

5 September 2008

Reference: IPA 0038/ 0141

## **Possible Occurrence of Deoxynivalenol (DON) in the UK Wheat Crop 2008**

Dear Stakeholder,

Due to another relatively wet summer and conditions favourable to development of fungal inoculum in autumn of 2007, it is probable that some of the UK wheat crop will again have significantly elevated levels of deoxynivalenol (DON). In 2007 there were a number of potential issues and it would appear that a similar situation may be occurring this year. The Agency has received a number of incident notification forms, which indicate that some wheat consignments contain DON above the maximum permitted level for unprocessed wheat placed on the market for first-stage processing for foods for human consumption.

This letter aims to remind industry of the responsibilities and duties placed on a Food Business Operator (FBO) in relation to consignments of wheat that exceed the maximum level and of the possible approaches available when dealing with consignments which have failed to meet the requirements of European (EC) legislation.

### **Background**

In certain conditions *Fusarium* fungi flourish on cereal crops and some of these produce toxins that may adversely affect human health if consumed in significant quantities. The *Fusarium* toxins include DON, zearalenone, fumonisins and T-2 and HT-2 toxins.



DON is a naturally occurring mycotoxin, which may be found in cereal grains and for which maximum levels are set in Commission Regulation (EC) No. 1881/2006, as amended by Commission Regulation (EC) 1126/2007. DON normally occurs at levels below those currently set in the legislation. Unfortunately this year, the wet weather around the harvest period combined with conditions that generated raised levels of fungal inoculum has provided the ideal conditions for DON to occur at elevated levels in grain such as wheat, which may lead to a number of consignments exceeding the maximum level of 1250 µg/kg prior to further processing. It therefore seems appropriate to issue further guidance to Food and Feed Business Operators to remind and advise them of their responsibilities under EC legislation.

### **Legislation (see also ‘Non-Compliant Consignments’)**

Article 1.1 of Commission Regulation (EC) 1881/2006 states that “the foodstuffs listed in the Annex shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level set out in the Annex”. The maximum level of DON permitted in unprocessed wheat consignments placed on the market for first-stage processing for foods for human consumption is 1250 µg/kg<sup>1</sup>. Therefore, it is the responsibility of the FBO to ensure that these maximum limits are adhered to under Article 1.1. This applies equally to foodstuffs produced within the European Union and to imports from third countries.

### **Good Practice**

One way in which compliance may be achieved is by the primary producer (e.g. farmer) carrying out a risk assessment and to this end grain passports have been modified as a mechanism to help ensure that this is done. Using a risk assessment will help to indicate the degree to which the wheat may have elevated levels of DON. Please see Annex 1 for further details. Where bulk loads or consignments of wheat are deemed to be high risk, the Agency would recommend as good practice that routine testing be carried out *prior* to them being sent for first stage processing to help minimise consumer risk, potential disruption of the food chain and commercial

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<sup>1</sup> Unprocessed cereals other than durum wheat, oats and maize. Please see annex 2 to this letter for further details on maximum levels.

costs. Further details on assessing the risk to a crop and definitions including 'First Stage Processing' can be found in annex 1 to this letter.

Reduction of mycotoxin levels may also be obtained by cleaning the grain after harvest, as stated in Commission Recommendation 2006/583. Please consult this document via the following web link for further advice on good agricultural practice.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:234:0035:0040:EN:PDF>.

### **Due Diligence and Testing of Consignments**

It is the responsibility of FBOs to satisfy themselves that specified products when placed on the market comply with the relevant legal requirements e.g. maximum levels. Businesses should assess what they consider appropriate to ensure compliance with the law. In the case of DON, the Agency would anticipate that FBOs involved in the supply chain for wheat take reasonable measures to ascertain that the wheat is in fact compliant e.g. by testing samples of high risk products on farm. Another way of checking compliance with the maximum levels is to test consignments for DON prior to processing.

The main factor, which must be taken into consideration when testing is that mycotoxins, including DON, do not have a homogeneous distribution in foodstuffs, but are often found in distinct "hot spots". Therefore any sampling conducted to assess compliance should be carried out in such a way so to ensure that a fully representative sample is taken. In general, this involves collecting a number of low weight incremental samples to make up the large aggregate sample for analysis.

Although it is the responsibility of the FBO to determine which sampling method to use, they may wish to follow the procedures set out in Regulation 401/2006, which lays down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. This is to ensure that the subsequent measurement of DON reflects as accurately as possible the contamination level in a given consignment.

