

*Status: Point in time view as at 31/12/2020.**Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 856/2005. (See end of Document for details)*

ANNEX

In Section 2 Mycotoxins of Annex I to Regulation (EC) No 466/2001, the following points 2.4, 2.5, 2.6, and 2.7 are added:

‘Product’ ^b	Maximum level(µg/kg)	Sampling method	Reference analysis method
2.4. DEOXYNIVALENOL (DON)			
2.4.1. Unprocessed cereals ^c other than durum wheat, oats and maize	1 250	Directive 2005/38/EC ^a	Directive 2005/38/EC
2.4.2. Unprocessed durum wheat and oats	1 750	Directive 2005/38/EC	Directive 2005/38/EC
2.4.3. Unprocessed maize	— ^d	Directive 2005/38/EC	Directive 2005/38/EC
2.4.4. Cereal flour, including maize flour, maize grits and maize meal ^e	750	Directive 2005/38/EC	Directive 2005/38/EC
2.4.5. Bread, pastries, biscuits, cereal snacks and breakfast cereals	500	Directive 2005/38/EC	Directive 2005/38/EC
2.4.6. Pasta (dry)	750	Directive 2005/38/EC	Directive 2005/38/EC
2.4.7. Processed cereal-based food for infants and young children and baby food ^f	200	Directive 2005/38/EC	Directive 2005/38/EC

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- a** See page 18 of this Official Journal.
- b** For the purpose of the application of maximum levels of deoxynivalenol, zearalenone, fumonisins B₁ and B₂, T-2 and HT-2 toxin established in points 2.4, 2.5, 2.6 and 2.7 only, rice is not included in “cereals” and rice products not included in “cereal products.”
- c** The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing. However, the maximum levels do apply for the cereals harvested and taken over, as from the 2005/2006 marketing year, in accordance with Commission Regulation (EC) No 824/2000 of 19 April 2000 establishing procedures for the taking-over of cereals by intervention agencies and laying down methods of analysis for determining the quality of cereals (OJ L 100, 20.4.2000, p. 31), as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50). “First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be “first stage processing” insofar as no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.
- d** If no specific level is fixed before 1 July 2007, the level of 1 750 µg/kg will apply thereafter to maize referred to in this point.
- e** This category includes also similar products otherwise denominated such as semolina.
- f** Processed cereal-based foods for infants and young children and baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33). The maximum level for processed cereal-based foods for infants and young children and baby food refers to the dry matter.

Product ^a	Maximum level(µg/kg)	Sampling method	Reference analysis method
2.5. ZEARALENONE			
2.5.1. Unprocessed cereals ^b other than maize	100	Directive 2005/38/EC	Directive 2005/38/EC
2.5.2. Unprocessed maize	— ^c	Directive 2005/38/EC	Directive 2005/38/EC
2.5.3. Cereal flour except maize flour	75	Directive 2005/38/EC	Directive 2005/38/EC
2.5.4. Maize flour, maize meal, maize grits and refined maize oil ^d	— ^c	Directive 2005/38/EC	Directive 2005/38/EC
2.5.5. — Bread, pastries, biscuits	50	Directive 2005/38/EC	Directive 2005/38/EC
— maize snacks and maize-based breakfast cereals	— ^c		
— other cereal snacks and breakfast cereals	50		

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2.5.6. — processed maize-based foods for infants and young children	— ^c	Directive 2005/38/EC	Directive 2005/38/EC
— other processed cereal-based foods for infants and young children and baby food ^e	20		

a For the purpose of the application of maximum levels of deoxynivalenol, zearalenone, fumonisins B₁ and B₂, T-2 and HT-2 toxin established in points 2.4, 2.5, 2.6 and 2.7 only, rice is not included in “cereals” and rice products not included in “cereal products.”

