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FINAL REPORT OF A MISSION

CARRIED OUT IN

INDIA

FROM 10 TO 18 NOVEMBER 2010

IN ORDER TO ASSESS THE CONTROL SYSTEM IN PLACE TO CONTROL AFLATOXIN
CONTAMINATION IN BASMATI RICE INTENDED FOR EXPORT TO THE EUROPEAN
UNION

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in India, from 10 to 18 November 2010. The objective was to assess the systems in place to control aflatoxin contamination in basmati rice intended for export to the European Union (EU).

This mission was included in the FVO 2010 inspection programme due to the high volume of exports of this commodity to the EU, and the increase in Rapid Alert System for Food and Feed (RASFF) notifications in 2007/2008. For the same reason, the commodity was listed in Annex I to Regulation (EC) No 669/2009 with effect from January 2010 (the physical checks frequency of 10% at EU border). Due to the significantly decreased frequency of RASFF notifications in 2009/2010 compared to 2007/2008, it was decided to de-list basmati rice from Annex I to Regulation (EC) No 669/2009 with effect from 1 October 2010.

There are administrative arrangements for the aflatoxin controls of basmati rice exported to the EU, consisting of mandatory sampling and analysis for aflatoxins of every consignment prior to export and aflatoxin controls in processing establishments as part of the auto-control systems. The competent authorities are clearly defined, with the Export and Inspection Council playing the main role. The establishments visited comply with the requirements of the Codex Alimentarius Code of General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003). The official laboratory and the processor's laboratories visited are accredited to ISO 17025 and perform well.

However, some deficiencies were identified concerning the legal basis for setting up the aflatoxin control measures, sampling of basmati rice for aflatoxin analysis and implementing HACCP based procedures and concerning the official staff training on sampling.

Overall the administrative arrangements for the aflatoxin controls cannot fully guarantee that all basmati rice exported to the EU comply with the aflatoxin limits specified in the Commission Regulation (EC) No 1881/2006 mainly due to the differences in the sampling procedure used.

The report makes a number of recommendations to the competent authorities of India to address the deficiencies identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
APEDA	Agricultural and Processed Food Products Export Development Authority
CA	Competent Authority
CAC/RCP/GL	Codex Alimentarius Committee/Recommended Code of Practice/Guidelines
CCA	Central Competent Authority
CCP	Critical Control Point
CWI	Consignment-Wise Inspection
EC	European Commission
EIA	Export Inspection Agency
EIC	Export Inspection Council
EU	European Union
EURACHEM	Network of organisations in Europe devoted to analytical chemistry and quality-related issues
FAPAS	Food Analysis Performance Assessment Scheme, UK
FBO	Food Business Operators
FERM	Federation of European Rice Millers
FVO	Food and Veterinary Office
GAP	Good Agricultural Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points

HPLC	High Performance Liquid Chromatography
IDP	Inter Department Panel
IPM	Integrated Pest Management
IPQC	In-Process Quality Control
ISO	International Organisation for Standardization
LOQ	Limit of Quantification
MOCI	Ministry of Commerce and Industry
MS	Member State
NABL	National Accreditation Board of Laboratories
OJ	Official Journal of the European Union
OTA	Ochratoxin A
RASFF	Rapid Alert System for Food and Feed
RCAC	Registration-Cum-Allocation Certificate
SANCO	Health and Consumers Directorate-General
SOP	Standard Operation Procedure
TC	Third Country

1 INTRODUCTION

The mission took place in India from 10 to 18 November 2010 in order to assess the control systems in place to prevent aflatoxin contamination in basmati rice intended for export to the EU. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State (MS) expert.

The mission was undertaken as part of the FVO's annual planned mission programme.

The mission team was accompanied during the whole mission by a representative from the central competent authority (CCA) the Export Inspection Council (EIC) under the Ministry of Commerce and Industry (MOCI), and during the on the spot visits by representatives from the Export Inspection Agency (EIA) in New Delhi (field agency of the EIC) and the Agricultural and Processed Food Products Export Development Authority (APEDA), an export promotion organisation attached to the MOCI.

An opening meeting was held on 10 November 2010 with the CCA. Also present were representatives of EIA-Delhi, APEDA and the European Union (EU) Delegation to India. At this meeting, the objectives and itinerary for the mission were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to verify whether the control systems are in place to control aflatoxin contamination in basmati rice intended for export to the EU within specified EU contaminant limits, complying with or being at least equivalent to Commission Regulation (EC) No 1881/2006.

In terms of scope, the mission reviewed the controls in place on production and export, including the national legislation in place, the organisation of the competent authority (CA), and its control and enforcement capability.

In pursuit of this objective, the following sites were visited in accordance with the itinerary agreed between EIC and FVO:

COMPETENT AUTHORITY		VISITS	COMMENTS
Competent authorities	Central	2	EIC, APEDA
	Provincial	1	Meetings with officials from the EIA in New Delhi during inspections observed
Laboratories			
		4	One EIC-approved laboratory for official analysis of aflatoxins in basmati rice Three in-house laboratories of basmati rice

		processors visited
Farmers/Producers		
	4	Basmati rice farms in Punjab state
	1	Auction market (Mandi market) in Haryana state
Processing establishments		
	3	Basmati rice processors in Haryana state
Ports		
	1	Inland container depot in Ghari-Harsaru, Haryana state

3 LEGAL BASIS FOR THE MISSION

3.1 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of EU legislation, in particular Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council, which stipulates that EU controls in third countries (TC) may verify the compliance or equivalence of TC legislation and systems with EU feed and food law and EU animal health legislation. These controls must have particular regard to the assurances that the TC can give regarding compliance with, or equivalence to, EU requirements.

3.2 LEGAL STANDARDS

Article 11 of Regulation (EC) No 178/2002 stipulates that food and feed imported into the EU for placing on the market there must comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent.

