



# Current EU Mycotoxin Legislation

October 2009



# Competence in Food and Feed Analysis

R-Biopharm is a leading developer of test solutions for clinical diagnostics and food and feed analysis. In both sectors, the R-Biopharm test kits offer high precision and accuracy, key requirements where patient and consumer health is at risk.

R-Biopharm AG was founded in 1988 as a subsidiary of Röhm GmbH in Darmstadt, Germany. In 1991 it was taken over by the present Managing Director, Dr. Ralf M. Dreher. Since 1996 R-Biopharm's quality management systems have been certified to the international standards ISO 9001 and EN 46001 (medical devices), and in 2003 the company gained ISO 13485 quality management certification. From January 2000 R-Biopharm acquired sole worldwide distribution rights to Enzymatic BioAnalysis, a product developed by Roche (formerly BOEHRINGER Mannheim). In 2002 R-Biopharm acquired Rhône Diagnostics Technologies in Scotland, another supplier of mycotoxin tests kits, resulting in successful expansion of its position in the food and feed analysis sector.

Today the German parent company R-Biopharm, with subsidiaries in the UK, USA, Italy, France, Spain, Latin America, China, Brazil and Australia. It is also represented worldwide by an extensive network of more than 80 distributors.

Many R-Biopharm test kits have undergone official validation and certification, and R-Biopharm products have a high worldwide reputation under the RIDASCREEN® and RIDA® trademarks.

In the field of food and feed analysis, the company offers a consistently impressive range of approved test formats provided as enzyme immunoassays, immunoaffinity columns, dip sticks, card tests and ready-to-use media sheets.

**The product portfolio contains various test kits for the analysis of:**

- **Constituents**, like sugars, acids, vitamins, amino acids and others.
- **Residues**, like mycotoxins, hormones, antibiotics and others.
- **GMOs**, like Bt11, Corn, RoundUp Ready Soya and others.
- **BSE / Risk Material / Identification of Animal Species** in the formats ELISA, PCR-ELISA, real-time PCR and Monoclonal Antibodies for the detection of prion proteins.
- **Microbiology / Hygiene**, like Total Count, Yeast & Mould, ATP and others.
- **Allergens**, like gliadin, peanut, hazelnut and others.

R-Biopharm's distinctive policy of partnership and teamwork is an approach valued by its customers and research partners alike. The company's key objective is to be a dependable point of contact for customers, providing competent advice on every sector it serves.

At R-Biopharm the future looks set to offer exciting prospects in the fields of clinical diagnostics and food and feed analysis. The foremost challenge is to advance the development of new and versatile fast tests. These will shorten the time it takes to obtain results from a wide range of analytical procedures.

## Technical Services

In addition to the manufacture of test kits for analysis of mycotoxins, microorganisms and food contaminants R-Biopharm Rhône also offer a range of support services to make it easy for our customers to obtain assistance if required. Literature, publications and posters are all available providing basic information, technical specifications and data on our products in a variety of different food/feed matrices.

The technical team at RBR is always available to give technical advice by telephone or e-mail. RBR also has a well-equipped microbiology and chemistry laboratory, which offers the provision of practical technical support, training, method development and confirmation to our customers worldwide.

RBR also has an active sales and distribution team in over 50 countries that can offer on site technical support and training and provide customers with information and data to support our range of products. So wherever our customer is, help is always at hand.

## ISO 9001:2001

R-Biopharm Rhône's commitment to quality is an integral part of the business. The Quality Management System is designed to give a frame to the organisations activities, in order to ensure that a high level of quality is maintained, from Research and Development right through to Sales and Dispatch. The Quality Management System is fully operational and accredited by the DQS to ISO 9001:2000.

Outstanding quality is consistently achieved by RBR through use of internal auditing, to systematically check completed work, the establishment of formal Procedures to ensure consistency of operations, regular maintenance and calibration of equipment to ensure accuracy of measurements and quality control analyses on intermediate and finished products.





