Commission Regulation (EC) No 856/2005 of 6 June 2005 amending Regulation (EC) No 466/2001 as regards Fusarium toxins (Text with EEA relevance)

COMMISSION REGULATION (EC) No 856/2005

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(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)] provides for maximum levels for certain contaminants in foodstuffs.

(2) Certain Member States have adopted or plan to adopt maximum levels for *Fusarium* toxins, such as deoxynivalenol (DON), zearalenone (ZEA) and fumonisins in certain foodstuffs. In view of the disparities between the level authorised in Member States and the consequent risk of distortion of competition, Community measures are necessary in order to ensure market unity while complying with the principle of proportionality.

(3) A variety of *Fusarium* fungi, which are common soil fungi, produce a number of different mycotoxins of the class of trichothecenes such as deoxynivalenol (DON), nivalenol (NIV), T-2 toxin and HT-2 toxin and some other toxins (zearalenone and fumonisins). The *Fusarium* fungi are commonly found on cereals grown in the temperate regions of America, Europe and Asia. Several of the toxin producing *Fusarium* fungi are capable of producing to a variable degree two or more of these toxins.

(4) The Scientific Committee for Food (SCF) has evaluated in a set of opinions the *Fusarium* toxins: deoxynivalenol (DON) in December 1999, zearalenone in June 2000, fumonisins in October 2000, updated in April 2003, nivalenol in October 2000 and T-2 and HT-2 toxin in May 2001 and a group evaluation of the trichothecenes in February 2002.

(5) The SCF considered that the available data did not support the establishing of group Tolerable Daily Intake (TDI) for the evaluated trichothecenes and established

— a TDI of 1 μg/kg body weight/day for deoxynivalenol (DON),

— a temporary TDI (t-TDI) of 0,7 μg/kg body weight/day for nivalenol,

— a combined temporary TDI of 0,06 μg/kg body weight/day for T-2 and HT-2 toxin.

For the other *Fusarium* toxins the SCF established

— a temporary TDI (t-TDI) of 0,2 μg/kg body weight/day for zearalenone,

— a TDI of 2 μg/kg bodyweight/day for the total of fumonisin B_1, B_2 and B_3, alone or in combination.

(6) 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[3], a scientific cooperation (SCOOP) task 3.2.10 'Collection of occurrence data on *Fusarium* toxins in food and assessment of dietary intake by the population of EU Member States'[4] was performed and finalised in September 2003. The results of that task demonstrate that *Fusarium* mycotoxins are widely distributed in the food chain in the Community. The major sources of dietary intake of *Fusarium* toxins are products made from cereals, in particular wheat and corn. While the dietary intakes of *Fusarium* toxins for the entire population and adults are often less than the TDI's for the respective toxin, for risk groups like infants and young children, they are close or even exceed the TDI in some cases.

(7) In particular for deoxynivalenol, the dietary intake for the group of young children and adolescents is close to the TDI. For T-2 and HT-2 toxin, the estimated dietary intake exceeded in most of the cases the t-TDI. However, it has to be noted that for T-2 and HT-2 toxin most occurrence data were obtained by making use of methods of analysis with a high limit of detection and taking into consideration that the amount of samples above the limit of detection was lower than 20 %, the dietary intake was strongly influenced by the limit of detection of the used analytical methods. For nivalenol all intakes were far below the t-TDI. As regards the other trichothecenes considered in the abovementioned SCOOP-Task, such as 3-acetyldeoxynivalenol, 15-acetyldeoxynivalenol, fusarenon-X, T2-triol, diacetoxyscirpenol, neosolaniol, monoacetoxyscirpenol and verrucol, as far as the information is available all dietary intakes are low.

(8) For zearalenone, the average daily intake is significantly lower than the TDI but attention should be paid to population groups not identified in the task which might have regularly high consumption of products with high incidence of zearalenone contamination and to food aimed for consumption among children, since the diversity of the diet is among young children is limited.

(9) For fumonisins, the estimated dietary intake for most population groups is far below the TDI. The dietary intake of fumonisins increases significantly when consumers only are considered. Nevertheless, the dietary intake is also for that group of consumers below the TDI. However, monitoring control results of the harvest 2003 indicate that maize and maize products can be very highly contaminated by fumonisins. It is appropriate that measures are taken to avoid that such unacceptably highly contaminated maize and maize products can enter the food chain.

