

codex alimentarius commission



FOOD AND AGRICULTURE
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

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DEOXYNIVALENOL (DON) CONTAMINATION IN CEREALS

(INFORMATION SUBMITTED IN RESPONSE TO CL 2004/9-FAC)

The following comments have been received from Argentina, European Community and Japan

Argentina:

Maximum reference levels used in Argentina are: 2 mg/kg for wheat and 1 mg/kg for flour and sub-products. The techniques used for analysis are thin layer chromatography (TLC), high performance liquid chromatography (HPLC) and gas chromatography.

With regard to reference levels, Argentina informs that reference values, 2 mg/kg for wheat and 1 mg/kg for flour, are based on FDA levels.

Also, the 1mg/kg value for flour and sub-products is the reference value that arose from the assessment conducted by JECFA in 2001, where it established a provisional maximum tolerable daily intake of 1ug/kg.

European Community:

The European Community welcomes also the discussion on deoxynivalenol in cereals and cereal products.

JECFA performed a risk assessment on DON in 2001 and established a provisional maximum tolerable daily intake (PMTDI) of 1 µg/kg body weight and concluded that intake at this level would not result in effects of DON on the immune system, growth or reproduction. Estimations of the dietary intake of deoxynivalenol on the basis of the single weighted mean concentrations and the GEMS/food regional diets resulted in values that exceed the PMTDI for four of the five regional diets. JECFA noted that there was considerable uncertainty in these intake estimates and that it can be expected that food processing would reduce the levels of deoxynivalenol to varying extents, resulting in lower estimates of dietary intake.

A study in the framework of the scientific co-operation between Member States (SCOOP) of the EU has been performed to evaluate the dietary intake of trichothecenes (in particular deoxynivalenol and T-2 and HT-2 toxin), zearalenone and fumonisins of the general European population and of high risk sub-groups of the population, in particular children.

The SCOOP report “Collection of Occurrence data of *Fusarium*-toxin in Food and Assessment of the Dietary Intake by the Population of EU Member States” has been finalised and has been made publicly available on the website of the DG Health and Consumer protection of the European Commission.

(<http://europa.eu.int/comm/food/fs/scoop/task3210.pdf>)

This study (see table below) indicates that the average level intake of deoxynivalenol do not exceed the PMTDI for the entire population as well as for the group adults. However for the group of young children the intake might approach TDI.

The intake of high level consumers, especially young children, might exceed the PMTDI.

Table Range of average dietary intakes* calculated as percentage of the PMTDI-value

Mycotoxin	PMTDI µg/kg bw/day	Population	Adults	Infants
Deoxynivalenol	1	1 % - 34 %	14 % - 46 %	11 % - 96 %

* **Average** food consumption and **average** occurrence data whereby the mean is calculated using LOD/2 for results lower than the LOD (LOD = limit of determination).

These exposure assessments indicate clearly the need to limit the presence of deoxynivalenol in cereals and cereal products in order to protect public health. It is therefore important that all prevention measures as outlined in the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Trichothecenes (CAC/RCP 51-2003), as adopted by the Codex Alimentarius Commission at its 26th session in Rome, July 2003 are put in place

The aforementioned SCOOP report contains also a compilation of occurrence data of deoxynivalenol in cereals and cereal products provided by the EU Member States. The analytical results of about 9350 samples were provided and 57 % of the samples had levels of deoxynivalenol above the LOD.

In Annex to this document a summary of occurrence data in cereals and cereal products is provided. Twelve countries provided data on deoxynivalenol from the period 1996 until 2002. It should be noted that detailed information on the analytical method, quality assurance, sampling method, sample size etc was not made available for all provided data.

The EC is currently discussing maximum levels for DON in cereals and cereal products. Also the associated sampling procedure for official control and performance requirements for the methods of analysis are discussed.

It is expected to finalise these discussions in the beginning of 2005 and the EC will be able to provide in advance of the meeting information on maximum levels, sampling procedures and methods of analysis for consideration at the 37th session of CCFAC.

