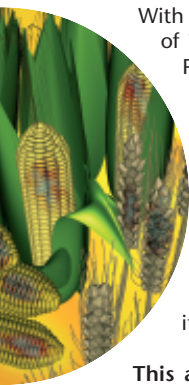


Amendment to the German regulation on maximum mycotoxin levels



With its memorandum BLL-059-2004 of 13 February 2004, the German Federation of Food Law and Food Science (BLL) sent the directive pertaining to the amendment of the German regulation on maximum mycotoxin levels and the German regulation on dietetic foods of 4 February 2004 (published 12.2.04 in the Federal Legal Gazette (Bundesgesetzblatt), page 151) to all its members.

This amendment redefines the maximum mycotoxin levels in foods as follows:

Ochratoxin A:

- 3 µg/kg (ppb) in roasted coffee
- 6 µg/kg (ppb) in instant coffee
- 2 µg/kg (ppb) in dried fruit, excluding grapes and figs
- 8 µg/kg (ppb) in dried figs

Deoxynivalenol (DON):

- 500 µg/kg (ppb) in cereal products (cereal grains intended for direct consumption and processed cereal products), excluding hard wheat products, bread, biscuits and pastry products
- 350 µg/kg (ppb) in bread, biscuits and pastry products

Fumonisin (B₁ and B₂):

- 500 µg/kg (ppb) in maize products (maize for direct consumption and processed maize products) with the exception of Cornflakes
- 100 µg/kg (ppb) in Cornflakes

Zearalenone:

- 50 µg/kg (ppb) in cereal products (cereal grains for direct consumption and processed cereal products)

Products whose values exceed the following limit values must not be used for the production of dietetic foods for infants and small children:

100 µg/kg (ppb) fumonisin (B₁ and B₂), either singularly or combined in maize products (maize for direct consumption and processed maize products)

20 µg/kg (ppb) zearalenone and 100 µg/kg (ppb) DON in cereal products (cereal grains for direct consumption and processed cereal products)

R-Biopharm offers you a wide range of highly sensitive mycotoxin ELISA test systems and immunoaffinity columns, which fully satisfy the analytical requirements arising from the amended maximum mycotoxin levels.

Shortly before the editorial deadline

A new BLL memorandum (BLL-128-2004 of 19.04.04) reached us referring to regulation (EC) no. 683/2004 in which the maximum levels of aflatoxins and ochratoxin A in foods for infants and small children has been amended or defined for the first time. This regulation applies from 1 November 2004 onwards.

Product	Maximum levels in µg/kg (ppb)		
	Aflatoxin B ₁	Aflatoxin M ₁	Ochratoxin A
Cereal and other complementary foods for infants and small children	0.10		0.50
Newborn baby formula and infant formula, including newborn baby milk formula and follow-on milk		0.025	
Dietetic food for special medical purposes, specifically intended for infants	0.10	0.025	0.50

About our Products

RIDASCREEN®FAST Aflatoxin Total (R4702)

Contrary to information posted in R-Biopharm News 1/04, enquiries from several customers have led us to once again offer the RIDASCREEN®FAST Aflatoxin Test with the art. no. R5202.

This product will therefore not be replaced with the new RIDASCREEN®FAST Aflatoxin Total test, as originally planned but will be offered in parallel under the modified art. no. R4702. The amendments mentioned above affect the antibody used (specificity), the standard range and hence the sensitivity and the incubation times. The standard range for the new tests lies within the range 4 - 50 µg/kg (ppb). The RIDASCREEN®FAST Aflatoxin Test (R5202), on the other hand, has a standard range of 1.7 - 45 µg/kg (ppb). The first incubation time of standard, enzyme conjugate and antibody solutions

has also been reduced from 10 to 5 minutes with the new test (R4702).

The RIDASCREEN®FAST Aflatoxin Total Test (R4702) has been approved by the US Department of Agriculture „Grain Inspection, Packers and Stockyards Administration“ (USDA / GIPSA) for the analysis of aflatoxin in cereals and animal feeds. The relevant certificate carries the no. FGIS 2003 - 101.



New R-Biopharm Rhône application notes based on CEN Mycotoxin Methods

Three new European standard analytical methods for mycotoxin analysis have been approved and published. In order to help our customers to adopt these methods, R-Biopharm Rhône have incorporated the procedures into method application notes using the R-Biopharm Rhône immunoaffinity columns. The application notes and the full CEN-EN standard methods are available from your local distributor.

CEN-EN 141 23: 2003:
HPLC method with immunoaffinity column clean-up and post column derivatisation for the determination of aflatoxin B₁ and total aflatoxins in peanuts, pistachios, figs and paprika powder

CEN-EN 141 32: 2003:
HPLC method with immunoaffinity column clean up for determination of ochratoxin A in barley and roasted coffee

CEN-EN 141 33: 2003:
HPLC method with immunoaffinity column clean up for determination of ochratoxin A in wine and beer

New customer reference for R-Biopharm Rhône products

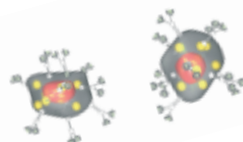
Whitworths Ltd., one of Europe's largest importers and processors of dried fruit have provided an excellent reference praising R-Biopharm Rhône's product quality, technical support and service and training. With R-Biopharm Rhône's help, Whitworths have achieved CLAS approval for Ochratoxin A analysis using both Ochrascan (RBRP15) and Ochraprep (RBRP14).



