direct human consumption.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 1881/2006. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(5) To allow maximum levels to be applied to dried, diluted, processed and compound foodstuffs, where no specific Community maximum levels have been established, food business operators should provide the specific concentration and dilution factors accompanied by the appropriate experimental data justifying the factor proposed.

(6) To ensure an efficient protection of public health, products containing contaminants exceeding the maximum levels should not be placed on the market either as such, after mixture with other foodstuffs or used as an ingredient in other foods.

(7) It is recognised that sorting or other physical treatments make it possible to reduce the aflatoxin content of consignments of groundnuts, nuts, dried fruit and maize. In order to minimise the effects on trade, it is appropriate to allow higher aflatoxin contents for those products which are not intended for direct human consumption or as an ingredient in foodstuffs. In these cases, the maximum levels for aflatoxins should be fixed taking into consideration the effectiveness of the above-mentioned treatments to reduce the aflatoxin content in groundnuts, nuts, dried fruit and maize to levels below the maximum limits fixed for those products intended for direct human consumption or use as an ingredient in foodstuffs.

(8) To enable effective enforcement of the maximum levels for certain contaminants in certain foodstuffs, it is appropriate to provide for suitable labelling provisions for these cases.

(9) Because of the climatic conditions in some Member States, it is difficult to ensure that the maximum levels are not exceeded for fresh lettuce and fresh spinach. These Member States should be allowed for a temporary period to continue to authorise the marketing of fresh lettuce and fresh spinach grown and intended for consumption in their territory with nitrate contents exceeding the maximum levels. Lettuce and spinach producers established in the Member States which have given the aforementioned authorisations should progressively modify their farming methods by applying the good agricultural practices recommended at national level.

(10) Certain fish species originating from the Baltic region may contain high levels of dioxins and dioxin-like PCBs. A significant proportion of these fish species from the Baltic region will not comply with the maximum levels and would therefore be excluded from the diet. There are indications that the exclusion of fish from the diet may have a negative health impact in the Baltic region.

(11) 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. Therefore, it is appropriate to grant a derogation to Finland and Sweden to place on the market for a temporary period certain fish species originating in the Baltic region and intended for consumption in their territory with levels of dioxins and dioxin-like PCBs higher than those set in this Regulation. The necessary measures must be implemented to ensure that fish and fish products not complying with the maximum levels are not marketed in other Member States. Finland and Sweden report every year to the Commission the results of their

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monitoring of the levels of dioxins and dioxin-like PCBs in fish from the Baltic region and the measures to reduce human exposure to dioxins and dioxin-like PCBs from the Baltic region.

(12) To ensure that the maximum levels are enforced in a uniform way, the same sampling criteria and the same analysis performance criteria should be applied by the competent authorities throughout the Community. It is furthermore important that analytical results are reported and interpreted in a uniform way. The measures as regards sampling and analysis specified in this Regulation provide for uniform rules on reporting and interpretation.

(13) For certain contaminants, Member States and interested parties should monitor and report levels, as well report on the progress with regard to application of preventative measures, to allow the Commission to assess the need to modify existing measures or to adopt additional measures.

(14) Any maximum level adopted at Community level can be subject to a review to take account of the advance of scientific and technical knowledge and improvements in good agricultural, fishery and manufacturing practices.

(15) Bran and germ can be marketed for direct human consumption and it is therefore appropriate to establish a maximum level for deoxynivalenol and zearalenone in these commodities.

(16) Codex Alimentarius has recently set a maximum level for lead in fish which the Community accepted. It is therefore appropriate to modify the current provision for lead in fish accordingly.

(17) Regulation (EC) No 853/2004 of the European Parliament and Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[(3)] defines foodstuffs of animal origin, and consequently the entries as regards foodstuffs of animal origin should be amended in some cases according to the terminology used in that Regulation.

(18) It is necessary to provide that the maximum levels for contaminants do not apply to the foodstuffs which have been lawfully placed on the Community market before the date of application of these maximum levels.

(19) As regards nitrate, vegetables are the major source for the human intake of nitrate. The Scientific Committee on Food (SCF) stated in its opinion of 22 September 1995[(4)] that the total intake of nitrate is normally well below the acceptable daily intake (ADI) of 3,65 mg/kg body weight (bw). It recommended, however, continuation of efforts to reduce exposure to nitrate via food and water.

(20) Since climatic conditions have a major influence on the levels of nitrate in certain vegetables such as lettuce and spinach, different maximum nitrate levels should therefore be fixed depending on the season.

(21) As regards aflatoxins, the SCF expressed in its opinion of 23 September 1994 that aflatoxins are genotoxic carcinogens[(5)]. Based on that opinion, it is appropriate to limit the total aflatoxin content of food (sum of aflatoxins B_1, B_2, G_1 and G_2) as well as the aflatoxin B_1 content alone, aflatoxin B_1 being by far the most toxic compound.

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For aflatoxin M_1 in foods for infants and young children, a possible reduction of the current maximum level should be considered in the light of developments in analytical procedures.

