

Brussels, 27 January 2010

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European Commission
DG Health and Consumer Protection

Fusarium Toxin Forum 2010 Position Paper

The European Flour Millers' association is the voice of the European flour milling industry both at European and international level. Current members are the national flour milling associations from 26 European countries.

With some 45 million tones of soft wheat and rye processed in the EU each year, the sector is the largest single user of EU domestic wheat and rye for the food industry. The European flour milling industry is committed to ensure the safety of its products.

T-2 and HT-2 toxins

As far as we know, temporary TDIs have been fixed on lacking toxicology basis, which are prerequisites to pursue the establishment of maximum regulatory limits for food consumption. It is necessary to have a recent, robust and scientific safety assessment on these two toxins. It is also necessary to have a recent dietary exposure study with low LoD. We look forward to the results of investigations on these matters.

To date, there are no validated EU-standardized rapid test kits which are available for use by companies for these toxins. For our members who are mostly small and medium-sized companies, there is obviously a need to have affordable validated practical test methodology in place before formal limits are introduced.

Research is needed at EU level to improve knowledge, identify the necessary actions of prevention and disseminate good practices. What is known about DON prevention does not seem to be applicable for T-2 & HT-2 toxins and Commission Recommendation of 17 August 2006 on the prevention and reduction of *Fusarium* toxins in cereals is not suitable for T-2 and HT-2 toxins.

Our members have carried out monitoring at national level for T-2 and HT-2 over the past few years. The data have been collected by national associations or companies using soft wheat and rye from different geographical locations over several harvest years. They sometimes have been collected in paired samples.

In general, the level found have been low or non-existing, the overwhelming majority being below the limit of quantification. The detailed data are being communicated below to DG SANCO prior to the next forum meeting of 1-2 February.

- Levels found in wheat (in ppb) by **German flour millers**:

T-2	<50	50-75	75-100	100-200	>200	Total samples
2003-2004	438	0	0	0	0	438
2004-2005	534	0	0	0	0	534
2005-2006	807	7	0	0	2	816
2006-2007	758	7	1	3	2	771
2008-2009 NEW!	723	0	0	0	0	723

HT-2	<50	50-75	75-100	100-200	>200	Total samples
2003-2004	436	0	1	0	0	437
2004-2005	534	1	0	1	0	536
2005-2006	806	1	2	1	5	815
2006-2007	742	9	5	9	5	770
2008-2009 NEW!	719	3	1	0	0	723

Level of detection: 50 ppb

Technique for assessment: GCMS-method

- Levels found in wheat (in ppb) by **French flour millers**:

T-2	Min.	Max.	Average	Total samples	Samples > LQ
2003	16	21	21,30	108	6
2004	13	16	18,85	93	2
2005	<LD	<LD	<LD	88	0
2006	1	14	14 ,16	177	17

Level of detection (LD):

2003: 15-50 ppb
 2004: 10-50 ppb
 2005: 15-50 ppb
 2006: 0,5-10 ppb

HT-2	Min.	Max.	Average	Total samples	Samples > LQ
2003	17	34	21,52	109	6
2004	12	18	18,86	96	3
2005	<LD	<LD	<LD	92	0
2006	4	269	16,11	172	27

Level of detection (LD):

2003: 10-50 ppb
 2004: 10-50 ppb
 2005: 20-50 ppb
 2006: 2-10 ppb

Level of quantification (LQ) = 2xLD

Technique for assessment: GC – HPLC

T-2 + HT-2	Min.	Max.	Average	Total samples	Samples > LQ
2007	3	50	10,17	172	13
2008 NEW !	4,25	41	13,77	165	23

Level of detection (LD): 2-10 ppb (and 2,5-50 ppb in 2008)

Level of quantification (LQ) = 2xLD

Technique for assessment: GC - HPLC

- Levels found in wheat (in ppb) by **British flour millers**

T-2	Min.	Max.	Average	Total samples
2003	<10	20	7,2	60
2004	<10	21	4	50
2005	5	14	7,1	45
2006	N/A	N/A	N/A	N/A