The Food Standards Agency has also produced a Sampling Advice document for Mycotoxins in Foodstuffs and this is available at:

<http://www.food.gov.uk/multimedia/pdfs/mycotoxinsguidance.pdf>

The Agency understands that in order to assess compliance with maximum levels, some FBOs employ a rapid test kit which is able to give an indication as to the compliance of a consignment.

In cases where there is an intention to use the consignment for first-stage processing in the human food chain and where rapid test kits have indicated the potential for DON to be present in the consignment above 1250 µg/kg, the Agency recommends the use of a further, quantitative method of analysis, such as HPLC to help ensure compliance with the maximum level of 1250 µg/kg.

### **Storage**

The Agency recommends that consignments containing DON are stored separately and away from any uncontaminated lots in order to avoid cross contamination and each should be clearly identified in order to prevent using them in error.

### **Non Compliant Consignments**

Non-compliant consignments should not be placed on the market for food use. To do so would be an offence under regulation 3(1) of the Contaminants in Food (England) Regulations 2007, as amended<sup>2</sup>. There are usually two main options available once a wheat consignment is found to be contaminated with DON above the maximum levels permitted for unprocessed wheat prior to first-stage processing for foods for human consumption:

1. Diversion into the animal food chain (if adhering to the requirements as detailed in the following section of this letter);
2. Disposal.

FBOs may also consider other uses.

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<sup>2</sup> S.I. 2007/210 as amended by S.I. 2007/2983.

Articles 19 and 20 of Regulation (EC) 178/2002 requires food and feed business operators to immediately initiate recall procedures and inform the competent authorities (The Food Standards Agency and the Local Authority) of results for products which show non-compliance with food safety requirements. In cases where contamination is found above the limit for human consumption an incident notification form (available at: <http://www.food.gov.uk/foodindustry/regulation/foodfeedform>) should be completed. A guidance note on filling out the notification form can also be found on this page. **It is important that all responsible FBOs including mills and merchants report the intended use of consignments that are potentially contaminated above 1250 µg/kg to ensure that the consignment in question is not redirected into the human food chain.** If this is not decided at the time of initial reporting, the attached annex 3 may be used for submitting this supplementary information.

If other options are not suitable then the consignment must be disposed of under the supervision of the local authority carrying out appropriate disposal procedures (usually deep burial at a suitably approved landfill site). Please contact your local authority for advice on alternative disposal procedures. In all circumstances, the Agency is happy to advise on a case-by-case basis. Under no circumstances should any consignment contaminated at or above 1250 µg/kg re-enter the human food chain as this would be an offence under regulation 3(1) of the Contaminants in Food (England) Regulations 2007 (as amended).

### **Animal Feed Diversion**

If the consignment is higher than the maximum DON limits for food (Commission Regulation (EC) 1881/2006), then it may be diverted for alternative use.

If the consignment is diverted for use as animal feed, you should be aware of European guidance values for DON in feed materials and compound manufactured feeds (summarised in the table below). The guidance values contained in annex 2 are not formal maximum permitted levels, but should be used as a guide as to what levels are appropriate for this use.

If consignments are not suitable for food or feed use, alternative uses may be considered.

If you require any further information, or have any questions please do not hesitate to contact us. Contact details of the relevant colleagues within the mycotoxins team are as follows:

Jonathan Briggs: [jonathan.briggs@foodstandards.gsi.gov.uk](mailto:jonathan.briggs@foodstandards.gsi.gov.uk), tel: 020 7276 8716;

Gavin Shears: [gavin.shears@foodstandards.gsi.gov.uk](mailto:gavin.shears@foodstandards.gsi.gov.uk), tel: 020 7276 8713;

Aattifah Teladia: [aattifah.teladia@foodstandards.gsi.gov.uk](mailto:aattifah.teladia@foodstandards.gsi.gov.uk), tel: 020 7276 8715.

Alternatively, you can send your queries to: [mycotoxins@foodstandards.gsi.gov.uk](mailto:mycotoxins@foodstandards.gsi.gov.uk).

If you have any queries relating to animal feed, please direct these to Ray Smith, email: [ray.smith@foodstandards.gsi.gov.uk](mailto:ray.smith@foodstandards.gsi.gov.uk), tel: 020 7276 8474.

