FOOD STANDARDS AGENCY

To: Directors of Trading Standards (England)
Heads of Environmental Health Services (England))

cc: APHA
CIEH
LACORS
APA
TSI

30 June 2009 Reference: **ENF/E/09/030**

Dear Colleague

Temporary relaxation of the permitted level of Zearalonone (ZON) in high-fibre breakfast cereals and bran for use as an ingredient

Following recent discussions at the EU Expert Working Group of Agricultural Contaminants and agreement of the Member States at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 19 June, a temporary increase in the permitted level for ZON to 100 ppb for high-fibre breakfast cereals (excluding maize based) produced before 31 October 2009, has been agreed. It has also been agreed that there should be a temporary permitted level of 125 ppb for ZON in wheat bran for use as an ingredient for the same duration (i.e. for foodstuffs produced before 31 October 2009). These temporary levels apply immediately although there will be no amendment of the legislation.

As the legislation will not be amended, the Food Standards Agency recommends that enforcement authorities take a pragmatic approach to the enforcement of ZON limits following the recommendation of SCoFCAH.

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The Agency conducted a detailed risk assessment using its own data and proposed a precautionary compromise position to industry and the European Commission to ensure that consumer safety would not be compromised, whilst ensuring production of certain breakfast cereals could continue. The agreed temporary limits are based on the Agency's proposal.

Annex I contains a table detailing the changes for easy reference and Annex II provides a copy of the resolution of the SCoFCAH for information.

Yours sincerely,

Colin Houston

Annex I

Table detailing new temporary limits for Zearalenone (ZON) in certain products

	Current limits as set out in Commission Regulation 1881/2006 (as amended)	New temporary limits until 31st October 2009*
ZON in high fibre breakfast cereals (excluding maize based).	50 ppb	100 ppb
ZON in wheat bran for use as an ingredient	N/A	125 ppb

*these may be adopted on a permanent basis pending an opinion from EFSA

Annex II

A large majority of delegations at the Standing Committee endorsed and agreed to the approach as outlined in the enclosed note.

NOTE TO

THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

Section "Toxicological safety of the Food Chain"

19 June 2009

Subject: High levels of zearalenone in wheat bran and consequently resulting in possibly non compliant results in high bran breakfast cereals

CEEREAL (the European Breakfast Cereal Association) requests a temporary increase of the level of zearalenone in high-fibre breakfast cereals from currently 50 µg/kg to135 µg/kg due to the fact that since March/April serious supply problems are experienced for wheat bran from the harvest 2008 to be used in high fibre breakfast cereals.

Although no maximum level for wheat bran used as ingredient has been established, the wheat bran for use in the high fibre breakfast cereals should not have a level of higher than 75 µg/kg in order to enable high fibre breakfast cereal producers to comply with the current maximum level of 50 µg/kg for breakfast cereals other than maize based breakfast cereals.

The Food Standards Agency (FSA) UK performed a risk assessment following this request for the application of a higher maximum level of 135 µg/kg zearalenone in breakfast cereals. The assessment concluded that there is unlikely to be a health risk from the increase of the zearalenone limit to 135 µg/kg for the 2008 harvest for high-fibre breakfast cereals. However, as a more precautionary approach, in particular as regards toddlers, a maximum level of 100 µg/kg should be considered.

It was confirmed by the DATEX Unit from EFSA that the consumption figures for breakfast cereals used in the FSA assessment are among the highest recorded in any EU Member State.

Based on this assessment and the information provided by CEEREAL and to ensure the supply and availability of high-fibre breakfast cereals, given their beneficial health effects, **it is recommended to the Member States to apply on a temporary basis**

for a limited period of time (i.e. breakfast cereals with production date before 31 October 2009) a level of 100 µg/kg of zearalenone for high-fibre breakfast cereals other than maize based breakfast cereals.

Although no maximum level for wheat bran used as ingredient has been established, the wheat bran for use in the high fibre breakfast cereals should not have a level of higher than 125 µg/kg in order to enable high fibre breakfast cereal producers to comply with the proposed temporary level of 100 µg/kg for high fibre breakfast cereals other than maize based breakfast cereals

In the meantime, EFSA is requested to provide a scientific opinion on the effects on consumer health risk, following a possible permanent increase of the maximum level for zearalenone from 50 µg/kg to 100 µg/kg in breakfast cereals.