## Competence in Food and Feed Analysis

### Aflatoxin in Food Legislation

Commodity	Maximum Level		
	B1	TOTAL	M1
Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.	8ppb	15ppb	-
Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption to use as an ingredient in foodstuffs.	5ppb	10ppb	-
Groundnuts, nuts, dried fruit and processed products thereof, intended for direct human consumption or as an ingredient in foodstuffs.	2ppb	4ppb	-
Oilseed intended for direct human consumption.	2ppb*	4ppb*	-
Oilseed for processing.	8ppb*	15ppb*	-
Maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.	5ppb	10ppb	-
Cereals (inc. buckwheat, Fagopyrum spp.) and processed products thereof intended for direct human consumption or as an ingredient in foodstuffs.	2ppb	4ppb	-
Cereals (including buckwheat, Fagopyrum spp.), with the exception of maize, to be subjected to sorting, or other physical treatment, before human consumption.	2ppb	4ppb	-
Rice, including brown rice (intended for milling).	5ppb*	10ppb*	-
Rice, including brown rice (intended for direct human consumption).	2ppb*	4ppb*	-
Following species of spices: Capsicum spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayene and paprika). Piper spp. (fruits thereof, including white and black pepper). Myristica fragrans (nutmeg). Zingiber officinale (ginger). Curcuma longa (turmeric).	5ppb	10ppb	-
Milk (raw milk, milk for the manufacture of milk based products and heat treated milk).	-	-	0.05ppb
Baby foods and processed cereal based foods for infants and young children	0.1 ppb	-	-
Infant formulae and follow-on formulae, including infant milk and follow-on milk.	-	-	0.025ppb
Dietary foods for special medical purposes intended specifically for infants.	0.1 ppb	-	0.025ppb

### Deoxynivalenol in Food Legislation

Commodity	Maximum Level
Unprocessed cereals (excluding durum wheat, oats and maize).	1250ppb
Unprocessed durum wheat and oats.	1750ppb
Unprocessed maize.	1750ppb
Cereals intended for direct human consumption, cereal flour (including maize flour, maize meal and maize grits), bran as end product intended for direct human consumption and germ.	750ppb
Bread, biscuits, pastries, cereal snacks and breakfast cereal.	500ppb
Dry pasta.	750ppb
Processed cereal based baby and infant food.	200ppb

### Fumonisin in Food Legislation

Commodity	Maximum Level (B1 & B2)
Unprocessed maize.	4000ppb
Maize and maize based foods intended for direct human consumption.	1000ppb
Maize based breakfast cereals and maize based snacks.	800ppb
Processed maize based foods and baby foods for infants and young children.	200ppb

\* Levels have still to be fixed, currently under discussion.



## Ochratoxin in Food Legislation

Commodity	Maximum Level
Unprocessed cereals.	5ppb
All products derived from unprocessed cereals (including cereal products and cereal grains intended for direct human consumption).	3ppb
Dried vine fruit (currants, raisins and sultanas).	10ppb
Dried figs.	8 - 10ppb*
Dried fruit other than dried vine fruit and dried figs.	1 - 2ppb*
Roasted coffee beans and ground roasted coffee.	5ppb
Soluble coffee (instant coffee).	10ppb
Cocoa products (cocoa powder, powder chocolate, chocolate powder, drinking chocolate, sweetened cocoa, chocolate, milk chocolate and white chocolate).	0.5 - 2ppb*
Wine (including sparkling wine, excluding liqueur wine and wine with an alcoholic strength of not less than 15% vol) and fruit wine.	2ppb
Aromatised wine, aromatised wine based drinks and aromatised wine product cocktails.	2ppb
Grape juice, concentrated grape juice as reconstituted, grape nectar, grape must and concentrated must as reconstituted, intended for direct human consumption.	2ppb
Beer <6% alcohol.	0.2ppb*
Liqueur wines.	2 - 4ppb*
Following species of spices: Capsicum spp. (dried fruits thereof, whole or ground, including chillies, chilli powder, cayene and paprika). Piper spp. (fruits thereof, including white and black pepper). Myristica fragrans (nutmeg). Zingiber officinale (ginger). Curcuma longa (turmeric).	15ppb or 30ppb*
Liquorice (Glycyrrhiza glabra), liquorice root, ingredient for herbal infusion.	5 - 20ppb*
Liquorice extract for use in confectionery.	80ppb*
Edible offal and products containing edible offal.	5 - 15ppb*
Blood products (such as black pudding and sausages).	2 - 5ppb*
Baby foods and processed cereal based foods for infants and young children.	0.5ppb
Dietary foods for special medical purposes intended specifically for infants.	0.5ppb

