

Legislation on mycotoxins in Europe & elsewhere

Monique de Nijs, Marco Jonker, Maryvon Noordam, Hans van Egmond

Joint IFSH/FRI Mycotoxin Symposium, April 12, 2012



RIKILT
WAGENINGEN UR

RIKILT – Institute of Food Safety

- Part of Wageningen UR since 1998;
- About 200 employees;
- Contaminants in food and feed



RIKILT
WAGENINGEN UR

Outline of presentation

1. What is a legal limit ?
Why legal limits ?
History legal limits mycotoxins
2. EU legislation
3. Mycotoxin regulations EU and elsewhere
4. Summary of conclusions



What is a legal limit – undesirable substances

Legal limit = allowed maximum tolerance level of undesirable substances:

- Based on risk assessment on undesirable effects (acceptance # of cases)
(*cancer; casualties; foetal abnormalities etc.*)
- Levels as low as possible



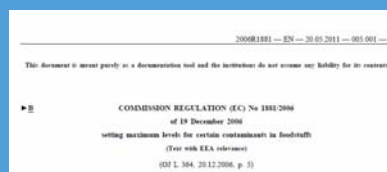
Why regulation for undesirable substances?

Legal limits:

- Protect health of inhabitants
 - food / feed produced in country
 - imported food /feed
- to prevent fraud
- meet quality criteria

Individual country

Regional harmonisation



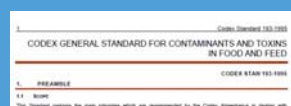
Legislation on mycotoxins

■ 1st harmonised legal limit EU:

- Feed: Directive 74/63/EEC
 - Each member state had to incorporate this regulation in its own legislation
 - Directive EC 2002/32: central regulation
- Food: Regulation (EC) No 1525/98 Aflatoxin

■ FAO WHO Food standard 193-1995

http://www.codexalimentarius.net/web/index_en.jsp



Legal limits - EU

General Food Law (GFL):

REGULATION (EC) No 178/2002

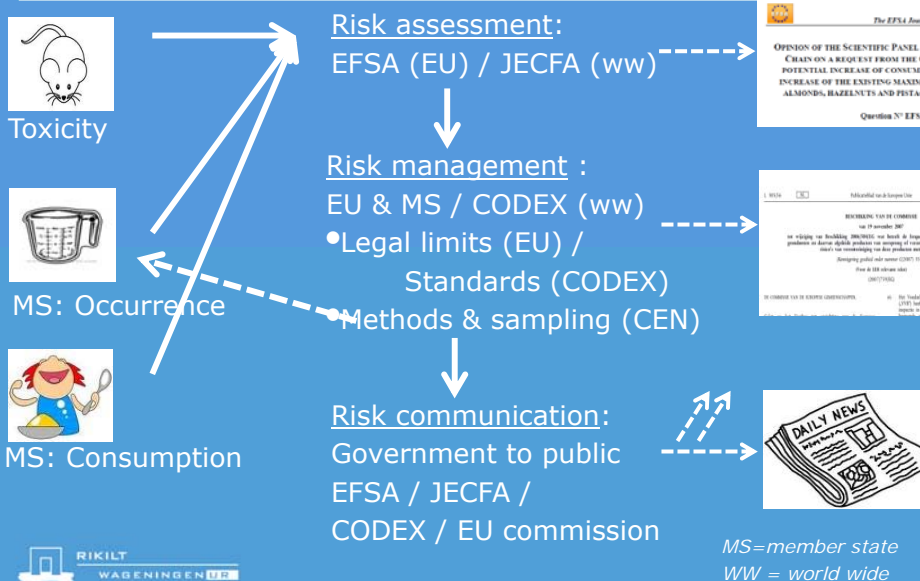
(18) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an **independent, objective and transparent manner, on the basis of the available scientific information and data.**

Article 6 Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, **food law shall be based on risk analysis** except where this is not appropriate to the circumstances or the nature of the measure.
2. **Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.**
3. **Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.**



Enactment of regulations EU / CODEX



EFSA opinions – latest developments

Mycotoxin	Target date EFSA opinion
T-2 and HT-2 toxin	Dec 2011
<i>Alternaria</i> toxins	Oct 2011
Ergot alkaloids	2012
Beauvericin & enniatins	2012
Moniliformin	
Diacetoxyscirpenol	
Nivalenol	2012
Citrinin	March 2012
Sterigmatocystin	2013
Phomopsins	February 2012