Article 10 of Regulation (EC) No 852/2004 stipulates that, as regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 include the requirements laid down in Articles 3 to 6 of the Regulation.

The Annex to Regulation (EC) No 1831/2003 sets maximum levels for mycotoxins in foodstuffs.

Commission Regulation (EC) No 401/2006 lays down the methods of sampling and analysis for official control of the levels of mycotoxins in foodstuffs.

Reference is also made to the following Codex Alimentarius standards:

- Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51 - 2003);
- Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26 – 1997);

- Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food (CAC/GL 27 - 1997).

A full list of the legal instruments referred to in this report is provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the most recently amended version.

4 BACKGROUND

4.1 FVO MISSIONS TO THIRD COUNTRIES REGARDING AFLATOXIN CONTAMINATION IN FOODSTUFFS

The European Commission has carried out missions to Iran, Egypt, Turkey, China, Brazil, India, Argentina and USA with the objective of evaluating official control systems for the prevention of aflatoxins contamination in foodstuffs originated from these countries. The reports of these missions are available on the DG Health and Consumer Protection (DG SANCO) Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm. This is the first mission to India concerning aflatoxins in basmati rice.

4.2 BACKGROUND TO PRESENT MISSION

According to Article 15(1) of Regulation (EC) No 882/2004, the competent authorities (CAs) of the MS must carry out regular official controls on food of non-animal origin imported into the EU. These controls are to be carried out at the point of entry, the point of release for free circulation, warehouses, the premises of the importing feed and food operator, or other points in the food and feed chain as established in Article 15(2). According to Article 16(1), the official controls must include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

Information on foodstuffs found to have public health implications is communicated in the form of alert notifications through the Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country. From 2007 to the time of the mission, seven notifications concerning aflatoxins in basmati rice from India were notified through the RASFF. This mission was included in the FVO 2010 inspection programme due to the high volume of exports of this commodity to the EU, and the increase in RASFF notifications in 2007/2008. For the same reason, the commodity was listed in Annex I to Regulation (EC) No 669/2009 with effect from January 2010.

According to data provided by the EIC, the total volume of Indian exports of basmati rice was 1 556 411 tonnes in 2008-2009 (around 28% of it was exported to the EU) and 2 016 775 tonnes in 2009-2010 (around 7% of it was exported to the EU). The breakdown of the volume of basmati rice exports from India to the EU is shown in the table below. Separate information is given for the export of companies under In-Process Quality Control (IPQC) system and companies under Consignment-Wise Inspection (CWI) system. Detailed description of these control systems is given under point 5.5.

Table: Statistics on basmati rice exports from India to the EU in tonnes

	2008-2009*	2009-2010*	2010 (Jan. to Sept.)
By companies under IPQC system	340 121	45 308	96 738

By companies under CWI system	96 738	89 082	74 679
Total	426 875	134 390	171 417

Source: EIC, MOCI, India

(*) - financial year from 1 April of a calendar year to 31 March of the next year

In 2009, there was only one rejection following aflatoxin controls at the EU borders. In 2010, by the time of the mission, there were none. Due to the significantly lower frequency of RASFF notifications in 2009/2010 compared to 2007/2008, it was decided to de-list basmati rice from Annex I to Regulation (EC) No 669/2009 with effect from 1 October 2010.

4.3 FOOD PRODUCT INFORMATION RELATED TO PUBLIC HEALTH ISSUES

Aflatoxins are mycotoxins produced by certain species of *Aspergillus*, which develop at high temperatures and humidity levels and may be present in a large number of foods. The aflatoxin group includes a number of compounds of varying toxicity and frequency in food. Aflatoxin B1 is the most toxic compound. For safety reasons, it is advisable to limit both the total aflatoxin content (compounds B1, B2, G1 and G2) of food and the aflatoxin B1 content. Maximum limits for aflatoxins in cereals are laid down in Annex (Section 2) of Commission Regulation (EC) No 1881/2006. The maximum admissible aflatoxin levels are as follows:

a) Cereals and all products derived from cereals (white rice for direct consumption):

2,0 µg/kg aflatoxin B1 content, and

4,0 µg/kg total aflatoxin content;

b) Maize and rice to be subjected to sorting or other physical treatment before human consumption or use as an ingredient in foodstuffs:

5,0 µg/kg aflatoxin B1 content, and

10,0 µg/kg total aflatoxin content

Ochratoxin A (OTA) is a mycotoxin produced by several fungi (*Penicillium* and *Aspergillus* species), and occurs naturally in a variety of plant products such as cereals, coffee beans, beans, pulses and dried fruit all over the world. Investigations of the frequency and levels of occurrence of OTA in food indicate that foodstuffs are frequently contaminated. Maximum limits for OTA in food were fixed in legislation. In accordance with the Annex (Section 2) of Commission Regulation (EC) 1881/2006, the maximum level for OTA in dried vine fruits (currants, raisins and sultanas) is 10,0 µg/kg.

In addition, sampling plays a crucial part in determining mycotoxin levels, which are very heterogeneously distributed in a consignment. Therefore, in Commission Regulation (EC) No 401/2006 methods of sampling, and criteria for sample preparation and for methods of analysis were established to ensure that laboratories in charge of the analysis use methods of analysis with comparable levels of performance.

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 stipulates that Community controls must have

particular regard, *inter alia*, to the legislation of the TC.

This mission covered the specific standards for the admissible levels of aflatoxins established in Regulation (EC) No 1881/2006 (as last amended) setting maximum levels for certain contaminants (including mycotoxins) in foodstuffs.

Because sampling and preparation/analysis of the samples play an important part in the reliability of controls, Regulation 401/2006 (as amended) lays down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

Findings

The Export (Inspection and Quality Control) Act, 1963, is the principle legislation governing the export of Indian goods. Under this Act certain commodities meant for export have been put on compulsory pre-inspection list and they can not be exported unless a certificate of inspection has been obtained from the EIC or from any of its regional EIAs.