## T2 & HT-2 in Food Legislation

Commodity	Maximum Level (T-2 & HT-2)
Unprocessed cereals and cereal products.	*

## Zearalenone in Food Legislation

Commodity	Maximum Level
Unprocessed cereals other than maize.	100ppb
Unprocessed maize.	350ppb
Cereals intended for direct human consumption, cereal flour, bran as end product for direct human consumption and germ.	75ppb
Maize intended for direct human consumption, maize based snacks and maize based breakfast cereals.	100ppb
Refined maize oil.	400ppb
Bread, pastries, biscuits, cereal snacks and breakfast cereals.	50ppb
Processed cereal based foods and baby foods for infants and young children.	20ppb
Processed maize based foods and baby foods for infants and young children.	20ppb

\* Levels have still to be fixed, currently under discussion.

## Aflatoxin in Feed Legislation

Commodity	Maximum Level (B1)
All feed materials.	0.02ppm
Complete feedingstuffs for cattle, sheep and goats.	0.02ppm
Complete feedingstuffs for dairy animals.	0.005ppm
Complete feedingstuffs for calves and lambs.	0.01ppm
Complete feedingstuffs for pigs and poultry.	0.02ppm
Other complete feedingstuffs.	0.01ppm
Complementary feedingstuffs for cattle, sheep and goats.	0.02ppm
Complementary feedingstuffs for pigs and poultry.	0.02ppm
Other complementary feedingstuffs.	0.005ppm

## Deoxynivalenol in Feed Legislation

Commodity	Maximum Level
Cereals and cereal products with the exception of maize by-products.	8ppm
Maize by-products.	12ppm
Complementary and complete feeding stuffs.	5ppm
Complementary and complete feeding stuffs for pigs.	0.9ppm
Complementary and complete feeding stuffs for calves (<4 months), lambs and kids.	2ppm

## Fumonisin in Feed Legislation

Commodity	Maximum Level (B1 & B2)
Maize and maize based products.	60ppm
Complementary and complete feedingstuffs for pigs, horses, rabbits and pet animals.	5ppm
Complementary and complete feedingstuffs for fish.	10ppm
Complementary and complete feedingstuffs for poultry, calves (<4 months), lambs and kids.	20ppm
Complementary and complete feedingstuffs for adult ruminants (>4 months) and mink.	50ppm