(22) As regards ochratoxin A (OTA), the SCF adopted a scientific opinion on 17 September 1998[6]. An assessment of the dietary intake of OTA by the population of the Community has been performed[7] in the framework of Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food[8] (SCOOP). The European Food Safety Authority (EFSA) has, on a request from the Commission, adopted an updated scientific opinion relating to ochratoxin A in food on 4 April 2006[9], taking into account new scientific information and derived a tolerable weekly intake (TWI) of 120 ng/kg bw.

(23) Based on these opinions, it is appropriate to set maximum levels for cereals, cereal products, dried vine fruit, roasted coffee, wine, grape juice and foods for infants and young children, all of which contribute significantly to general human exposure to OTA or to the exposure of vulnerable groups of consumers such as children.

(24) The appropriateness of setting a maximum level for OTA in foodstuffs such as dried fruit other than dried vine fruit, cocoa and cocoa products, spices, meat products, green coffee, beer and liquorice, as well as a review of the existing maximum levels, in particular for OTA in dried vine fruit and grape juice, will be considered in the light of the recent EFSA scientific opinion.

(25) As regards patulin, the SCF endorsed in its meeting on 8 March 2000 the provisional maximum tolerable daily intake (PMTDI) of 0,4 μg/kg bw for patulin[10].

(26) In 2001, a SCOOP-task 'Assessment of the dietary intake of patulin by the population of EU Member States' in the framework of Directive 93/5/EEC was performed[11].

(27) Based on that assessment and taking into account the PMTDI, maximum levels should be set for patulin in certain foodstuffs to protect consumers from unacceptable contamination. These maximum levels should be reviewed and, if necessary, reduced taking into account the progress in scientific and technological knowledge and the implementation of Commission Recommendation 2003/598/EC of 11 August 2003 on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages[12].

(28) As regards Fusarium toxins, the SCF has adopted several opinions evaluating deoxynivalenol in December 1999[13] establishing a tolerable daily intake (TDI) of 1 μg/kg bw, zearalenone in June 2000[14] establishing a temporary TDI of 0,2 μg/kg bw, fumonisins in October 2000[15] (updated in April 2003)[16] establishing a TDI of 2 μg/kg bw, nivalenol in October 2000[17] establishing a temporary TDI of 0,7 μg/kg bw, T-2 and HT-2 toxin in May 2001[18] establishing a combined temporary TDI of 0,06 μg/kg bw and the trichothecenes as group in February 2002[19].

(29) In the framework of Directive 93/5/EEC the SCOOP-task 'Collection of occurrence data on Fusarium toxins in food and assessment of dietary intake by the population of EU Member States' was performed and finalised in September 2003[20].

(30) Based on the scientific opinions and the assessment of the dietary intake, it is appropriate to set maximum levels for deoxynivalenol, zearalenone and fumonisins. As regards fumonisins, monitoring control results of the recent harvests indicate that maize and maize products can be very highly contaminated by fumonisins and it is appropriate that measures are taken to avoid such unacceptably highly contaminated maize and maize products can enter the food chain.

(31) Intake estimates indicate that the presence of T-2 and HT-2 toxin can be of concern for public health. Therefore, the development of a reliable and sensitive method, collection of more occurrence data and more investigations/research in the factors involved in the presence of T-2 and HT-2 toxin in cereals and cereal products, in particular in oats and oat products, is necessary and of high priority.

(32) It is not necessary due to co-occurrence to consider specific measures for 3-acetyl deoxynivalenol, 15-acetyl deoxynivalenol and fumonisin B_3, as measures with regard to in particular deoxynivalenol and fumonisin B_1 and B_2 would also protect the human population from an unacceptable exposure from 3-acetyl deoxynivalenol, 15-acetyl deoxynivalenol and fumonisin B_3. The same applies to nivalenol for which to a certain degree co-occurrence with deoxynivalenol can be observed. Furthermore, human exposure to nivalenol is estimated to be significantly below the t-TDI. As regards other trichothecenes considered in the abovementioned SCOOP-task, such as 3-acetyldeoxynivalenol, 15-acetyldeoxynivalenol, fusarenon-X, T2-triol, diacetoxyscirpenol, neosolaniol, monoacetoxyscirpenol and verrucol, the limited information available indicates that they do not occur widely and the levels found are generally low.

(33) Climatic conditions during the growth, in particular at flowering, have a major influence on the Fusarium toxin content. However, good agricultural practices, whereby the risk factors are reduced to a minimum, can prevent to a certain degree the contamination by *Fusarium* fungi. Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products[(21)] contains general principles for the prevention and reduction of Fusarium toxin contamination (zearalenone, fumonisins and trichothecenes) in cereals to be implemented by the development of national codes of practice based on these principles.

(34) Maximum levels of Fusarium toxins should be set for unprocessed cereals placed on the market for first-stage processing. Cleaning, sorting and drying procedures are not considered as first-stage processing insofar as no physical action is exerted on the grain kernel itself. Scouring is to be considered as first-stage processing.

(35) Since the degree to which Fusarium toxins in unprocessed cereals are removed by cleaning and processing may vary, it is appropriate to set maximum levels for final consumer cereal products as well as for major food ingredients derived from cereals to have enforceable legislation in the interest of ensuring public health protection.

(36) For maize, not all factors involved in the formation of Fusarium toxins, in particular zearalenone and fumonisins B_1 and B_2, are yet precisely known. Therefore, a time period is granted to enable food business operators in the cereal chain to perform