2007	<10	<10	<10	50
2008	<10	<10	<10	44
2009 NEW!	<10	<10	<10	39

HT-2	Min.	Max.	Average	Total samples
2003	<10	29	12,5	60
2004	<10	70	10	50
2005	5	24	9,6	45
2006	N/A	N/A	N/A	N/A
2007	<10	<10	<10	50
2008	<10	<10	<10	44
2009 NEW!	<10	<10	<10	39

Level of detection: 10 ppb

Technique for assessment: LC – MS/MS

- Levels found in wheat (in ppb) by **Scandinavian flour millers** (origin: Sweden Denmark and Norway)

T-2	<10	10-50	50-75	75-100	100-200	>200	Total samples
2005	32	0	0	0	0	0	32
2006	49	5	0	0	0	1	55
2007	72	0	0	0	0	0	72
2008 NEW!	77	0	0	0	0	0	77
2009 NEW!	39	0	0	0	0	0	39

HT-2	<10	10-50	50-75	75-100	100-200	>200	Total samples
2005	27	5	0	0	0	0	32

2006	40	14	0	0	0	1	55
2007	72	0	0	0	0	0	72
2008 NEW!	76	1	0	0	0	0	77
2009 NEW!	38	1	0	0	0	0	39

Level of detection: 10 ppb

Technique for assessment: LC – MS/MS

- Levels found in **rye** (in ppb) by **German flour millers**

T-2	<5	5-10	10-20	20-30	30-40	40-50	>50	Total samples
2007/08	155	2	0	0	0	0	0	157
2008/09 NEW!	143	1	0	0	0	0	1	145

HT-2	<5	5-10	10-20	20-30	30-40	40-50	>50	Total samples
2007/08	121	27	6	2	1	0	0	157
2008/09 NEW!	126	10	8	0	0	0	0	145

Level of detection: 5 ppb

Technique for assessment: GCMS-method

Monitoring for rye has also been done for the previous years with a detection rate at 50 ppb. Results were always at zero. Results in rye have been continuously low.

Conclusion and recommendation:

In the view of the European Flour Millers, the data do not at this stage justify the establishment of maximum limits for T-2 and HT-2 in wheat and rye or wheat and rye processed products. In any event, consumer exposure would appear to be low.

Implementation of existing limits (DON)

The European flour millers' members take food safety very seriously, not least because consumers trust flour millers to produce consistently safe, wholesome products. Flour millers have locally helped to diffuse good agricultural and storage practices amongst wheat and rye producers and storekeepers during the last few years. They have also improved traceability and hygiene control (HACCP), cleaning of raw materials and control of the storage temperature at mill.

There are however a few matters of principle that should be taken into account in any future discussion of the existing maximum levels:

- Although data on the effects of processing have been provided over the last few years, the limits established do not exactly reflect these data. In general, the Regulation over-estimates reductions in fusarium toxin levels associated with processing. This means that in order to ensure compliance with the final product limits, many consumer manufacturers are specifying maximum levels in their raw materials (wheat and rye) below those set in the Regulation. In a more challenging year, this will cause significant supply problems.
- In particular, it has been observed - during the last two years- that specific regions provided flour millers with soft wheat which did not allow the expected reduction from 1250 ppb to 750 ppb. Rainfalls during flowering – which is nevertheless increasingly common in a context of climate change - have been put forward as one of the reasons for this.

Recommendation:

In the framework of the review of the legislation and further to the last Fusarium Toxins forum, the European flour millers would like to confirm their recommendation for a higher maximum limit (1250 ppb) to apply to flour with a higher extraction rate. This should be fixed together with a higher maximum limit for wholemeal bread in agreement with the European bakers.

The concept of “wholemeal flour” does not appear to be practically relevant, since there exists no official definition and its significance varies slightly between Member States. Practically speaking, we suggest that the best parameters to define high-extraction flour would be:

min. 0.75% ash in 100 g dry matter	Specification used by flour millers in the vast majority of Member States
min. 2% crude fibre on a dry matter basis	Used by the UK food law enforcement agencies

We still remain at your disposal, should you need more information.

Best regards,
Laurent Reverdy
Secretary-General