b The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing. However, the maximum levels do apply for the cereals harvested and taken over, as from the 2005/2006 marketing year, in accordance with Commission Regulation (EC) No 824/2000 establishing procedures for the taking over of cereals by intervention agencies and laying down methods of analysis for determining the quality of cereals (OJ L 100, 20.4.2000, p. 31), as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50). “First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be “first-stage processing” insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.

c If no specific level is fixed before 1 July 2007, the level of

- 200 µg/kg will apply thereafter to unprocessed maize
- 200 µg/kg will apply thereafter to maize flour, maize meal, maize grits and refined maize oil
- 50 µg/kg will apply thereafter to maize snacks and maize-based breakfast cereals
- 20 µg/kg will apply thereafter to processed maize-based foods for infants and young children.

d This category includes also similar products otherwise denominated such as semolina.

e Processed cereal-based foods for infants and young children and baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33). The maximum level for processed cereal-based foods for infants and young children and baby food refers to the dry matter.

Product	Maximum level FB ₁ + FB ₂ (µg/kg)	Sampling method	Reference analysis method
2.6.			
FUMONISINS^a			
2.6.1. Unprocessed maize ^b	— ^c	Directive 2005/38/EC	Directive 2005/38/EC
2.6.2. Maize grits, maize meal and maize flour ^d	— ^c	Directive 2005/38/EC	Directive 2005/38/EC
2.6.3. Maize-based foods	— ^c	Directive 2005/38/EC	Directive 2005/38/EC

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	for direct consumption with the exception of 2.6.2 and 2.6.4			
2.6.4.	Processed maize-based foods for infants and young children and baby food ^e	— ^c	Directive 2005/38/EC	Directive 2005/38/EC
a	The maximum level applies to the sum of Fumonisin B ₁ (FB ₁) and Fumonisin B ₂ (FB ₂).			
b	The maximum level set for “unprocessed maize” applies to maize placed on the market for first-stage processing. However, the maximum levels do apply for the maize harvested and taken over, as from the 2006/2007 marketing year, in accordance with Commission Regulation (EC) No 824/2000 establishing procedures for the taking over of cereals by intervention agencies and laying down methods of analysis for determining the quality of cereals (OJ L 100, 20.4.2000, p. 31), as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50). “First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be “first stage processing” insofar as no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.			
c	If no specific level is fixed before 1 October 2007, the level of — 2 000 µg/kg will apply thereafter to unprocessed maize — 1 000 µg/kg will apply thereafter to maize flour, maize meal, maize grits and refined maize semolina — 400 µg/kg will apply thereafter to maize based foods for direct consumption — 200 µg/kg will apply thereafter to processed maize based foods for infants and young children and baby food.			
d	This category includes also similar products otherwise denominated such as semolina.			
e	Processed cereal-based foods for infants and young children and baby food as defined in Article 1 of Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.2.2003, p. 33). The maximum level for processed cereal-based foods and baby food for infants and young children refers to the dry matter.			

Product ^b	Maximum level(µg/kg)	Sampling method	Reference analysis method
2.7. T-2 AND HT-2 TOXIN^a			
2.7.1. Unprocessed cereals ^c and cereal products	— ^d	Directive 2005/38/EC	Directive 2005/38/EC
a	The maximum level refers to the sum of T-2 and HT-2 toxin.		
b	For the purpose of the application of maximum levels of deoxynivalenol, zearalenone, fumonisins B ₁ and B ₂ , T-2 and HT-2 toxin established in points 2.4, 2.5, 2.6 and 2.7 only, rice is not included in “cereals” and rice products not included in “cereal products”.		
c	The maximum levels set for “unprocessed cereals” applies to cereals placed on the market for first-stage processing. “First-stage processing” shall mean any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be “first stage processing” insofar as no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting.		
d	A maximum level will be fixed, if appropriate, before 1 July 2007. Data on the presence of T-2 and HT-2 toxin are for the time being limited. 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,		

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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 particularly in oats and oat products is necessary and of high priority.'

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