Yours sincerely

A handwritten signature in black ink, appearing to read 'J Briggs'.

Jonathan Briggs

Mycotoxins Team

Food Protection Division

## **Annex 1**

### **Definitions**

#### **Food Business Operator**

The term 'Food Business Operator' is defined in Article 3(3) of Regulation (EC) 178/2002 as 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control'. In relation to limits for DON in cereals the definition of the FBO needs to be taken into consideration at the point in the food chain where the limits apply (see footnote 18 to Annex 1 of Commission Regulation 1881/2006).

#### **First Stage Processing**

Footnote 18 of the Annex to the Regulation 1881/2006 specifies first stage processing as "any physical or thermal treatment, other than drying, of or on the grain. Cleaning, sorting and drying procedures are not considered to be first stage processing insofar no physical action is exerted on the grain kernel itself and the whole grain remains intact after cleaning and sorting. In integrated production and processing systems, the maximum level applies to the unprocessed cereals in case they are intended for first-stage processing."

### **Assessing the Risk of your Crop**

The obligations of the Food Business Operator under Regulation (EC) 178/2002 can be found at:

[http://ec.europa.eu/food/food/foodlaw/responsibilities/obligations\\_en.pdf](http://ec.europa.eu/food/food/foodlaw/responsibilities/obligations_en.pdf). There are

also a number of good practice documents that are aimed at assisting growers in reducing the risk of producing crops containing high levels of mycotoxins. These include the Food Standards Agency Code of Practice on reduction of mycotoxins in UK cereals <http://www.food.gov.uk/multimedia/pdfs/mycotoxincop2007.pdf> and the HGCA mycotoxin risk assessment tool at:

<http://www.hgca.com/content.output/2764/2764/Resources/Tools/Fusarium%20Mycotoxin%20Risk%20Assessment%20.msp>.

The Agency recommends that all consignments of wheat intended for the human food chain are accompanied by a risk assessment, for example as part of, or attached to, the grain passport. The risk assessment is intended to help provide an indication as to which consignments may be at high risk of mycotoxin contamination and assist in prioritising which consignments should be tested prior to first stage processing. Guidance on how to complete a risk assessment may be found here: <http://www.hgca.com/content.output/2764/2764/Resources/Tools/Fusarium%20Mycotoxin%20Risk%20Assessment%20.mspix>.

## Annex 2

### Maximum permitted levels for DON in foods intended for human consumption<sup>3</sup>

Mycotoxin	Foodstuff	Maximum levels (µg/kg)
Deoxynivalenol (DON)	Unprocessed cereals other than durum wheat, oats and maize	1250
	Unprocessed durum wheat, and oats	1750
	Unprocessed maize	1750
	Cereals intended for direct human consumption, cereal flour (including maize flour, maize meal and maize grits, bran as end product marketed for direct human consumption and germ, with the exception of processed cereal-based foods and baby foods for infants and young children	750

### Animal Feed Guidance Values

Mycotoxin	Product intended for animal feed	Guidance value in mg/kg (ppm)	Guidance value in µg/kg
Deoxynivalenol (DON)	Cereals and cereal products	8	8000
	Maize by-products	12	12,000
	Complementary and complete feedingstuffs, <b>except:</b>	5	5000
	Complementary and complete feedingstuffs for pigs	0.9	900
	Complementary and complete feedingstuffs for calves (<4 months) lambs and kids	2	2000

<sup>3</sup> Please see Commission Regulation (EC) No. 1881/2006 for full details and relevant footnotes.

**Annex 3**

**Details of the Consignment Rejected for Food Use and action required**

Date of Incident Notification to FSA	Miller Rejecting Consignment	Consignment/Lot Number	Intended Use

**PLEASE CAN YOU CONFIRM WHETHER OR NOT THIS REJECTED CONSIGNMENT HAS GONE FOR ANIMAL FEED, BIOFUELS OR SOME OTHER NON-FOOD USE. WE ALSO REQUIRE THE DETAILS OF THE ESTABLISHMENT WHERE THE CONSIGNMENT HAS GONE.**

**PLEASE SEND THIS INFORMATION TO GARY FORDER IN OUR INCIDENTS TEAM E-MAIL TO [foodincidents@foodstandards.gsi.gov.uk](mailto:foodincidents@foodstandards.gsi.gov.uk) OR FAX 020 7276 8446 TO INFORM US AS SOON AS POSSIBLE. THANK YOU.**