<http://www.efsa.europa.eu/en/topics/topic/mycotoxins.htm>



Mycotoxins / issues for which EFSA opinion **might** be requested *Mr. F. Verstrete (March 23, 2012; MYCODAY)*

- Penitrem A (mainly feed - food (?)) – *Penicillium*
- Cyclopiazonic acid (food/feed) - *Penicillium*
- Mycophenolic acid - *Penicillium*
- Roquefortine (A,B) C - *Penicillium*
- Emodin - *Aspergillus*
- Penicillic acid – *Penicillium*
- Fusarenon-X - *Fusarium*



Legal limits mycotoxins – EU - Food

- Commission *Regulation* (EC) No 1881/2006 (and its amendments): Setting **maximum levels** for certain contaminants in food



http://eur-lex.europa.eu/RECH_menu.do?ihmlang=en

- Commission *Decision* (EC) No 401/2006 (and its amendments): Laying down the methods of **sampling and analysis** for the official control of the levels of mycotoxins in food

Legal limits mycotoxins – EU - Feed

- *Directive* (EC) of the European Parliament and the Council No 2002/32 (and its amendments): On undesirable substances in animal feed (**Limits**)
- Commission *Recommendation* 2006/576/EC: On the presence of deoxynivalenol, zearalenon, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding (**Guideline on limits**)



Legal limits mycotoxins – EU - Feed

- Commission *Regulation* (EC) No 152/2009: Laying down the methods of sampling and analysis for the official control of feed



Regulations - EU import controls

- Commission *Regulation* (EC) No 669/2009 (and its amendments): Implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC
- Commission *Regulation* (EC) No 1152/2009: imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC

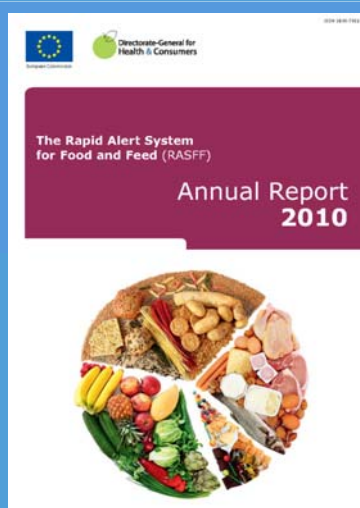


Legal limits – Food – EU 2003-2012

Benchmark: FAO food and nutrition paper 81

EU-Food	Food categories		Regulatory limits µg/kg	
	2003	2012	2003	2012
Aflatoxin B ₁	7	15	2-8	2-12 0.10 infant/baby/YC
Aflatoxin B ₁ , B ₂ , G ₁ , G ₂	7	13	4-15	4-15
Aflatoxin M ₁	1	3	0.05	0.05 0.025 infant
Ochratoxin A	3	13	3-10	2-80 0.50 infant/baby/YC
Patulin	6	5	25-50 10 infant/YC	25-50 10 infant/YC
Deoxynivalenol	2	9	500-750	500-1750 200 infant/YC
Zearalenone	-	10	-	50-400 20 Infant/baby/YC
Fumonisin B ₁ , B ₂	-	6	-	800-4000 200 infant/baby/YC
Total	26	74		