(10) *Fusarium* species infect the grain pre-harvest. In connection with *Fusarium* infection and Mycotoxin formation several risk factors have been identified. Climatic conditions during the growth, in particular at flowering, have a major influence on the mycotoxin

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.

(11) It is important for the protection of public health that maximum levels are set on unprocessed cereals in order to avoid that highly contaminated cereals can enter the food chain and to encourage and ensure that all measures are taken during the field, harvest and storage stage of the production chain (by applying good agricultural, harvest and storage practices). It is appropriate to apply the maximum level on unprocessed cereals to cereals placed on the market for first stage processing as the intended use (for food, feed or industrial) of the cereals is known at this stage. Cleaning, sorting, drying procedures are not considered as first-stage processing insofar no physical action is exerted on the grain kernel itself while scouring is to be considered as first-stage processing.

(12) Maximum levels are set at a level taking into account the current human exposure in relation with the tolerable intake of the toxin in question and which can be reasonably achieved by following good practices at all stages of production and distribution. Such an approach ensures that food business operators apply all possible measures to prevent/reduce the contamination as far as possible in order to protect public health.

(13) 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 investigations on the sources of the formation of these mycotoxins and on the identification of the management measures to be taken to prevent their presence as much as reasonably possible. Maximum levels based currently available occurrence data are proposed to apply from 2007 in case no specific maximum levels based on new information on occurrence and formation are set before that time.

(14) Through cleaning and processing the content of *Fusarium* toxins in raw cereals can be reduced at a varying degree in processed cereal products. Given the varying degree of reduction, it is appropriate to set a maximum level for final consumer cereal products to protect the consumer and necessary to have an enforceable legislation. In setting maximum levels for final consumer cereal products, a pragmatic approach has to be followed. Furthermore the setting of a maximum level for major food ingredients derived from cereals is appropriate in order to ensure an efficient enforcement in the interest of ensuring public health protection.

(15) Given the low contamination levels of *Fusarium* toxins found in rice, no maximum levels are proposed for rice or rice products.

(16) It is not necessary due to co-occurrence to consider specific measures for 3-acetyl deoxynivalenol, 15-acetyl deoxynivalenol and Fumonisin B_3, as possible measures with regard to in particular deoxynivalenol and Fumonisin $B_1 + B_2$ 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 and human exposure to nivalenol is estimated to be significantly below the t-TDI.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 856/2005. (See end of Document for details)*

(17) Data on the presence of T-2 and HT-2 toxin are for the time being limited. There is also an urgent need for the development and validation of a sensitive method of analysis. However intake estimates indicate clearly that the presence of T-2 and HT-2 can be of concern for public health. Therefore, the development of a sensitive method, collection of more occurrence data and more investigations/research in the factors involved in the presence of T-2 and HT-2 in cereal and cereal products, in particular in oats and oat products, is necessary and of high priority.

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

(19) 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) In Article 2, paragraph 3 is replaced by the following:

3. Without prejudice to Articles 3(1) and 4(3), the following shall be prohibited

a to use products, which do not comply with the maximum levels set out in Annex I, as food ingredients for the production of compound or other foodstuffs;

b to mix products complying with the maximum levels with products exceeding the maximum levels set out in Annex I;

c to deliberately detoxify products by chemical treatments in the case of contaminants listed in section 2 (Mycotoxins) of Annex I.

(2) In Article 5, the following paragraph 5 is added:

5. The Commission shall review points 2.4, 2.5, 2.6 and 2.7 of section 2 of Annex I by 1 July 2008 as regards the maximum limits for deoxynivalenol, zearalenone and fumonisin B_1+B_2 and with a view to including a maximum level for T-2 and HT-2 toxin in cereals and cereal products.

For that purpose, the Member States and interested parties shall communicate each year to the Commission the results of investigations undertaken including occurrence data and the progress with regard to the application of prevention measures to avoid contamination by deoxynivalenol, zearalenone, T-2 and HT-2 toxin and fumonisin B_1+B_2.

(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 Union*.

It shall apply from 1 July 2006. This Regulation shall not apply to products which were placed on the market before 1 July 2006 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, 6 June 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission