

Worldwide regulations for mycotoxins in food and feed in 2003

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Introduction

Regulations for mycotoxins have been established in food and animal feed in many countries since the late 1960's to protect the consumer from the harmful effects that mycotoxins may cause. Various factors influence the decision-making process of setting limits for mycotoxins. These include scientific factors such as data about effects on man and animals, the levels of human exposure, as well as the availability of methods of sampling and analysis. Economical factors such as commercial interests and sufficiency of food supply have their impact as well.

Over the last 2 decades various international inquiries on worldwide limits and regulations for mycotoxins were published. Several of these were carried out by RIVM for the Food and Agriculture Organization (FAO) of the United Nations. The latest completed inquiry resulted in the publication "Worldwide regulations for mycotoxins in food and feed in 2003" (FAO Food and Nutrition Paper nr. 81, 2004, ISBN 92-5-105162-3). An international inquiry formed the basis for this publication

International inquiry

In 2002/2003 we held an international inquiry among the Agricultural Services of the Dutch Embassies around the world, with the request to gather up-to-date information from the local authorities on the situation regarding mycotoxin regulations, in as many countries of the world as possible. Where this procedure did not lead to the desired information, personal contacts were used.

The questions in the inquiry concerned:

- the existence of mycotoxin regulations;
- the types of mycotoxins and products for which regulations are in force or proposed, together with maximum permissible levels;
- the authorities responsible for control of mycotoxins;
- the use of official and published methods of sampling and analysis;
- the disposal of consignments containing inadmissible amounts of mycotoxins.

In 2002 and 2003 data were received from approximately 90 countries. Together with information gathered in previous inquiries, detailed information is now available about the existence or absence of specific mycotoxin limits and regulations in human food and animal feed, in about 120 countries. All data were inspected, interpreted to the best of our knowledge and summarized in a table "Maximum tolerated levels of mycotoxins in foodstuffs, dairy products and animal feedstuffs (2002/2003 survey)". An excerpt of this table with relevant data for the EU is given as an example in Fig. 1. The collection of this updated information leads to the following conclusions in a Tour-du-monde.

Tour-du-monde

On a worldwide basis, at least 99 countries had mycotoxin regulations for food and/or feed in late 2003, an increase of 30 % compared to 1995. The total population in these countries represents approx. 87 % of the world's inhabitants. Mycotoxins for which currently (proposed) limits and regulations exist include the naturally occurring aflatoxins, aflatoxin M₁, agaric acid, deoxynivalenol, diacetoxyscirpenol, the fumonisins B₁, B₂ and B₃, HT-2 toxin, ochratoxin A, patulin, phomopsins, sterigmatocystin, T-2 toxin and zearalenone. On a regional basis the following observations can be made (situation per 31 December 2003):

Africa

- 15 countries with known regulations (59 % of inhabitants of the region)
- majority of countries: regulations unknown or non-existent
- several countries indicated: regulations should be developed
- most regulations exist for aflatoxins
- most detailed regulations: Morocco

Asia/Oceania

- 26 countries with known regulations (88 % of inhabitants of the region)
- regulations for total aflatoxins dominate in food; regulations for aflatoxin B₁ dominate in feed
- harmonized regulations exist for Australia & New Zealand
- "exotic" regulations exist in Australia/New Zealand: agaric acid & phomopsins
- most detailed regulations: China and Iran

Europe

- 39 countries with known regulations (99 % of inhabitants of the region)
- limits for many different matrix-toxin combinations
- EU harmonized regulations exist for aflatoxins, ochratoxin A and patulin
- EU harmonized recommendations exist for deoxynivalenol
- EU harmonized regulations are in development for several *Fusarium* toxins in foods, baby foods and feedstuffs
- most detailed regulations: several candidate-EU countries

Latin America

- 19 countries with known regulations (91 % of inhabitants of the region)
- harmonized aflatoxin regulations exist in MERCOSUR member states
- aflatoxin regulations are mostly set for total aflatoxins
- most detailed regulations: Uruguay

North America

- 2 countries with known regulations (100 % of inhabitants of the region)
- aflatoxin regulations are set for total aflatoxins
- Canada: detailed tolerances for *Fusarium* damaged kernels (% FDK) and for ergot (% by weight); HT-2 toxin regulated in feed.
- USA: detailed tolerances for total fumonisins (B₁, B₂, B₃) in a wide variety of foods and feedstuffs.

Conclusions

Comparing the situations in 1995 and 2003, it appears that in 2003 more mycotoxins are regulated in more commodities and products, whereas tolerance limits generally tend to decrease. Regulations have become more diverse and detailed with newer requirements regarding official procedures for sampling and analytical methodology. At the same time, several regulations have been harmonized between countries belonging to economic communities, or they are in some stage of harmonization. Nevertheless the regulatory requirements remain substantially different across many countries.