Order No S.O. 67 (E) dated 23 January 2003, requires quality certification of the basmati rice prior to export through quality control and inspection against the standards annexed to the Order or the national standards of the importing country.

Export of Basmati Rice (Quality Control and Inspection) Rules No S.O. 68 (E) dated 23 January 2003, set out the two types of pre-shipment quality control inspections of the exported basmati rice, namely the CWI and the IPQC system.

Executive Instructions for Certification of Basmati Rice (March 2004) provide the procedures for conducting the quality certification of the exported basmati rice through the CWI and IPQC system, including the quality control sampling procedure.

According to the Community special rules basmati rice varieties from India are eligible for a zero import duty. Therefore one of the required documents for import clearance is a certificate of authenticity issued by the EIC. The procedure for granting this certificate requires a set of documents to be submitted to the EIC. One of these documents is a certificate of inspection, issued on the basis of satisfactory quality control and inspection of the exported consignment.

In March 2010 the EIC has introduced the following measures for aflatoxin control of basmati rice consignments intended for export to the EU, with effect from 1 April 2010:

- EIA in New Delhi should check at least once per month basmati rice samples for aflatoxin contamination from the consignments processed for EU export by the companies controlled under the IPQC certification system (approved IPQC companies);
- EIA in New Delhi should check all basmati rice consignments exported to the EU under the CWI system for aflatoxin contamination together with export quality control and inspection;
- Aflatoxin tests include both parameters — aflatoxin B1 and total aflatoxin;
- Sampling for aflatoxin contamination of EU destined basmati rice started from the first week of April 2010;
- Approved IPQC companies exporting basmati rice, have to include aflatoxin control in their HACCP plan and this is to be monitored by the EIAs;
- FBOs processing basmati rice for EU export have to maintain a well documented auto-control system with control measures for aflatoxin monitoring and checks at various production steps such as receipt of paddy (raw basmati rice), in-process, and end-product ready for dispatch, including storage;

- Decision limits (preferably, 4 µg/kg for aflatoxin B1 and 8 µg/kg for total aflatoxin) below the maximum permitted limits of 5 µg/kg for aflatoxin B1 and 10 µg/kg for total aflatoxin have to be monitored for issuing a caution notice to exporters if the results of sampling for aflatoxin analysis are close to the EU limits. The issuance of a caution notice does not hold up the consignment from export.

However, the legal basis for these pre-export aflatoxin controls is not clear. There is no legislation in place on the sampling procedure and analyses for aflatoxins in basmati rice. The written instructions sent to the parties concerned (the EIAs and the food business operators (FBOs) exporting basmati rice to the EU) also do not provide any reference about the sampling method.

Notification No 55 (RE-2008)/2004-2009 of the Director-General of Foreign Trade of the MOCI from 5 November 2008, restricts the export of basmati rice to six seaports, namely Kandla, Kakinada, Kolkata, JNPT Mumbai, Mundra and Pipavav.

Document EIC/LAB.SCH/January 2010 'EIC Laboratory Approval Scheme — 2010', issued under the Export (Inspection and Quality Control) Act, sets out the procedure for the approval of private laboratories to perform laboratory analysis for official purposes. The assessment of the laboratories includes the requirement to have accreditation according to ISO 17025.

Official control of food placed on the domestic market is covered by the Prevention of Food Adulteration Act (PFA) and Rules. This legislation regulates the inspection of FBOs and the quality standards for foodstuffs. Rule 57 establishes a level of 30 ppb for total aflatoxin content in all foods and Appendix B to rule 5 contains quality standards for rice. There is no obligation for FBOs processing rice for export to the EU to implement and maintain food safety procedures based on HACCP principles.

Conclusions

Quality control and pre-shipment inspection are pre-requisite for exporting basmati rice to the EU according to the national legislation in place.

There is no clear legal basis for the adoption of the measures introduced by the EIC in 2010, regarding the pre-export aflatoxin controls of basmati rice for EU export. There is no legislation in place for the methods of sampling and analysis of basmati rice for aflatoxins.

5.2 COMPETENT AUTHORITIES

Legal requirements

Article 46(1)(b) of Regulation (EC) No 882/2004 stipulates that Community controls must have particular regard to, *inter alia*, the organisation of the TC's CAs, their powers and independence and the authority they have to enforce the applicable legislation effectively.

Article 46(1)(c) of Regulation (EC) No 882/2004 stipulates that Community controls must have particular regard to the training of staff in the performance of official controls.

Findings

5.2.1 Competent Authorities

The export inspection system set up under the Export (Inspection and Quality Control) Act operates through an organisation structure comprising the MOCI (the regulatory body), the EIC (an advisory body) and the EIAs (the implementation field agencies).

The MOCI frames policy and issues orders, rules and regulations concerning the quality control of exported products, recognises the inspection agencies, provides financial grants to the EIC and EIAs.

The EIC is constituted as an advisory body to the MOCI. Its principal functions are to advise the MOCI on measures to be taken to enforce quality control and the inspection of exports, issue certificates of authenticity to exporters of EU-destined basmati rice, approve/designate official laboratories for testing exported goods, exercise technical and administrative control over the EIAs and grant or withdraw approval certificates to companies approved for IPQC certification (IPQC companies) (see point 5.7).

There are five EIAs headquartered in New Delhi, Chennai, Kochi, Kolkata and Mumbai with a network of 34 sub-offices, including laboratories in important ports and industrial centres in India, to carry out its functions. The EIAs carry out a large part of the export certification work. Under the scope of this mission, the main functions of these agencies are to certify export basmati rice through pre-shipment inspection or surveillance over quality control exercised by the basmati rice processors and to issue certificates of inspection for exported basmati rice consignments that comply with the export standard specifications.