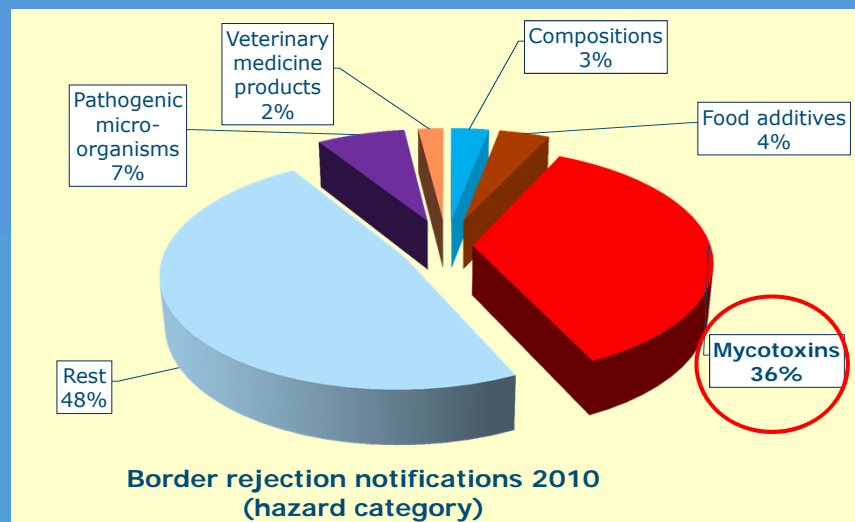
EU Rapid alert system for food & feed



- Quick information-exchange in the EU on risks to human health;
- Allows MS to identify potential problems and take measures;
- In 2010: 679 mycotoxin issues incl 586 border rejections

<https://webgate.ec.europa.eu/rasff-window/portal/>

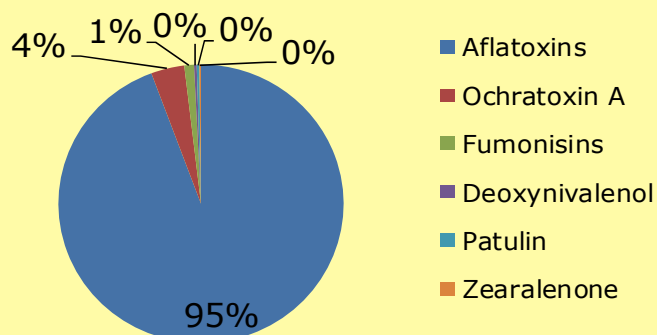
EU Rapid alert system for food & feed



EU Rapid alert system for food & feed

Specific mycotoxin hazards RASFF

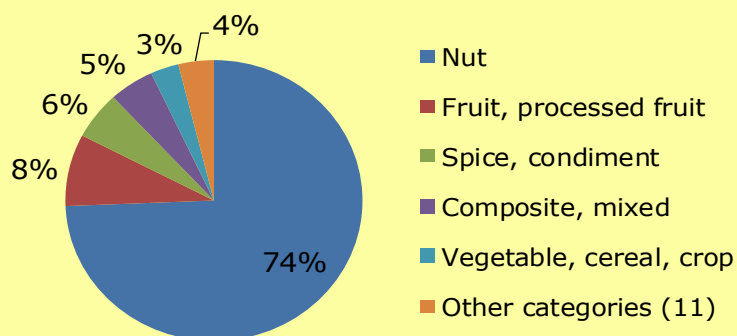
July 2003 - June 2009



EU Rapid alert system for food & feed

Mycotoxin-containing products RASFF

July 2003 - June 2009



Legislation on mycotoxins – Elsewhere

Benchmark: *FAO food and nutrition paper 81*

- Partial update in a selection of economically important regions and countries
- Compared to the 2003 FAO inventory study

Questionnaire:

1. Current legislation on mycotoxins in food and feed.
Including responsible authority and documents
2. Enactment of regulations
3. Notification alert system

Legislation on mycotoxins - Elsewhere

Regional harmonisation;

1. European Union (EU)
2. Australia & New Zealand (AU&NZ)
3. Gulf Cooperation Council (GCC)#
4. MERCOSUR (MERC)*

Individual countries;

5. Brazil (BR)
6. Canada (CA)
7. China (CH)
8. India (IN)
9. Japan (JP)
10. South Africa (SA)
11. USA (US)



United Arab Emirates; The Kingdom of Bahrain; The Kingdom of Saudi Arabia; The Sultanate of Oman; Qatar; Kuwait

* Mercado Común del Sur; Argentina; Brazil; Paraguay; Uruguay; Venezuela



Legislation on mycotoxins - Elsewhere

Contact persons: Dr. Bao, Nega Beru, Dr. Bhatnagar, Henri Bietlot, Wayne Bryden, Peter, Cressy, Dr. Dattamazumdar, Dr. Devegovda, Kathleen D'Ovidio, Elisabeth Elliot, Mark Feeley, Samuel Godefroy, Dr. Goto, Tom Hauschild, Dr. Herbst, Kelly Hyslop, Catharine Italiano, Henry Kim, Luc Dugal, MAclaulan, Pelletier, Anne-Marie St Laurent, Barbara Lee, Ken Marcynuk, Dr. Sabino, Annie Savaoie, Dr. Sharma, John Sheenan, Dr. F. Verstraete, Garnett Wood.