## Ochratoxin in Feed Legislation

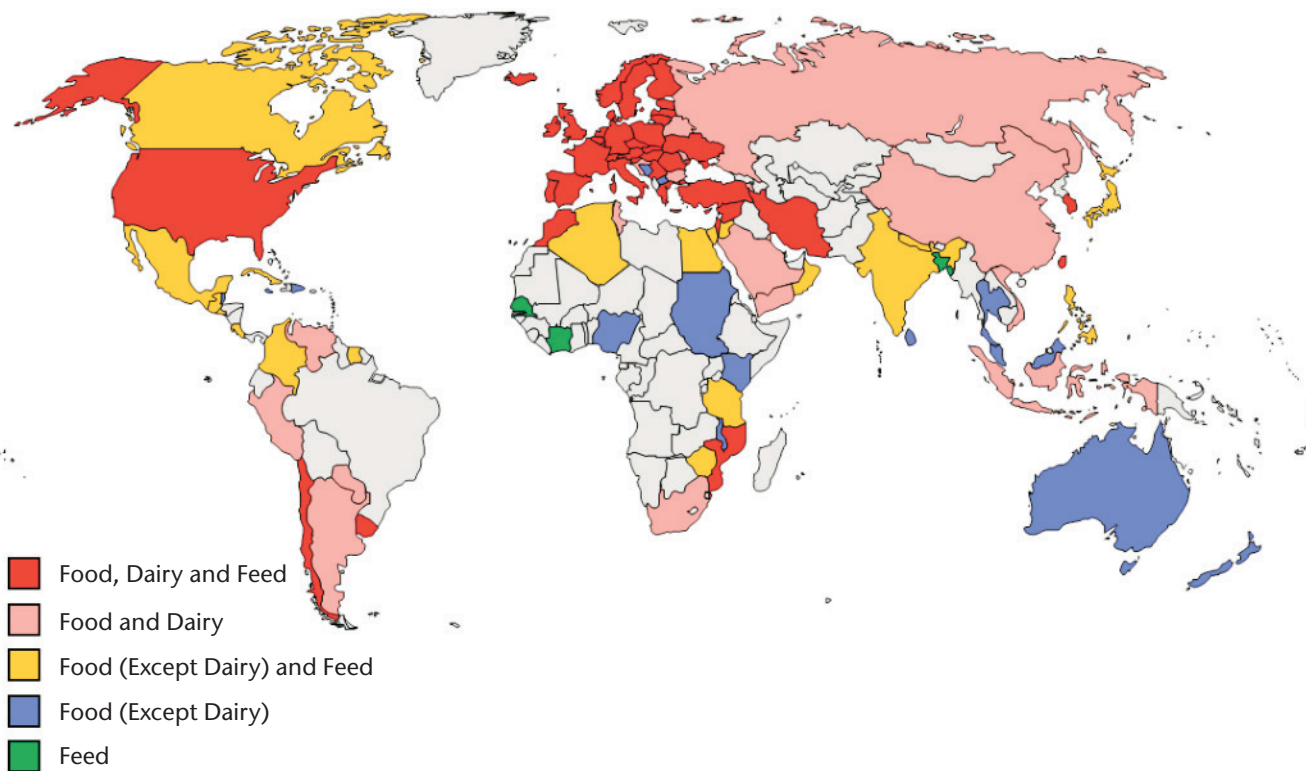
Commodity	Maximum Level
Cereal and cereal products.	0.25ppm
Complementary and complete feedingstuffs for pigs.	0.05ppm
Complementary and complete feedingstuffs for poultry.	0.1ppm

## Zearalenone in Feed Legislation

Commodity	Maximum Level
Cereal and cereal products with the exception of maize by products.	2ppm
Maize by products.	3ppm
Complementary and complete feedingstuffs for piglets and gilts (young sows).	0.1ppm
Complementary and complete feedingstuffs for sows and fattening pigs.	0.25ppm
Complementary and complete feedingstuffs for calves, dairy cattle, sheep (including lamb) and goats (including kids).	0.5ppm



## Current Mycotoxin Regulations In Place



Source: Worldwide regulations for mycotoxins in food and feed in 2003, FAO 2004.

### Food & Feed Legislation References

Commission Regulation (EC) No. 1126/2007 of 28 September 2007 amending Regulation (EC) No. 1181/2006 setting maximum levels for certain contaminants in foodstuffs as regards Fusarium toxins in maize and maize products.

Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products.

Commission Recommendation 2006/576/EC of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding.

Commission Regulation (EC) 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

Commission Regulation (EC) No. 856/2005 of 6 June 2005 amending Regulation (EC) No. 466/2001 as regards Fusarium toxins.

Commission Regulation (EC) No. 123/2005 of 26 January 2005 amending Regulation (EC) No. 466/2001 as regards ochratoxin A.

Commission Regulation (EC) No. 2174/2003 of 12 December 2003 amending Regulation (EC) No. 466/2001 as regards aflatoxin.

Commission Directive 2003/100/EC of 31 October 2003 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed.

Commission Regulation (EC) No. 472/2002 of 12 March 2002 amending Regulation (EC) No. 466/2001 setting maximum levels for certain contaminants in foodstuffs.

Commission Regulation (EC) No. 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.



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