The EIA in New Delhi is responsible for basmati rice sampling for the aflatoxin controls of basmati rice for EU export. A total of three officials are involved in this task.

Communication between the EIC and EIAs is via circulars and instructions. Some communications were shown to the mission team, such as a circular (from 23 March 2010) informing the EIAs about renewal of the approval of the private laboratory performing aflatoxin analysis of exported basmati rice and letters concerning renewal of the approval of IPQC companies processing and exporting basmati rice.

The EIC has delegated its responsibilities for aflatoxin analysis of basmati rice intended for export to an EIC-approved private laboratory.

APEDA has been established by an Indian Parliament Act of 1985, to control and promote exports. It is also responsible for the registration of export contracts for basmati rice through the issuance of a 'Registration-cum-Allocation' Certificate (RCAC).

The EIC plays an important role in communication with industry where basmati rice exports are concerned. Communication between the EIC and stakeholders is via meetings and letters. The mission team was provided with an EIC letter regarding EIC Executive Order of April 2010 for aflatoxin control of basmati rice intended for EU export, which was sent to all IPQC-approved companies and exporters for information and compliance.

The Ministry of Health and Family Welfare is responsible for official food control at domestic level and on import. The Food (Health) Authorities appointed by the State Health Authorities or the local authorities are responsible for the licensing and hygiene inspection of food processors. Only in one processing unit visited the mission team was provided with a licence issued by the local health authority. There was no evidence of food hygiene inspections performed in any of the processors

visited.

The Ministry of Agriculture, via its State Departments of Agriculture, is responsible for supervision of basmati rice growing, guidance on Integrated Pest Management (IPM) and Good Agricultural Practice (GAP) for basmati rice cultivation, training, and dissemination of information to basmati rice growers. In the Punjab area visited, there was very little activity by these authorities regarding the prevention of aflatoxin contamination in basmati rice.

5.2.2 Customs authorities

Customs has the ultimate responsibility for releasing basmati rice consignments outside India. The customs authorities will approve the consignment for export after verification of the certificate of authenticity together with the other export documentation. Custom clearance of basmati rice consignments for export to the EU is carried out at the six designated seaports. However, it can be arranged at Inland Container Depots (ICD) as well. The government authorities have established these ICDs to facilitate multi-modal transport of export cargo in containers.

Conclusions

The allocation of responsibilities between the CAs with regard to the subject of the mission is clearly defined, with the EIC being the CCA.

Communication between the EIC and EIAs, and between the EIC and stakeholders, is adequate.

5.3 PROCESS CONTROLS IN THE BASMATI RICE PRODUCTION CHAIN

Legal requirements

Art. 46 (1) (e) and (b) of Reg. (EC) No 882/2004 stipulate that Community controls shall have, *inter alia*, particular regard to the existence and operation of documented control procedures and control systems based on priorities, and the CA's capability to enforce applicable legislation;

Article 10 of Regulation (EC) No 852/2004, in conjunction with its Article 3, requires food business operators (FBOs) to ensure that all stages in the production, processing and distribution of food under their control comply with the relevant hygiene requirements laid down in this Regulation.

Article 10 of Regulation (EC) No 852/2004, in conjunction with its Article 4(1), requires that FBOs carrying out primary production and associated operations listed in Annex I comply with the general hygiene provisions laid down in part A of Annex I.

Article 10 of Regulation (EC) No 852/2004, in conjunction with its Article 4(2), requires that FBOs engaged in any stage in the production, processing and distribution of food after those stages to which Article 4(1) applies comply with the general hygiene requirements laid down in Annex II.

Article 10 of Regulation (EC) No 852/2004, in connection with its Article 5, requires FBOs to put in place, implement and maintain a permanent procedure or procedures based on HACCP principles.

Art. 10 of Reg. (EC) No 852/2004 in connection with Art. 6 of the same Regulation requires that every food business operator shall notify the appropriate CA of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Codex Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51 – 2003), contains recommended practices based on GAP, Good Manufacturing Practice (GMP) and Good Storage Practices.

Findings

5.3.1 Basmati rice cultivation

Basmati rice is grown in the states of Punjab, Haryana, Himachal Pradesh, Uttarakhand, Delhi, and some districts of the states of Uttar Pradesh and Jammu & Kashmir. According to the data submitted by the EIC, the total basmati rice cultivation area was about 1 637 000 ha in 2008-2009 and 1 708 000 ha in 2009-2010. Total raw basmati rice (paddy) production was 6 237 000 tonnes in 2008-2009 and 6 780 000 tonnes in 2009-2010. The farmers met stated that the ratio of non-basmati to basmati rice cultivation was 70 % to 30 %.

The basmati rice crop is sown in May and harvested in November after an average of 145 days growing.

The mission team visited 4 basmati rice farms in Punjab state. Generally, the farm holdings are estimated to be about 1 ha.

Growing practices are according to the available resources and based on the farmers' own experience. Farmers primarily depend on personal observation or on other farmers for information about harvesting practices, irrigation, use of fertilisers and pesticides.

The farmers visited stated that they obtain additionally, some GAP information through the mass media (local TV channels, radio, local agricultural magazines/newspapers), fairs and seminars organised by the Punjab Agricultural University, APEDA or basmati rice processors. They also could visit the advisers of the local agricultural extension offices.

Most farmers practice a crop rotation pattern on the same field, mainly with basmati rice and wheat, but sometimes also basmati rice and vegetables.

Paddy is harvested manually. The crop is allowed to sun-dry in the field. Drying takes 3 to 8 days with no protection from birds, insects or dust. The dried rice bundles are threshed manually in the field to get the paddy.