Based on provisional data

World population covered

	Region/ Country	Population		% of world population
1	EUROPE	502.748071	853.507964	12%
2	Australia (21.766711) & New Zealand (4.290347)	26.057058		
3	MERCOSUR	282.602835		
4	Gulf Cooperation Council	42.100000		
5	Brazil (203.429773)		3048.633246	44%
6	Canada	34.030586		
7	China	1336.718015		
8	India	1189.172906		
9	Japan	126.475664		
10	South Africa	49.004031		
11	USA	313.232044		56%
Population in countries of search		3902.141210		
World Population		6967.126795		



<http://www.internetworldstats.com/list2.htm>

Enactment – Risk assessment

Responsible for Risk assessment	
EU	European Food Safety Authority*
Brazil	National Health Surveillance Agency ANVISA (part of Ministry of Health)
CA	Canadian Food Inspection Agency
China	National Center for Food Safety Risk Assessment (Ministry of Health)
Japan	Food: Food Safety Commission; Feed: MAFF
USA	Food and Drug Administration

*Documents on: <http://www.efsa.europa.eu/en/efsajournal/pub/2567.htm>



Based on provisional data

Enactment – Risk management 1/3

	Responsible for risk management	Documents (legislation)	Details
EU	SCFCAH - Section on Toxicological safety of the food chain-mycotoxins in food Section on Animal nutrition-Mycotoxins in feed Decision on regulatory limits European Commission	http://eur-lex.europa.eu/nl/legis/index.htm	Food: Commission Regulation (EC) No 1881/2006 Feed: EU Directive 2002/32 and EU Recommendation 2006/576/EC
AU & NZ	Food Standards Australia New Zealand (FSANZ)	http://www.foodstandards.gov.au/foodstandards/foodstandardscode.cfm	
MERCOSUR	No response yet	http://www.mercosur.int/p_searchresult.jsp?query=mycotosin	(In Spanish and Portuguese)

Enactment – Risk management 2/3

	Responsible for risk management	Documents (legislation)	Details
Brazil	National Health surveillance agency ANVISA (part of ministry of health)	Ministry of health	http://portal2.saude.gov.br/saudelegis/leg_norma_pesq_consulta.cfm
		Ministry of agriculture	http://sistemasweb.agricultura.gov.br/sislegis/action/detalhaAto.do?method=abreLegislacaoFederal&chave=50674&tipoLegis=A
CA	Canadian Food Inspection agency	http://www.inspection.gc.ca/animals/feeds/regulatory-guidance/mycotoxins/eng/1328860069173/1328860172463	
China	Food Safety National Evaluation committee Opinion in regulatory limit Ministry of Health	http://www.moh.gov.cn/publicfiles/business/htmlfiles/zwgkzt/pzcfg/list.htm	(In Chinese)

Enactment – Risk management 3/3

	Responsible for risk management	Documents (legislation)	Details
India	APEDA	http://www.apeda.gov.in/apeda/website/index.asp	Quality/groundnut export regulation/Regulation of export of peanuts and peanut products through control of aflatoxins
South Africa	Department of Health	http://www.doh.gov.za/healthtopics.php?t=FoodControl&c=Legislation	Regulations governing tolerance for fungus-produced toxins in foodstuffs Government notice (No. 26849) No. R. 1145 8 October 2004 Regulations governing tolerance for fungus-produced toxins in foodstuffs Government notice (No. 26849) Amendment No. R. 751 17 July 2009
USA	Food and Drug Administration	http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm	e.g. CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products e.g. CPG Sec. 527.400 Whole Milk, Low fat Milk, Skim Milk - Aflatoxin M ₁

Enactment – Additional risk communication

Rapid alert systems	
EU	https://webgate.ec.europa.eu/rasff-window/portal/
CA	http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recalls-and-allergy-alerts/eng/1299076382077/1299076493846
USA	http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/FoodSafety/rss.xml

Current legislation – Elsewhere

	Food	Dairy products	Feed
EU	71	3	5
Australia & New Zealand	3	-	-
Gulf Cooperation Council	3	1	-
MERCOSUR	1	2	-
Brazil	40	3	X
Canada	3	-	X
China	8	1	X
India	6	1	X
Japan	3	-	X
South Africa	5	1	-
USA	6	1	X