ANNEX

Summary of occurrence of DON in cereals and cereal products in various EU Member States					
Food product	N° samples	Max. value (µg/kg)	Mean (1) ¹ µg/kg	Mean (2) ¹ µg/kg	Median µg/kg
Wheat	265	764	175	258	143
wheat	2250	5000	239	399	?30
wheat	3	744	256	744	
wheat	159	2153	60	90	17
Wheat	30	2125	132	325	3
Wheat	22	170	11	170	3
Wheat	1	0	50		50
Wheat	1	85	105	85	40
Wheat	3	120	100	95	50
wheat	955	1723	145	258	40
Soft wheat	31	230	22	149	3
Soft wheat	82	1500	270	319	190
Soft wheat	72	700	62	201	15
Soft wheat	71	1900	216	313	100
Soft wheat	276	1520	283		190
Soft wheat	252	1038	95		25
wheat grains	47	504	63	343	<LOQ
Durum wheat	16	1000	263	412	170
Durum wheat	16	1600	372	649	175
Durum wheat	13	730	169	238	110
Durum wheat	52	3600	689	891	470
Durum wheat flour	33	2591	1155	1155	1233
Buckwheat	1		30		30
Buckwheat	5		30		30
Buckwheat	3		33		33
Buckwheat	15		33		33
Buckwheat	1		16		16
Buckwheat	3	70	35	70	16

¹ Mean 1 accounts for all the individual provided values according to the following criteria:

- If LOD and LOQ are available, participants were requested to calculate mean level using LOD/2 for results lower than the LOD. For results between LOD and LOQ, numerical values, if available, were used.
- If only LOQ is available, or if numerical values between LOD and LOQ are not available, LOQ/6 for values below the LOQ was used.

Mean 2 accounts for all positives above LOD values and it accounts for the distribution and level of positive results.

Food product	N° samples	Max. value (µg/kg)	Mean (1) µg/kg	Mean (2) µg/kg	Median µg/kg
Barley	9	35	6	35	3
barley	40	510	75	284	<50
Barley	20	60	26	47	15
rye	64	61	43	46	15
rye	37	220	106	164	<220
rye	47	351	15	51	20
oat	23	-	34	-	-
oat	36	174	16	38	18
Oats	204	1300	93	157	46
Corn	29	8850	494	841	50
Corn	25	4800	1056	1140	
Corn	59	3390	475		300
Corn	107	5400	903		650
corn	115	3920	653	668	510
Sweet corn	4	222	33	222	33
Sweet corn	9	224	57	142	33
Cereal grains	549	690	216	485,8	<LOQ
Malting barley	30		15		15
Malting barley	52	200	10	200	5
Malting barley	44	500	5	173	5
Malting barley	68	310	21	156	5
Malting barley	59	550	50		10
Malting barley	47	350	61		35
Malting barley	50	550	46		10
Malting barley	64	350	65		37
Wheat bran	1		17		17
Wheat bran	6		33	33	33
Wheat bran	3		33		33
Wheat bran	39	3600	205	352	50
Wheat bran	8	650	166	189	86
Wheat bran	9	2000	526	526	240
Wheat bran	8	170	59	64	13
Wheat bran	13	915	222	310	140
Wheat bran	20	2050	711	830	543
wheat bran	4	1821	761	1510	