The growers transport the paddy to the mandi (market yard) for wholesale. They usually sell the paddy at harvest time through the state mandi system. Sometimes, to take advantage of price differentials over time, growers store the produce inside their houses up to 6 months. Generally, storage conditions at the farms visited were not adequate or sufficiently protected to prevent contamination of the commodity.

The farmers met had access to sufficient irrigation facilities and fertilisers. They used organic manure and chemical fertilisers based on soil analysis undertaken by local agricultural extension offices or non-governmental organisations. The farmers stated that they used urea once per growing season, and herbicides and insecticides depending on need. Generally, the plant protection products were applied by authorised external services.

None of the farmers met kept log books of their farming activities. Therefore, the application of GAP could not be verified by the mission team.

Regarding research activities, some studies have been carried out by scientists from the Department of Plant Pathology, Directorate of Rice Research, Rajendranagar, Hyderabad, on the detection of *Aspergillus spp.* and aflatoxin B1 in rice in India. However, no practical outcome for the prevention of aflatoxin contamination has been reported.

The mission team was informed that annual agricultural fairs were organised by the Central Rice Research Institute.

Training activities for farmers included brochures and advice on the prevention of diseases during growing, harvesting and drying. The prevention of aflatoxin contamination forms only a minor part of these activities since their main emphasis is on improving quality in production and organic farming practices.

APEDA provided information on 10 workshops held during 2009 and 12 during 2010 in all basmati-growing states by the Basmati Export Development Foundation on 'Quality improvement in the production of basmati rice for export'. In total, about 1800 farmers attended the workshops in 2010. The main objectives of the workshops were to train farmers in the identification and control of insect pests and diseases of basmati rice and in integrated nutrient and water management and to provide a forum for interaction between farmers and scientists to ascertain the problems of different states. However, none of the farmers visited had attended any of these seminars.

The mission team was provided with a leaflet concerning some GAP advice, called 'Do's and don't's of aflatoxin (rice and maize)', prepared by APEDA and circulated to all companies exporting to the EU.

5.3.2 Basmati rice processors visited

According to the EIC, for 2010-2011 there are 6 basmati rice processors exporting basmati rice under the IPQC system (approved IPQC processors) and 15 business operators exporting under the CWI system, of which 10 are processors exporting basmati rice and 5 are solely exporters.

The mission team visited 3 basmati rice processors exporting brown basmati rice to the EU in the state of Haryana. Two of them were approved IPQC processors and the other one was operating under the CWI system. Milling (removal of husk from paddy grains) is the process used to produce brown basmati rice.

The processors visited purchase the paddy only through the state mandi system. Before a particular paddy lot is purchased, it is subject to various checks including moisture content. Every processor visited had experienced selectors, paddy experts and approved agents, who assess the crop before the auction. A lot is purchased only when it meets the stringent quality requirements of the processor. The maximum acceptable paddy moisture content at purchase is 15 %. The moisture decision is made by hand-husking of the paddy.

The mandi visited was an open market yard where paddy was stored in bulk or in bags directly on the ground. The auctions were conducted in one or two days and then the paddy was transported to the processors. Some of the processors visited had set up weather stations at selected mandis, equipped with electronic systems for recording weather conditions such as temperature, humidity, rainfall, sunshine hours, wind direction and speed. The information is used for predicting potential weather problems and alerting farmers.

On arrival at the processing facilities visited, the incoming paddy is inspected at 100 % frequency with regard to moisture content and at 10 % for aflatoxin contamination. Paddy with a moisture content of more than 14 % at arrival is immediately dried by hot air (40°C) to below 13 %. The product is then stored in silos or warehouses before milling.

The milling process starts with the cleaning of paddy. This is a multi-step process where foreign material such as straws, mud balls, stones and metal particles is removed from the basmati rice via sieving, suction, magnets, etc.. Afterwards, the husk is removed from the grain, which then undergoes sizing to remove over- and under-size grains and length-width grading to remove broken

and shrivelled grains. Processing involves the use of husk removers, stone removers, graders, magnetic separators, and electronic colour sorters. Exporting is via bulk packing of 20-25 tonnes containers.

The application of HACCP principles is not mandatory in India for basmati rice processing. All the basmati rice processors visited stated that they implement HACCP systems generally at the request of trading partners. Their HACCP plans included parameters for the control of aflatoxins as a hazard, e.g. at the drying stage, a critical control point (CCP) for moisture content with a critical limit of 11-12.7 %, and a CCP for aflatoxin content in the end product with a critical limit corresponding to the EU aflatoxin limits. Aflatoxin controls were supported by operational programmes at the receiving, milling and storage stages. The HACCP systems of the processors visited were certified by external private companies.

No evidence was found at the visited premises that health inspectors had checked implementation of the measures and HACCP plans described. Two of the processors provided the mission team with licences issued annually by the local health authorities.

According to the EIC, all six approved IPQC processors had put in place HACCP based food safety procedures. However, the EIC could not confirm the total number of the processors exporting to the EU who had implemented and maintained HACCP systems.

The processors visited had sampling plans for monitoring aflatoxin contamination. Sampling and aflatoxin analysis were performed on the finished product and during the receiving stage.

In the plants visited, the basmati rice was stored after processing in well-protected facilities or in silos with controlled temperature and humidity. One of the processors had online temperature monitoring of the filled silos.

All companies visited had adequate traceability systems. It was demonstrated that traceability of the final product was limited to the mandi level due to the various lot sizes produced by farmers, purchasing from intermediaries and subsequent mixing of the paddy at the processing (intake) stage.

All processors visited had in-house laboratories for auto-control purposes. These laboratories were accredited to ISO 17025 by the National Accreditation Board of Laboratories (NABL). The scope of accreditation included aflatoxin testing. All the laboratories participated in ring tests or proficiency testing schemes like FAPAS (Food Analysis Performance Assessment Scheme, UK).