Results of the PWG interlaboratory study

The R-Biopharm RIDASCREEN® Gliadin test kit was successfully tested in an interlaboratory study conducted by the Prolamin Working Group in 20 laboratories. The 12 samples partly consisted of raw materials and partly of processed (heat treated) foodstuffs. Some of the samples were naturally contaminated or had been spiked with the PWG standard (IRMM 480).

A good correlation was demonstrated between the target concentrations and the measured results. Table 1 compares the actual concentration with the results obtained from the 20 laboratories as a mean value.



RIDASCREEN® Gliadin clearly distinguishes between negative samples and samples containing gliadin. The test kit shows good accuracy at low concentrations (e.g. approx. 14 ppm). The repeatability and reproducibility are measured using solid statistics and, at $r = 18\%$ und $R = 30\%$, fall within the normal range for ELISA methods. The test is therefore extremely well suited, e.g. for monitoring the production of gluten-free foodstuffs.

R-Biopharm offers a set of 3 Gliadin Test Controls (R7010) for internal quality control. There is one negative sample and two homogenised flour samples.

Additional products for gliadin and gluten detection are the RIDA®QUICK Gliadin (immunochromatographic test, test time just 5 min.) and the RIDASCREEN®FAST Gliadin (sandwich ELISA, test time 30 min.).



Table 1 Gliadin concentrations* in ppm for the R-Biopharm kit

Sample	Target concentration	Mean value	Standard deviation
heat treated			
1 Maize + PWG std.	168	134	9,7
2 Maize + PWG std.	35	33	1,7
3 Maize + PWG std.	79	71	5,2
4 Maize	approx. 8,5	8,7	0,7
non heat treated			
5 Rice + PWG std.	41	36	2,0
6 Rice	0	(< std. 2)	n.d.
7 Rice + PWG std.	147	112	7,6
8 Wheat starch	14	14	1,0
9 Rice flour	13	16	1,1
10 Wheat starch	12-15	15	1,3
11 Maize flour	< 1,5	(< std. 2)	n.d.
12 Maize flour	< 1,5	(< std. 2)	n.d.

* gluten = 2 x gliadin n.d. = not detectable

New genetic engineering labelling

New regulations on the labelling of genetically engineered foods apply EU-wide from 18 April 2004. From now on, all products, as well as ingredients and additives, produced from genetically modified organisms (GMOs) are subject to mandatory labelling. Also animal feeds containing GMOs must be labelled with immediate effect. Mandatory labelling applies if the GMO component constitutes more than 0.9% of the foodstuff, animal feed or the ingredient. Even products such as oils and starch, in which genetically modified components such as DNA or proteins are no longer detectable, are also subject to this regulation for reasons of mandatory traceability. The German food industry and retail trade have therefore stepped up their internal monitoring recently and have carried out the relevant GMO analyses.

required, with which all GM plants can be reliably measured. GMO components must be quantitatively measured with precision. Since 2001, R-Biopharm has offered an extensive program of test systems for DNA detection of GMOs (SureFood® GMO).

SureFood® GMO is a modular test system and as a result is especially user-friendly. It comprises of DNA preparation, amplification with PCR and detection with PCR-ELISA or real-time PCR. SureFood® GMO screening covers all GMOs licensed in Europe. Specific test kits are also available for the species mainly grown commercially in North America (principally soya, maize and rape-seed).

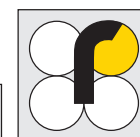
Analysis

In order to satisfy the new legal requirements, accurate analytical tests are

If you are interested

in our products, please contact your local distributor for more information.

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Trade Fairs and Conferences



- 10 - 13 June** VIV Turkey 2004, Istanbul CNR Expo Center, booth No: F16
representatives: Pablo Altmann, local distributor
- 5 - 6 July** Food Allergens, International Fresenius Conference, Mainz,
Germany

A special event „Allergen measurement with ELISA“ will be held 7 July 2004 at R-Biopharm in Darmstadt (40 km from Mainz). The conference participants will have the opportunity to carry out practical work with ELISA test systems.

For further information, please contact Frau Lindeke 0049-6151-8102-92 or send an e-mail to: s.lindeke@r-biopharm.de.

- 14 - 16 July** Shrimp School, University of Florida (Aquatic Food
Products Lab, AFPL), Gainesville
representative: Pablo Altmann
- 7 - 9 September** VIV China 2004, Shanghai Everbright Convention and
Exhibition Center
representatives: Pablo Altmann, local distributor

Distributor Meetings



- 6 - 8 July** Latin American Distributor Meeting,
Buenos Aires, Argentinien
representatives: Pablo Altmann, Gesa Krause, Pat Taylor
- 24 - 29 September** First MENA Clinical and Food & Feed Distributor
Meeting/Training, Egypt, Sharm El Sheik
representatives:
Pablo Altmann, Jens-Uwe Wuensch, Boutros Kerbaje

The next R-Biopharm^{news} will be published during the III. quarter 2004

R-Biopharm^{news} is edited by

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