Current legislation – Elsewhere

	number of regions + countries	
	Food	Feed
Aflatoxin B ₁	11	6
Aflatoxin B ₁ , B ₂ , G ₁ , G ₂		-
Aflatoxin M ₁	4	2
Ochratoxin A	8	0
Patulin	7	4
Deoxynivalenol	3	3
Zearalenone	3	1
Fumonisin B ₁ , B ₂ (B ₃)	2	1
Ergot alkaloids	1	0
Phomopsins	-	1
T-2 (guidelines)	-	1
HT-2 (guidelines)	-	1
Diacetoxyscirpenol (guidelines)	-	1

Current legislation – FOOD Elsewhere

FOOD 2012	Aflatoxin B ₁	Aflatoxin B ₁ , B ₂ , G ₁ , G ₂	Aflatoxin M ₁	Ochratoxin A	Patulin	Deoxy-nivalenol	Zearalenone	Fumonisin B ₁ , B ₂ (B ₃)	Ergot alkaloids	Phomopsins
EU	X	X	X	X	X	X	X	X	-	-
AU & NZ	-	X	-	-	-	-	-	-	X	X
GCC	-	X	X	-	X	-	-	-	-	-
MERCOSUR	-	X	X	-	-	-	-	-	-	-
Brazil	-	X	X	X	X	X	X	X	-	-
Canada	-	X	-	-	-	X	-	-	-	-
China	X	-	X	X	X	X	X	-	-	-
India	-	X	X	X	X	X	-	-	-	-
Japan	-	X	-	-	X	X	-	-	-	-
South Africa	X	X	X	-	X	-	-	-	X	-
USA	-	X	X	-	X	X	-	X	-	-

Aflatoxin and DON limits in FOOD out of 11 regions / countries

	Out of 11 regions / countries	Limit µg/kg
Aflatoxin B ₁ , B ₂ , G ₁ , G ₂	6	<15
	4	15-20
Deoxynivalenol	3	200-3000
	3 & 1	1000 & 1100

Current legislation – FEED Elsewhere

FEED 2012	Aflatoxin B ₁	Aflatoxin B ₁ , B ₂ , G ₁ , G ₂	Ochratoxin A	Patulin	Deoxynivalenol	Zearalenone	Fumonisin B ₁ , B ₂ , (B ₃)	Ergot alkaloids	Phomopsins	T-2 toxin	HT-2 toxin	Diacetoxyscirpenol
EU	X	-	-	-	-	-	-	X	-	-	-	-
AU & NZ	-	-	-	-	-	-	-	-	-	-	-	-
GCC	-	-	-	-	-	-	-	-	-	-	-	-
MERCOSUR	-	-	-	-	-	-	-	-	-	-	-	-
Brazil	-	X	-	-	-	-	-	-	-	-	-	-
Canada	-	X	X	-	X	X	-	X	-	X	X	X
China	X	-	X	-	X	X	-	-	-	-	-	-
India	X	-	-	-	-	-	-	-	-	-	-	-
Japan	X	-	-	-	X	X	-	-	-	-	-	-
South Africa	-	-	-	-	-	-	-	-	-	-	-	-
USA	-	X	-	-	X	-	X	-	-	-	-	-

Current legislation - Overview

- Two harmonised regions have not changed legislation since 2003: Mercosur and Australia & New Zealand;
- 9 Regions /countries have changed legislation since 2003;
- Adjustments:
 - all lower legal limits (including from afa B₁ to sum of afa B₁, B₂, G₁, G₂);
 - extended the number of food categories;

Discussion

- Transparency of Risk Assessment and Risk Management
- EFSA vs JECFA
- Food vs Feed
- Risk communication
- Discussion at MYCODAY (23/3/2012) by Dr. F. Verstraete:
 - *Development of adequate sampling procedures*
 - *Cost – benefit considerations (impact assessment)*
 - *New risk assessment approaches: the Margin of Exposure (MOE) approach, Threshold of Toxicological Concern (TTC)*
 - *Research/science as driving force for regulation versus science as limiting factor for regulation*

Thank you



Info: monique.denijs@wur.nl