5.3.3 Non-conforming products

According to data provided by the EIC, from 1 April 2010 up to the time of the mission, 328 samples of exported basmati rice were analysed for aflatoxins and 6 samples were found to be non-compliant. This represents a rejection rate of 1.83 %. The number of basmati rice consignments exported to the EU was 1380 in 2008-2009, 1500 in 2009-2010 and 1052 in the first nine months of 2010. There were 2 RASFF notifications in 2008 and one RASFF notification in 2009.

The mission team was informed that consignments rejected and returned to India are treated as re-exports and not as imports. For that reason, responsibility for dealing with them lies with the EIC. The CAs stated that there had been no such cases.

The Executive Instructions for the certification of basmati rice set out the procedure to be followed for complaints received from importing countries (EU and non-EU), and is as follows:

- The received complaint is immediately referred to the EIA concerned.
- The processor involved is immediately placed 'on alert' by the relevant EIA, which means increased frequency of the monitoring visits and granting export approval after 10

consecutive compliant results of analysed consignments.

- The EIC simultaneously seeks complete details from the complainant.
- The relevant EIA immediately visits the processor to collect complete information on the consignment, the results of the investigation undertaken by the processor, and the action taken by the processor to prevent recurrence of the problem.
- In addition, the processing establishment is assessed by a team of EIA officers or an Inter-Departmental Panel, comprising officials from the EIA/EIC and APEDA, to determine the cause of the complaint.

This procedure does not cover consignments rejected or returned from the EU because of aflatoxin contamination. However, it had been followed in the investigation to follow up an RASFF notification received (see point 5.7).

There is no clear legal basis for enforcement where the issuing of a certificate of inspection is refused because of non-compliant aflatoxin analysis results.

Conclusions

Basmati rice is cultivated mainly by small farmers. The implementation of good farm practices could not be verified and assessed as no written evidence was provided at the farms visited.

The storage conditions at the farms visited do not fully comply with the requirements set out in the Codex Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51 - 2003).

All processors visited were very well aware of potential aflatoxin contamination in basmati rice and followed the requirements set out in the Codex Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1 - 1969, Rev. 4 - 2003).

It is not mandatory for the processors exporting basmati rice to the EU to have procedures based on the HACCP principles that is not in line with the requirements laid down in Article 10 of Regulation (EC) No 852/2004 in conjunction with Article 5 of the same Regulation.

There are no clear instructions to be followed in the case of basmati rice consignments rejected at EU border with aflatoxin levels exceeding the maximum permitted limits.

5.4 METHOD OF SAMPLING FOR BASMATI RICE CONSIGNMENTS

Legal requirements

Article 1 of Regulation (EC) No 401/2006 requires that sampling for the official control of mycotoxin levels in foodstuffs be carried out in accordance with the methods set out in its Annex I. Concerning cereals (e.g. basmati rice), the method of sampling is laid down in Annex I.B.

Findings

5.4.1 Sampling procedure

Sampling procedures for aflatoxins in basmati rice are not formally laid down in the Indian legislation and no sampling instructions are provided by the CCA. At the mission team's request, the EIC provided, after the mission, a document entitled 'Procedure for export of maize and maize products through control of aflatoxins' produced by APEDA. It was stated that the sampling

procedure described in that document was used for basmati rice sampling as well¹. However, documentary evidence for this was not provided.

In the case of CWI processors/exporters, sampling is undertaken by the EIA staff. In the case of approved IPQC processors/exporters, samples are taken by the company itself.

The mission team observed a demonstration of sampling undertaken by the staff of the EIA in New Delhi. There were no written procedures or instructions for the task. The sampler was experienced in sampling foodstuffs but had not received any specific training in sampling for aflatoxin analysis. The official ensured that the lot was defined (976 bags of 50 kg each) and took incremental samples from 150 bags using a metal sample scoop. Every single incremental sample (250 g) was collected in a plastic bag and quartered individually. Quartering was repeated until three samples of 1 kg were obtained. The samples were packed in opaque cloth bags, sealed and labelled. One sample (1 kg) and the associated documentation were sent to the EIC-approved laboratory for aflatoxin analysis. Usually, the samples are sent by courier.

The sampling procedure observed differed from the procedure set out in Regulation (EC) No 401/2006 in particular as the quartering of the incremental samples were used and the aggregate sample was smaller in quantity than required by the above-mentioned Regulation.

At the first approved IPQC processor visited, a 10 kg aggregate sample is formed from the incremental samples taken. From this aggregate sample, a 3 kg laboratory sample is withdrawn by a sample divider. After dehusking, a 1 kg portion is taken for aflatoxin testing.

At the second approved IPQC processor visited, the incremental samples taken result in a 30 kg aggregate sample. From this aggregate sample, a 5 kg sample is withdrawn by quartering. After dehusking, a 1 kg portion is taken for aflatoxin testing.

The sampling undertaken by the approved IPQC processors is not supervised during the EIA monitoring visits.

Conclusions

There is currently no standardised sampling procedure for aflatoxin analysis of basmati rice.

The procedure followed by the official during the sampling observed were not equivalent to the requirements of Regulation (EC) No 401/2006.

Apart from some small practical details, the sampling procedures used by the approved IPQC processors conformed satisfactorily to the requirements of Regulation (EC) No 401/2006.

No specific training on aflatoxin sampling has been provided to the staff assigned to take samples for aflatoxin analysis of basmati rice exported to the EU.

5.5 PROCEDURE FOR EXPORTING BASMATI RICE TO THE EU

Legal requirements

Art. 46 (1) (b) of Reg. (EC) No 882/2004 stipulates that Community controls shall have, inter alia,

1 In their response to the draft report the Competent Authority noted that the sampling procedure for aflatoxin testing in basmati rice, demonstrated by EIA officer during the visit to the IPQC approved unit as well as in routine practice is in line with IS:14818:2000 procedure (national standard).

particular regard to the organisation of the TC's CAs, their powers and independence, and the authority they have to enforce the applicable legislation effectively.