Food product	N° samples	Max. value	Mean (1)	Mean (2)	Median
wheat flour	409	2650	109	232	<50
Wheat flour	88	527	114	135	87
Wheat products	3		30		30
Wheat products	5		33		33
Wheat products	75	1826	286	538	235
Wheat products	2		33		33
Wheat products	8	502	348	902	33
Wheat products	10	800	67	450	50
Wheat products	2	160	66	103	41
Wheat products	1	289	289	289	289
Wheat products	15	250	105	235	40
Wheat products	7	220	100	220	50
Wheat products	24	600	67	208	50
Wheat products	1		66		66
Wheat products	12	1000	993	410	45
Wheat products	15	410	105	236	40
Wheat products	3	220	100	220	50
wheatbran	20	360	75	169	<50
White wheat flour	15	500	156	316	125
White wheat flour	1		125	125	125
White wheat flour	170	1213	143	324	33
White wheat flour	11	136	46	101	33
White wheat flour	46	595	63	322	17
White wheat flour	308	300	67	123	50
White wheat flour	57	330	66	91	41
White wheat flour	55	50000	993	1183	45
White wheat flour	38	400	105	174	40
White wheat flour	33	330	100	184	50
White wheat flour	14	200	67	127	50
White wheat flour	4	130	66	97	41
White wheat flour	10	300	153	993	45
White wheat flour	4	280	105	220	40
White wheat flour	3	0	50		50
White wheat flour	37	2100	304		220
White wheat flour	101	328	53		25
White wheat flour	29		30		30
white wheat flour	3	333	119	333	
Rice flour	1		33		33
Rice flour	1		17		17

Food product	N° samples	Max. value	Mean (1)	Mean (2)	Median
Rye flour	69	257	43	55	14
Rye flour	1	120	120	120	120
Rye flour	2		33		33
Rye flour	1		33		33
Rye flour	3	595	174	595	33
Rye flour	11	350	104	292	33
Corn fractions	1		50		50
Corn fractions	1		50		50
Corn fractions	1		50		50
Corn fractions	17	1400	105	559	40
Corn fractions	7	825	100	271	50
Corn fractions	1	340	340	340	340
Corn fractions	1	620	620	620	620
Corn meal	2	450	435	435	435
Corn meal	3	1400	331	480	340
Corn meal	1	245	245	245	245
Corn products	2	611	33	33	33
Corn products	1		33		33
Corn products	8	320	238	92	226
Barley products	1		30		30
Barley products	9		33		33
biscuits	80	420	60	147	<50
biscuits including babyfood	15	<LOQ	31	0	<LOQ
bran	5	475	128	475	<LOQ
bread	38	560	70	394	<LOQ
bread	51	557	103	192	<50
Breakfast cereals	14	235	63	243	33
Breakfast cereals	1		33		33
Breakfast cereals	24	100	67	50	50
Breakfast cereals	8	25700	66	3229	41
Breakfast cereals	9	250	993	42	45
Breakfast cereals	1	0	105		40
Breakfast cereals	4	80	100	80	50
cereal breakfast	10	426	162	162	161
Composite grain product	19	86	25	39	21
muesli	46	390	56	185	<50
muëсли bars	5	<LOQ	42	0	<LOQ

Food product	N° samples	Max. value	Mean (1)	Mean (2)	Median
Oat products	1		30		30
Oat products	11		33		33
Oat products	3		33		33
Oat products	5		8		8
pasta	29	716	126	430	<LOQ
Pasta	1		33		33
Pasta	110	3200	219	227	150
pasta	163	840	92	231	<10
Pizza	1	150	150	150	150
Pizza	1	216	216	216	216
Polenta	1		33		33
Polenta	3		64	88	25
Rice products	1		30		30
Rice products	7		33		33
Rice products	1		17		17
Rice products	3		33		33
starch	24	320	97	199	<50
Oat baby porridge	28		10	0	10
infant food	21	270	81	99	70
Maize baby porridge	19	1022	451	475	609
Baby food	164	1075	102	120	74
Rice baby porridge	16		10	0	10
Wheat baby porridge	39	183	28	63	10

Japan:

Surveillance on deoxynivalenol (DON) in domestically produced wheat grains was carried out in Japan in 2003. The results of the surveillance will be submitted to the CCFAC before its next Session.

We are now conducting new surveillance on DON in wheat grains produced in 2004. The result will be submitted to the CCFAC after June 2005.

Data have been collected on: the occurrence of DON in domestically produced rice and domestic or imported wheat flour; and the influence of milling or cooking of wheat flour. The results and related information will be submitted to the CCFAC in due course.