Fig. 1. Excerpt of data summarized for EU (status December 2003)

Country	Commodity	(Sum of) Mycotoxin(s)	Limit (µg/kg)	Legal basis	Responsible authority	Sampling method		Analytical method		Remarks							
						status	ref.	status	ref.								
EUROPEAN UNION [EU] 2003																	
EU member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom																	
EU candidate member states: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia will join the European Union per 1 May 2004; the other EU candidate member states - Bulgaria, Romania and Turkey - may join the EU later.																	
Food																	
	groundnuts, nuts and dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs	afla B ₁	2	EU2	various	official	EU7	official	EU7	Performance criteria for methods of analysis are given. A specific limit has been proposed for afla B ₁ in baby foods and processed cereal-based foods for infants and young children, and in dietary foods for special medical purposes intended specifically for infants; these limits are expected to come into force in May 2004.							
		afla B ₁ B ₂ G ₁ G ₂	4														
	groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	afla B ₁	8														
		afla B ₁ B ₂ G ₁ G ₂	15														
	nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	afla B ₁	5														
		afla B ₁ B ₂ G ₁ G ₂	10														
	cereals (including buckwheat, <i>Fagopyrum sp.</i>) and processed products thereof intended for direct human consumption or use as an ingredient in foodstuffs	afla B ₁	2														
		afla B ₁ B ₂ G ₁ G ₂	4														
	cereals (including buckwheat, <i>Fagopyrum sp.</i>) , with the exception of maize, to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	afla B ₁	2														
		afla B ₁ B ₂ G ₁ G ₂	4														
	maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	afla B ₁	5								EU3						
		afla B ₁ B ₂ G ₁ G ₂	10														
	spices: <i>Capsicum spp.</i> (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne and paprika); <i>Piper spp.</i> (fruits thereof,	afla B ₁	5								EU4			EU8		EU8	

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Country	Commodity	(Sum of) Mycotoxin(s)	Limit (µg/kg)	Legal basis	Responsible authority	Sampling method		Analytical method		Remarks
						status	ref.	status	ref.	
	including white and black pepper); <i>Myristica fragrans</i> (nutmeg); <i>Zingiber officinale</i> (ginger); <i>Curcuma longa</i>	afla B ₁ B ₂ G ₁ G ₂	10							
	raw cereal grains (including raw rice and buckwheat)	ochratoxin A	5		various		EU9		EU9	Performance criteria for methods of analysis are given. A specific limit has been proposed for ochratoxin A in baby foods and processed cereal-based foods for infants and young children, and in dietary foods for special medical purposes intended specifically for infants; these limits are expected to come into force in May 2004.
	all products derived from cereals (including processed cereal products and cereal grains intended for direct human consumption)		3							
	dried vine fruit (currants, raisins and sultanas)		10							
	fruit juices and fruit nectar, in particular apple juice, and fruit juice ingredients in other beverages	patulin	50	EU5	official	EU10	official	EU10	since 1 november 2003; prevention and reduction of patulin contamination [see EU 11]; performance criteria for methods of analysis are given	
	concentrated fruit juice after reconstitution as instructed by the manufacturer		50							
	spirit drinks, cider and other fermented drinks derived from apples or containing apple juice		50							
	solid apple products, including apple compote, apple puree intended for direct consumption		25							
	apple juice and solid apple products, including apple compote and apple puree, for infants and young children and labelled and sold as intended for infants and young children		10							
	other baby food (as defined in Article 1 of [EU1])		10							
	cereal products as consumed and other cereal products at retail stage	DON	500	EU6						draft Commission Recommendation

Fig. 1. Excerpt of data summarized for EU (status December 2003)

Country	Commodity	(Sum of) Mycotoxin(s)	Limit (µg/kg)	Legal basis	Responsible authority	Sampling method		Analytical method		Remarks
						status	ref.	status	ref.	
	flour used as raw material in food products		750							see above
Dairy										
	milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined by Council Directive 92/46/EEC, as last amended by Council Directive 94/71/EC)	afla M ₁	0.05	EU2	various	official	EU7	official	EU7	Performance criteria for methods of analysis are given. A specific limit has been proposed for afla M ₁ in infant formulae and follow-on formulae, including infant milk and follow-on milk; these limits are expected to come into force in May 2004.
Feed										
	all feed materials	afla B ₁	20	EU12	various	official	EU14	official	EU15 EU16	Maximum content relative to a feedingstuff with a moisture content of 12 %
	complete feedingstuffs for cattle, sheep and goats with the exception of:		20							
	- complete feedingstuffs for dairy animals - complete feedingstuffs for calves and lambs									
	complete feedingstuffs for dairy animals		5							
	complete feedingstuffs for calves and lambs		10							
	complete feedingstuffs for pigs and poultry (except young animals)		20							
	other complete feedingstuffs		10							
	complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs)		20							
	Complementary feedingstuffs for pigs and poultry (except young animals)		20							
	other complementary feedingstuffs		5							

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Country	Commodity	(Sum of) Mycotoxin(s)	Limit (µg/kg)	Legal basis	Responsible authority	Sampling method		Analytical method		Remarks
						status	ref.	status	ref.	
	All feedingstuffs containing unground cereals	Rye ergot ^{*)} (<i>Claviceps purpurea</i>)	1000000	EU13						Maximum content relative to a feedingstuff with a moisture content of 12 %; ^{*)} see footnote
^{*)} ergot means the sclerotium or dormant winter form of the fungus <i>Claviceps purpurea</i> . The limit refers to the weight of ergot kernels per total commodity weight, and not toxin concentration.										

EU1 to EU16 are references to documents on legislation. Full details are provided in FAO Food and Nutrition Paper No. 81