Art. 46 (1) (h) of Reg. (EC) No 882/2004 stipulates that Community controls shall have, inter alia, particular regard to the assurances which the TC can give regarding compliance with, or equivalent to, Community legislation.

Findings

Basmati rice consignments are subject to export certification through quality control and inspection prior to export. The EIC measures introduced with effect from April 2010 require formal aflatoxin analysis on each basmati rice consignment intended for EU export.

The export procedure starts with registration of the export contracts with APEDA and the issue of a RCAC. Then, the quality of the consignments has to be certified by a certificate of inspection. The validity of the certificate of inspection is 45 days from the day of the inspection. It may be revalidated for another 15 days. The validity of the certificate may not, in any case, exceed 60 days from the day of inspection. The certificate of inspection is one of the required documents for the issuance of a certificate of authenticity by the EIC. This certificate identifies the variety of the basmati rice and is not covered by the scope of this mission.

The two systems of export certification for basmati rice quality are the CWI and IPQC systems.

Under the CWI system, the exporters present their consignments intended for shipment to officials of the relevant EIA who carry out sampling. The samples are tested at the EIAs laboratories for compliance with the required quality standards and at the EIC approved laboratory for aflatoxins (since April 2010). If the results are satisfactory, the EIA issues a certificate of inspection declaring the consignment as export worthy and export is allowed. If the consignment is found to be non-compliant, the EIA issues a rejection letter to the exporter with the reasons for rejection and export is not allowed.

Under the IPQC system, the EIA makes preliminary assessment of the quality control system of the company applying for IPQC approval. If the result is satisfactory, the company is approved and receives the right to issue certificates of inspection on their own. However, the companies are not obliged to attach to the certificate the results of the laboratory analysis for the aflatoxins. Periodic checks and sampling are carried out by the EIA. The approvals issued under IPQC system are renewable, following a reassessment.

Most of the companies visited export their product directly. Basmati rice is exported in bulk usually in standard containers (20-25 tonnes). All exports are containerised and transported under ambient temperature conditions. There are two ways to export basmati rice:

- Consignments are loaded into the containers at the processor's facilities, sealed by the processor, and transported to an ICD (dry port). At the ICD, the exporter files the necessary export documents. The goods are examined, sealed and released by the customs officers present at the ICD. Then the consignments are transported to the seaport of export by an authorised company/agency, usually by rail.
- The exporter takes non-containerised consignments to an ICD and files the necessary export documents. The goods are examined by the customs officers and stuffed into containers, which are then sealed and released by the customs authorities. Then the containers are transported to the seaport of export as described above.

The mission team visited the ICD in Ghari-Harsaru, Haryana, managed by a private company. The

mission team met two customs officials present at the ICD. The export procedure at customs consisted of the following steps:

- Exporter files the necessary documents such as certificate of authenticity, RCAC issued by APEDA, shipping bill, invoice, packing list, etc..
- Customs officers carry out documentary checks and enter the data in the EDI system (Electronic Data Interface for customs).
- Customs officers carry out identity and physical checks on 5 % of the presented consignments.
- After the checks, customs officers seal the consignments and sign the certificate of authenticity.
- The consignments are customs cleared and an export permit is issued.

The customs officials met explained that they have no official function in the control of aflatoxins in basmati rice.

Conclusions

The new measures introduced by the EIC regarding aflatoxin control of basmati rice intended for export to the EU have been implemented only since April 2010, and it is too early to fully assess their efficiency.

There is no requirement for the approved IPQC companies to attach to the certificate of inspection for the basmati rice exported to the EU the results of the laboratory analysis for aflatoxins.

The customs authorities are responsible for releasing basmati rice consignments exported to the EU as long as they have a certificate of authenticity and do not require any other accompanying documents regarding aflatoxin controls.

5.6 LABORATORY SERVICES

Legal requirements

Art. 46 (1)(d) and (c) of Reg. (EC) No 882/2004 stipulate that Community controls shall have, *inter alia*, particular regard to the resources including diagnostic facilities available to CAs, and the training of staff in the performance of official controls.

Article 2 of Regulation (EC) No 401/2006 requires that sample preparation and methods of analysis used for the official control of mycotoxin levels in foodstuffs comply with the criteria set out in its Annex II.

Points 41 and 42 of the Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997).

Findings

The EIC has developed a scheme for laboratory approval. It was put in place in 2002, and the current version was updated in 2010. The procedure requires the submission of details of equipment, staff, and quality procedures and requires an on-site assessment by EIC staff. Recognition is then granted for a period of two years. Details of the approval procedure are also available on the EIC website. Currently, one designated private laboratory is authorised by the EIC

for the analysis of aflatoxins in basmati rice. The laboratory is accredited to ISO 17025 by the NABL. Details of the current status of accreditation and the scope of the accredited methods are available on its website: www.nabl-india.org.

5.6.1 Laboratories visited

Official laboratory

One EIC-approved laboratory was designated for aflatoxin analysis of basmati rice samples taken under the CWI system and during the EIA's monitoring visits to IPQC-approved processors. It also performed chemical analyses to detect pesticide residues, and carried out analysis not only of food samples, but also of environmental (water) and petroleum (oil) samples. The laboratory was well-equipped and staffed. It had been accredited to ISO 17025 by the NABL since 1988. The scope of accreditation covered the determination of aflatoxins. In March 2010, the laboratory switched from High Performance Liquid Chromatography (HPLC) to Liquid Chromatography coupled with Mass Spectrometry (LC/MS triple quadrupole). The laboratory received properly sealed 1 kg samples, which were anonymously entered in their Laboratory Information Management System (LIMS). The whole laboratory sample was dry-milled. After 3-times quartering, an analytical portion of 100 g was obtained for further analysis. Matrix-matched calibration was applied, with aflatoxin M1 as an internal standard. Control charts with spiked blank were available. The limit of quantification (LOQ) was 0.1 µg/kg for aflatoxin B1, well below the limits in Regulation (EC) No 1881/2006. An expanded measurement uncertainty was calculated according to the 2000 EURACHEM guide, but not yet reported. The analytical result was reported as corrected for recovery and delivered within 48 hours. The laboratory did not participate in proficiency tests for the analysis covered by this mission. However, evidence was shown to the mission team that the laboratory had applied for participation in 2011.

Processor's laboratories

The mission team visited the laboratories of the three basmati rice processors visited. All the laboratories were accredited to ISO 17025 by the NABL and participated in international ring (e.g. Federation of European Rice Millers) and proficiency tests (Food Analysis Performance Assessment Scheme (FAPAS)) with satisfactory results.

The three laboratories performed similar procedures. After dehusking, a 1 kg sample is taken for aflatoxin testing. The whole sample is dry-milled, portion-wise, in centrifugal mills. The completely milled sample is mixed and an analytical portion is taken for further extraction and analysis by means of aflatoxin screening cards, as delivered by the supplier, at the detection limit of 2 ppb for aflatoxin B1 and 4 ppb for total aflatoxin. The detection limit as given by the supplier of this test has to be interpreted as LOQ.

Conclusions

There is an EIC approval scheme for laboratories carrying out aflatoxin analysis in basmati rice. Accreditation to ISO 17025 is a requirement for laboratories to conduct aflatoxin analysis of basmati rice exported to the EU.

The EIC-approved laboratory is currently the only laboratory authorised for aflatoxin analysis of basmati rice samples for export.

All the laboratories visited were accredited to ISO 17025, had sufficient qualified staff, procedures and equipment with which to carry out aflatoxin analysis of basmati rice.

Minor deficiencies were noted in the EIC approved laboratory with regard to proficiency testing, homogeneity of the milling process and measurement uncertainty.

5.7 RESPONSE TO RASFF NOTIFICATIONS

Legal requirements

Point 6 of Codex Guidelines for the exchange of information between countries on rejections of imported food (CAC/GL 25-1997).

Findings

The MOCI is the authority responsible for receiving RASFF notifications concerning aflatoxin contamination in basmati rice exported to the EU. According to the EIC, only one RASFF notification (Ref. No 2008.0864) out of seven (since 2007) concerning aflatoxin contamination in basmati rice had been received from the MOCI for follow-up investigation. The mission team was able to confirm that six notifications had been sent to the MOCI via the EU Delegation to India. However, since 2009 the EIC has automatic access to the EU RASFF system.

Basmati rice consignments rejected at the EU border and returned to India are treated as re-exports and not as imports. For that reason, responsibility for dealing with the consignment lies with the EIC.

No written procedures are in place for the management of the RASFF notifications. When an RASFF notification is received, the EIA officials proceed according to the procedure for complaints received from importing countries, set out in the Executive Instructions (see point 5.3.3).

The mission team saw satisfactory evidence about the follow-up carried out in response to the RASFF notification Ref. No 2008.0864.

Conclusions

The follow-up RASFF investigation examined by the mission team was satisfactory.

The rejection rate for consignments of basmati rice presented both in India for export and at the EU borders is very low (one RASFF for 2009 and none for 2010 by the time of the mission).

6 OVERALL CONCLUSIONS

India has administrative arrangements for the aflatoxin controls of basmati rice exported to the EU, consisting of mandatory sampling and analysis for aflatoxins of every consignment prior to export and aflatoxin controls in processing establishments as part of the auto-control systems. The competent authorities are clearly defined, with the EIC playing the main role. The establishments visited comply with the requirements of the Codex Alimentarius Code of General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003). The official laboratory and the processor's laboratories visited are accredited to ISO 17025 and perform well.

However, some deficiencies were identified concerning the legal basis for setting up the aflatoxin control measures, sampling of basmati rice for aflatoxin analysis and implementing HACCP based procedures, and concerning the official staff training on sampling.

Overall the administrative arrangements for the aflatoxin controls cannot fully guarantee that all basmati rice exported to the EU comply with the aflatoxin limits specified in the Commission Regulation (EC) No 1881/2006 mainly due to the differences in the sampling procedure used.

7 CLOSING MEETING

A closing meeting was held on 18 November 2010 with the cCCA, the EIC. Representatives of the EIA in New Delhi, APEDA and the EU Delegation to India were also present. At this meeting, the main findings and preliminary conclusions of the mission were presented by the mission team.

The representatives of the CAs present offered initial comments but did not express any major disagreement with these findings and conclusions.

8 RECOMMENDATIONS

To the competent authorities of India

The CAs are invited to provide details of the actions taken and planned, including for deadlines for their completion ("action plan"), aimed at addressing the recommendations set out below, within 25 working days of receipt of this report:

Nº.	Recommendation
1.	Consider establishing a clear legal basis for the control of aflatoxins in basmati rice intended for export to the European Union.
2.	Ensure the application of good agricultural practice principles recommended in the Codex Alimentarius Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Cereals, CAC/RCP 51 -2003, by all farmers producing basmati rice for export.
3.	Ensure that food business operators exporting basmati rice to the European Union implement standards at least equivalent to Article 5 of Regulation (EC) No 852/2004 on food safety procedures based on HACCP principles.
4.	Ensure that sampling of basmati rice consignments to be exported to the European Union is carried out in a uniform way and in equivalence to the Regulation (EC) No 401/2006.
5.	Consider that staff involved in the aflatoxin sampling are suitably trained so that the sampling procedure can be carried out adequately.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_in_2010-8597.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 315/93	OJ L 37, 13.2.1993, p. 1-3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs